AE Onset Date / Rx Day	[redacted]20[redacted] / 269
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 269): NPTST048-BLOOD CULTURES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	271
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，中下腹部の注入部位蜂巣炎を発現した。

Event 15 の臨床経過：

関連する病歴は，パーキンソン病，元喫煙者（1 日 20 本を 2 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。

本期間を通してABBV-951の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与269日目，被験者は中下腹部に注入部位蜂巣炎を発現した。投与271日目，中下腹部の注入部位蜂巣炎は消失した。

本事象の発現前，プロトコールに則り，被験者はカニューレを中下腹部の新しい注入部位にいつものように移動させた。投与266日目，被験者が新しい注入部位での投与を開始した翌日，被験者は中下腹部に非重篤の注入部位紅斑を発現した。抗生物質を 24 時間以上投与されたが，わずかな改善しかみられなかった。投与268日目，被験者は中下腹部に非重篤な注入部位蜂巣炎を発現し，2 番目の抗生物質の投与を開始した。被験者は抗生物質の静脈内投与のため，緊急治療室を受診するよう指示された。

投与269日目，被験者は中下腹部の蜂巣炎に対する抗生物質静脈内治療のため入院した。徴候や症状には，中下腹部の紅斑，熱感，及び圧痛が含まれた。投与270日目，被験者は左下腹部に非重篤な注入部位紅斑を発現した。投与271日目，蜂巣炎は消失し，経口抗生物質投与にて退院した。

被験者にバンコマイシン，オーグメンチン，ドキシサイクリン，及びセフェピムが投与された。

The patient's past medications include:

CARBIDOPA/ LEVODOPA for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

KEFLEX for GRADE 2 SITE REACTION ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.0] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS TO MID-LOWER ABDOMINAL INFUSIONSITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURES:** Negative; No infection detected. No growth.

[redacted] **20[redacted] ULTRASOUND OF THE ABDOMEN:** No abscess noted, induration only.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19	X			
幻覚				X
注入部位蜂巣炎				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
DEPRESSION	NOT REPORTED
DIVERTICULOSIS	19[redacted]
APPENDICITIS	19[redacted]
MENOPAUSE	19[redacted]
ARTHRITIS	19[redacted]
LUMBAR BACK PAIN	19[redacted]
ANXIETY	20[redacted]
DIZZINESS	20[redacted]
DYSPNEA	20[redacted]
GASTRO ESOPHAGEAL REFLUX	20[redacted]
PARKINSON'S DISEASE	20[redacted]
NEUROPATHY	20[redacted]
HYPERTENSION	20[redacted]
HAMMER TOE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
APPENDECTOMY	19[redacted]
DEEP BRAIN STIMULUS	20[redacted]
EXCISION OF LEFT TOE	20[redacted]
EXCISION OF RIGHT TOE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	6	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.5	0	0	0	0	20[redacted]/1
ABBV-951	0.5	0	0	0	0	20[redacted]/2
ABBV-951	0.5	0	0	0	0	20[redacted]/8
ABBV-951	0.5	0	0	0	0	20[redacted]/15
ABBV-951	0.5	0	0	0	0	20[redacted]/22
ABBV-951	0.5	0	0	0	0	20[redacted]/29
ABBV-951	0.5	0	0	0	0	20[redacted]/34
ABBV-951	0.5	0	0	0	0	20[redacted]/43
ABBV-951	0.5	0	0	0	0	20[redacted]/50
ABBV-951	0.48	0	0	0	0	20[redacted]/76
ABBV-951	0.46	0	0	0	0	20[redacted]/92
ABBV-951	0.46	0	0	0	0	20[redacted]/106
ABBV-951	0.46	0	0	0	0	20[redacted]/118
ABBV-951	0.46	0	0	0	0	20[redacted]/134
ABBV-951	0.42	0	0	0	0	20[redacted]/148
ABBV-951	0.42	0	0	0	0	20[redacted]/162
ABBV-951	0.2	0	0	0	0	20[redacted]/176
ABBV-951	0.16	0	0	0	0	20[redacted]/183

ABBV-951	0.18	0	0	0	0	[redacted]/190
ABBV-951	0.18	0	0	0	0	[redacted]/203
ABBV-951	0.2	0	0	0	0	[redacted]/218
ABBV-951	0.2	0	0	0	0	[redacted]/232
ABBV-951	0.22	0	0	0	0	[redacted]/246
ABBV-951	0.22	0	0	0	0	[redacted]/260
ABBV-951	0.22	0	0	0	0	[redacted]/262
ABBV-951	0.21	0	0	0	0	[redacted]/288
ABBV-951	0.21	0	0	0	0	[redacted]/301
ABBV-951	0.21	0	0	0	0	[redacted]/316
ABBV-951	0.21	0	0	0	0	[redacted]/330
ABBV-951	0.21	0	0	0	0	[redacted]/344
ABBV-951	0.21	0	0	0	0	[redacted]/363

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1408.68		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	725.68		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1408.68		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25

ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62

ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
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ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
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ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
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ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1974.89	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1934.25	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
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ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
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ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 123	[redacted] / 123
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 124	[redacted] / 124
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 125	[redacted] / 125
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ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 131	[redacted] / 131
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 132	[redacted] / 132
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 133	[redacted] / 133
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 134	[redacted] / 134
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 135	[redacted] / 135
ABBV-951	1967.04	SC / CONTINUOUS	[redacted] / 136	[redacted] / 136

ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
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ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358

ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	414.23	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	853.40	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
LISINOPRIL	5 mg	QD	Y-M: 20[redacted]
SERTRALINE	150 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	195.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ROTIGOTINE	8.000 mg	QD	Y-M: 20[redacted] / -322

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
SERTRALINE	150 mg	QD	Y-M: 20[redacted]	ONGOING
LISINOPRIL	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 41
VANCOMYCIN	1000 mg	OTHER: ONCE	Y-M: 20[redacted] / 24	Y-M: 20[redacted] / 24
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 24	Y-M: 20[redacted] / 34
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 24	Y-M: 20[redacted] / 34
LISINOPRIL	20 mg	QD	Y-M: 20[redacted] / 41	ONGOING
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 148
SALBUTAMOL	90 MCG/INH OTHER: MCG/INH	PRN	Y-M: 20[redacted] / 265	ONGOING

Event #1: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF RIGHT ABDOMINAL WALL INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 24
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	45
Duration of AE	22 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 54
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	168
Duration of AE	115 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 168
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	169
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	COVID
Preferred term	COVID-19
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	358
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	COVID 19 VIRUS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，COVID を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，ニューロパチー，高血圧，脳深部刺激療法，うつ病，中等度背側不安定症，元喫煙者（1 日 10 本を 6 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 346 日目，被験者は COVID を発現した。投与 358 日目，COVID は消失した。

投与 348 日目，被験者は咳嗽，発熱，及び息切れを突然発現し，COVID の治療のため緊急治療室を受診した。観察時間が 24 時間を超えたため，有害事象から重篤な有害事象に変更された。投与 350 日目，被験者は酸素投与も併用薬もなく良好な状態で退院した。

被験者には本事象発現に関するリスク因子がなかった。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

RYTARY for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PFIZER COVID SHOT for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) COVID-19 (10084268) (COVID-19 (10084268)) [v.24.1] [10084268]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of COVID

- Investigator: Covid-9 Virus

- AbbVie: More likely related to the SARS Co-2 Viral pandemic in an elderly patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST XRAY:** Normal

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
血腫	X			X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
POST MENOPAUSAL	19[redacted]
OSTEOARTHRITIS	20[redacted]
PARKINSON'S DISEASE	20[redacted]
DEPRESSION	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
INSOMNIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LEFT TOTAL KNEE REPLACEMENT	20[redacted]
DEEP BRAIN STIMULATION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.44	0	0	0	0	[redacted]/1
ABBV-951	0.44	0	0	0	0	[redacted]/2
ABBV-951	0.45	0	0	0	0	[redacted]/9
ABBV-951	0.46	0	0	0	0	[redacted]/12
ABBV-951	0.48	0	0	0	0	[redacted]/15
ABBV-951	0.49	0	0	0	0	[redacted]/16
ABBV-951	0.49	0	0	0	0	[redacted]/22
ABBV-951	0.52	0	0	0	0	[redacted]/29
ABBV-951	0.54	0	0	0	0	[redacted]/36
ABBV-951	0.55	0	0	0	0	[redacted]/44
ABBV-951	0.57	0	0	0	0	[redacted]/50
ABBV-951	0.58	0	0	0	0	[redacted]/64
ABBV-951	0.58	0	0	0	0	[redacted]/82
ABBV-951	0.59	0	0	0	0	[redacted]/92
ABBV-951	0.59	0	0	0	0	[redacted]/106
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/120
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/134
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/148
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/162
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/176
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/192
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/193
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/204
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/218
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/232
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/262
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/276
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/304
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/320
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/333
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/348

ABBV-951	0.6	0.61	0.59	0	0	[redacted]/361
ABBV-951	0.6	0.61	0.59	0	0	[redacted]/367

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1036.79		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1788.09		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1788.09		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1803.12		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1841.02		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1925.37		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1967.04		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1967.04		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1967.04		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1967.04		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1972.33		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1982.91		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1957.81		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	2008.02		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31

ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2154.18	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2194.47	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68

ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	2069.14	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	2366.93	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	2376.84	SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
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ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
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ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327

ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

ABBV-951	2465.97	SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.250 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
MELATONIN	5 mg	QD	Y-M: 20[redacted]-[redacted]
BUSPIRONE	50 MG mg	BID	Y-M: 20[redacted]-[redacted]
TRAZODONE	100 mg	QD	Y-M: 20[redacted]-[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
MELATONIN	5 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
BUSPIRONE	50 MG mg	BID	Y-M: 20[redacted]-[redacted]	ONGOING
TRAZODONE	100 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
SERTRALINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 248	ONGOING

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 309
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	309
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] Infusion Set	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	LARGE LEFT THIGH HEMATOMA
Preferred term	血腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 309
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	312
Duration of AE	4 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左大腿部大血腫を発現した。

Event 2 の臨床経過：

関連する病歴は，変形性関節症，パーキンソン病，左膝関節全置換術，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 309 日目，被験者は左大腿部大血腫を発現した。投与 312 日目，左大腿部大血腫は消失した。

投与 309 日目，被験者は卓球中に自分の足につまずき，思いがけず尻もちをついた（非重篤）。被験者は腰の内出血及び不快感があり脚に体重を乗せることができなかったため，緊急治療室を受診した。X 線検査で骨折は確認されなかった。同日，被験者は疼痛と血腫の更なる管理のため入院した。投与 311 日目，被験者は退院した。

治験責任医師によると，被験者はパーキンソン病に関連するバランスや歩行の問題があった。

The patient's past medications include:

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA SUSTAINED RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hematoma (10019428) (Haematoma (10018852)) [v.24.1] [10019428]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of LARGE LEFT THIGH HEMATOMA

- Investigator: Fall

- AbbVie: More likely related accidental fall from tripping while playing ping pong in an elderly subject with history of Parkinson's disease, osteoarthritis and left total knee replacement.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BASELINE NEUROLOGICAL EXAMINATION:** MOTOR SYSTEM- PARKINSON'S BRADYKYNESIA LEFT GREATER THAN RIGHT SENSORY SYSTEM- DECREASE VIBRATION RIGHT LOWER EXTREMITY UNTIL ANKLE GAIT- MILD SHUFFLING

[redacted] **20[redacted] X-RAY:** No fracture

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
投与部位漏出				X
挫傷				X
転倒				X
幻覚				X
幻視				X
感覚鈍麻				X
注入部位内出血				X
注入部位蜂巣炎				X
注入部位不快感				X
注入部位紅斑				X
注入部位皮膚剥脱				X
注入部位血管外漏出				X
注入部位感染				X
注入部位刺激感				X
注入部位腫瘤				X
注入部位結節				X
注入部位浮腫				X
注入部位疼痛				X
注入部位異常感覚				X
注入部位反応				X
注入部位熱感				X
注射部位結節				X
精神病性障害	X			X
皮膚裂傷				X
体重減少				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
NEAR SIGHTED	19[redacted]
RIGHT ELBOW FRACTURE	19[redacted]
HEPATITIS C	19[redacted]
CATARACS	20[redacted]
OSTEOARTHRITIS	20[redacted]
READING GLASSES	20[redacted]
RHEUMATOID ARTHRITIS	20[redacted]
KERATOSIS	20[redacted]
ANXIETY	20[redacted]
GERD	20[redacted]
MUSCLE CRAMPS	20[redacted]
POST MENOPAUSAL	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LIVER BIOPSY	19[redacted]
LASIK SURGERY	20[redacted]
LEFT WRIST REPAIR	20[redacted]
RIGHT KNEE REPLACEMENT	20[redacted]
RIGHT KNEE REVISION	20[redacted]
LIVER BIOPSY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.63	0.72	0.55	75	0.3	[redacted]/1
ABBV-951	0.72	0.76	0.67	60	0.15	[redacted]/3
ABBV-951	0.77	0.78	0.76	75	0.15	[redacted]/8
ABBV-951	0.78	0.81	0.76	75	0.19	[redacted]/15
ABBV-951	0.78	0.81	0.76	75	0.19	[redacted]/22
ABBV-951	0.78	0.81	0.76	75	0.19	[redacted]/31
ABBV-951	0.5	0.58	0.39	75	0.19	[redacted]/37
ABBV-951	0.5	0.58	0.39	75	0.19	[redacted]/43
ABBV-951	0.58	0.61	0.5	75	0.19	[redacted]/92
ABBV-951	0.7	0.78	0.6	75	0.19	[redacted]/107
ABBV-951	0.7	0.78	0.6	75	0.19	[redacted]/184
ABBV-951	0.74	0.78	0.7	75	0.19	[redacted]/206
ABBV-951	0.6	0.56	0.54	75	0.19	[redacted]/240
ABBV-951	0.6	0.56	0.54	75	0.19	[redacted]/276
ABBV-951	0.6	0.56	0.54	75	0.19	[redacted]/346

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1194.05		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		153.67	SC / ONCE	[redacted] / 2	
ABBV-951	2503.36		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		25.61	SC / ONCE	[redacted] / 3	
ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2469.55		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		51.22	SC / ONCE	[redacted] / 5	
ABBV-951	2839.91		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		25.61	SC / ONCE	[redacted] / 6	
ABBV-951	2933.48		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		51.22	SC / ONCE	[redacted] / 7	
ABBV-951	2841.96		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		51.22	SC / ONCE	[redacted] / 8	
ABBV-951	3047.88		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8

ABBV-951	3089.72		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		51.22	SC / ONCE	[redacted] / 10	
ABBV-951	3007.24		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	3103.21		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		76.83	SC / ONCE	[redacted] / 12	
ABBV-951	3076.57		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		25.61	SC / ONCE	[redacted] / 13	
ABBV-951	3156.48		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		25.61	SC / ONCE	[redacted] / 14	
ABBV-951	3100.13		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		32.44	SC / ONCE	[redacted] / 15	
ABBV-951	2916.75		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		64.88	SC / ONCE	[redacted] / 16	
ABBV-951	3126.43		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		32.44	SC / ONCE	[redacted] / 17	
ABBV-951	3154.77		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		64.88	SC / ONCE	[redacted] / 18	
ABBV-951	2850.15		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		64.88	SC / ONCE	[redacted] / 19	
ABBV-951	3196.44		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		32.44	SC / ONCE	[redacted] / 20	
ABBV-951	3132.92		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		32.44	SC / ONCE	[redacted] / 21	
ABBV-951	3103.21		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		64.88	SC / ONCE	[redacted] / 22	
ABBV-951	3116.52		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		97.32	SC / ONCE	[redacted] / 23	
ABBV-951	2956.70		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		129.77	SC / ONCE	[redacted] / 24	
ABBV-951	3156.48		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		129.77	SC / ONCE	[redacted] / 25	
ABBV-951	3242.03		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951		97.32	SC / ONCE	[redacted] / 26	
ABBV-951	3181.07		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		64.88	SC / ONCE	[redacted] / 27	
ABBV-951	3111.91		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		32.44	SC / ONCE	[redacted] / 28	

ABBV-951	3153.41		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	3222.56		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	3098.08		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	3236.39		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	3305.54		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	3291.71		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1120.29		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	648.85		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1885.25		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1558.26		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1840.17		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1914.10		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	2199.60		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	2327.32		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
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ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217

ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254

ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	2805.42		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 274	
ABBV-951	2296.92		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	2160.67		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	2387.08		SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
COLECALCIFEROL	1000 IU	BID	Y-M: 20[redacted]-[redacted]
CALCIUM CARBONATE	1-2 OTHER: TABS	PRN	Y-M: 20[redacted]-[redacted]
HYDROXYCHLOROQUINE	200 mg	BID	Y-M: 20[redacted]-[redacted]
BOTULINUM TOXIN TYPE A	400 IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]-[redacted]
GABAPENTIN	200 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -314
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted] / -256
CLONAZEPAM	1.5 mg	QD	Y-M: 20[redacted]-[redacted] / -239
CARBIDOPA;LEVODOPA	195.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -178

CYCLOBENZAPRINE	5 mg	TID	Y-M: 20[redacted] / -119
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / -119
METHOTREXATE	15 mg	OTHER: WEEKLY	Y-M: 20[redacted] / -119
PRAMIPEXOLE	1.000 mg	QID	Y-M: 20[redacted] / -88
DICLOFENAC SODIUM	1% g	PRN	Y-M: 20[redacted] / -47

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
COLECALCIFEROL	1000 IU	BID	Y-M: 20[redacted]	ONGOING
CALCIUM CARBONATE	1-2 OTHER: TABS	PRN	Y-M: 20[redacted]	ONGOING
HYDROXYCHLOROQUINE	200 mg	BID	Y-M: 20[redacted]	ONGOING
BOTULINUM TOXIN TYPE A	400 IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	1.5 mg	QD	Y-M: 20[redacted] / -239	ONGOING
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / -119	ONGOING
METHOTREXATE	15 mg	OTHER: WEEKLY	Y-M: 20[redacted] / -119	ONGOING
CYCLOBENZAPRINE	5 mg	TID	Y-M: 20[redacted] / -119	Y-M: 20[redacted] / 184
DICLOFENAC SODIUM	1% g	PRN	Y-M: 20[redacted] / -47	ONGOING
PREDNISONE	20 mg	QD	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 106
ESOMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 80	ONGOING
VITAMIN B12 NOS	500 OTHER: MCG	QD	Y-M: 20[redacted] / 92	ONGOING
BOTULINUM TOXIN TYPE A	170 IU	OTHER: Q 3 MONTHS	Y-M: 20[redacted] / 184	Y-M: 20[redacted] / 184
CYCLOBENZAPRINE HYDROCHLORIDE	10 mg	OTHER: BID, PRN	Y-M: 20[redacted] / 184	Y-M: 20[redacted] / 332
CLONAZEPAM	1 mg	OTHER: QHS	Y-M: 20[redacted] / 276	ONGOING
SERTRALINE	25 mg	QD	Y-M: 20[redacted] / 276	Y-M: 20[redacted] / 283
SERTRALINE	50 mg	QD	Y-M: 20[redacted] / 284	ONGOING
QUETIAPINE FUMARATE	25 mg	BID	Y-M: 20[redacted] / 295	ONGOING
CEFALEXIN	100 mg	QD	Y-M: 20[redacted] / 326	Y-M: 20[redacted] / 331
CYCLOBENZAPRINE HYDROCHLORIDE	5 mg	OTHER: BID, PRN	Y-M: 20[redacted] / 333	ONGOING
CEFALEXIN	100 mg	BID	Y-M: 20[redacted] / 333	Y-M: 20[redacted] / 338
CEFALEXIN	100 mg	QID	Y-M: 20[redacted] / 340	Y-M: 20[redacted] / 345

CLINDAMYCIN	300 mg	QID	Y-M: 20[redacted] / 355	Y-M: 20[redacted] / 361
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 361	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BURNING AT INFUSION SITE
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	3
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE DISCOMFORT
Preferred term	注入部位不快感
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	4
Duration of AE	2 DAYS
Severity	MODERATE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	TINGLING AT INFUSION SITE
Preferred term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 3

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	3
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	CANNULA DISCOMFORT (SLIGHT) AT INFUSION SITE
Preferred term	注入部位不快感
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	8
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	TINGLING AT INFUSION SITE
Preferred term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	8
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注射部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MEDICATION POOLING UNDER SKIN, AT INFUSION SITE
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DRUG DRIPPED FROM THE SKIN FOR 30 MINUTES. AT INFUSION SITE
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 22

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL ILLUSIONS
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	13 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	A CONE SHAPED POOLING OF MEDICATION UNDER THE SKIN
Preferred term	投与部位漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	74 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMEN REDNESS AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	74 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest - Infusion Site Related Infections

Event Description	ABDOMEN INFUSION SITE INFECTION
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	74 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	CONE-SHAPED AREA POOLING OF MEDICATION AT INFUSION SITE
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 36

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	12 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Falls And Associated Injuries

Event Description	FALL- TRIPPED
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 40
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	40
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	59 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #17: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	70
Duration of AE	22 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #18: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN IRRITATION AT THE INFUSION SITE
Preferred term	注入部位刺激感
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	59 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #19: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	HARD SIZE OF A QUARTER AT THE INFUSION SITE
Preferred term	注入部位腫瘤
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	70
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #20: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULES AT HER PRIOR INFUSION
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	70
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #21: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SORE SPOT (PAIN) ABOUT THE SIZE OF A FIST AT THE INFUSION SITE
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	70
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #22: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS AROUND INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	78
Duration of AE	11 DAYS
Severity	MODERATE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #23: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	CONE SHAPED 10 CM SIZE NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	78
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #24: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	WARM TO TOUCH AROUND THE SITE AT INFUSION SITE
Preferred term	注入部位熱感
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	78
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #25: Event of Interest - Hallucinations/Psychosis

Event Description	RARE VISUAL ILLUSIONS
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	296
Duration of AE	205 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #26: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA, READILY VISIBLE; OR MINIMAL AT THE INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	113
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #27: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT THE INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	113
Duration of AE	22 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #28: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT GLAZED APPEARANCE AT THE INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	113
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #29: Event of Interest -Falls And Associated Injuries

Event Description	RAKE HIT; RIGHT FOREHEAD BRUISE
Preferred term	挫傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	5[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	114
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #30: Event of Interest -Falls And Associated Injuries

Event Description	CUT RIGHT FINGER
Preferred term	皮膚裂傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	114
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #31: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	346
Duration of AE	163 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #32: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	2 CM BRUISE LEFT ABDOMEN AT INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	211
Duration of AE	28 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #33: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	1-2 CM NODULES ON LEFT ABDOMEN- PREVIOUS INJECTION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	211
Duration of AE	28 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #34: Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	184
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #35: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	TINGLING SENSATION AT INFUSION SITE UPON INSERTION OF [redacted]
Preferred term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 233
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	233
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #36: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 240
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #37: Event of Interest - Polyneuropathy

Event Description	FACE NUMB
Preferred term	感覚鈍麻
AE Onset Date / Rx Day	[redacted]20[redacted] / 265
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	266
Duration of AE	2 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #38: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 294
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 294): CALCIUM: 2.1 [2.12 - 2.62] MMOL/L; ERYTHROCYTES: 3.1 [3.7 - 5.2] 10^12/L; GLUCOSE: 4.9 [3.9 - 5.6] MMOL/L; HEMATOCRIT: 0.31 [0.35 - 0.49] FRACTION OF 1; HEMOGLOBIN: 110 [120 - 150] G/L; LEUKOCYTES: 10.7 [3.6 - 10.6] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	295
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #39: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS INFECTION LEFT THIGH AT INFUSION SITE
Preferred term	注入部位蜂巣炎

AE Onset Date / Rx Day	[redacted]20[redacted] / 326
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	40 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #40: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN REDNESS AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 326
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	40 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #41: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	2 MM SUBCUTANEOUS NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 326
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	40 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #42: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE; BARELY PERCEPTIBLE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)

Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #43: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #44: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PEELING AT INFUSION SITE

Preferred term	注入部位皮膚剥脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #45: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN PEELING AT THE INFUSION SITE
Preferred term	注入部位皮膚剥脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #46: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	GLAZING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #47: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN CRACKING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #48: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN GLAZING CRACKING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病を発現した。

Event 38 の臨床経過：

関連する病歴は，パーキンソン病，不安，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。

投与 294 日目，被験者は精神病を発現した。

投与 294 日目，被験者はストーキングされていると信じていたが，夫と姉妹に信用されなかったため口論となった。被験者は車に乗り道に迷うまで運転した。その後，被験者が他人のドアをノックしたため，救急隊が呼ばれ被験者は病院に運ばれた。同日，被験者は入院した。検査は問題がなかったが，被験者は非重篤の低体温を発現した。投与 296 日目，被験者は退院した。

被験者に幻覚及び精神病の病歴のリスク因子があった。

被験者にセロクエルが投与された。

The patient's past medications include:

RYTARY for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Psychosis (10037234) (Psychotic disorder (10061920)) [v.23.1] [10037234]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to progression of Parkinson's disease in a patient with a history of anxiety and concomitant medications clonazepam and sertraline.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] GLUCOSE:** 88 mg/dL (normal 70 to 100)

[redacted] **20[redacted] WBC:** 10.7 k/cumm (normal 4.0 to 11.0)

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 7[redacted] kg. Weight at time of event 6[redacted] kg. Weight loss occurred over a period of 4 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced increased stress and anxiety, previous episode of activity increase/more active since treatment began, previous episode of dyskinesia worsening since treatment began, temporal episode of depression and/or other psychiatric disorders, previous episode of infection, and previous episode of immune disorder.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
脳出血				X
顔面損傷	X			X
転倒	X			X
出血	X			X
幻視				X
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位皮膚剥脱				X
注入部位感染				X
注入部位結節				X
注入部位浮腫				X
注入部位丘疹				X
注入部位反応				X
意識消失	X			X
錯感覚				X
眼窩周囲痛	X			X
眼窩周囲腫脹	X			X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
ARRYTHMIA-AFIB	19[redacted]
HYPERTENSION	19[redacted]
GLASSES- READING	20[redacted]
LBP (LOWER BACK PAIN)	20[redacted]
CONSTIPATION- OCCASIONALLY	20[redacted]
DEPRESSION	20[redacted]
BPH (BENIGN PROSTATIC HYPERPLASIA	20[redacted]
KERATOSIS	20[redacted]

MILD CATARACTS	20[redacted]
BLADDER INCONTINENCE	20[redacted]
GYRAL PETECHIAL HEMORRHAGE	20[redacted]
CONCUSSION	20[redacted]
NOSE BLEEDS FREQUENT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LASIX	20[redacted]
KERATOSIS REMOVED	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.33	0.39	0.26	60	0.15	[redacted]20[redacted]/1
ABBV-951	0.33	0.39	0.26	60	0.15	[redacted]20[redacted]/3
ABBV-951	0.36	0.39	0.33	60	0.15	[redacted]20[redacted]/8
ABBV-951	0.42	0.44	0.4	60	0.19	[redacted]20[redacted]/15
ABBV-951	0.42	0.43	0.4	60	0.19	[redacted]20[redacted]/22
ABBV-951	0.42	0.43	0.4	60	0.19	[redacted]20[redacted]/31
ABBV-951	0.42	0.43	0.4	60	0.19	[redacted]20[redacted]/43
ABBV-951	0.42	0.43	0.4	60	0.19	[redacted]20[redacted]/50

ABBV-951	0.42	0.43	0.4	60	0.19	[redacted]/92
ABBV-951	0.44	0.43	0.45	60	0.19	[redacted]/185
ABBV-951	0.44	0.43	0.45	60	0.19	[redacted]/278
ABBV-951	0.48	0.46	0.5	60	0.19	[redacted]/299
ABBV-951	0.48	0.46	0.5	60	0.19	[redacted]/367

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	625.45		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1335.43		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		25.61	SC / ONCE	[redacted] / 7	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1377.95		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		25.61	SC / ONCE	[redacted] / 11	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		76.83	SC / ONCE	[redacted] / 13	
ABBV-951	1584.90		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		76.83	SC / ONCE	[redacted] / 14	
ABBV-951	1551.60		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		64.88	SC / ONCE	[redacted] / 15	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		97.32	SC / ONCE	[redacted] / 16	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		32.44	SC / ONCE	[redacted] / 17	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		64.88	SC / ONCE	[redacted] / 18	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		64.88	SC / ONCE	[redacted] / 19	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19

ABBV-951		32.44	SC / ONCE	[redacted] / 20	
ABBV-951	1666.00		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1670.95		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		97.32	SC / ONCE	[redacted] / 23	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		64.88	SC / ONCE	[redacted] / 24	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		97.32	SC / ONCE	[redacted] / 25	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951		64.88	SC / ONCE	[redacted] / 26	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		97.32	SC / ONCE	[redacted] / 27	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		162.21	SC / ONCE	[redacted] / 28	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951		97.32	SC / ONCE	[redacted] / 29	
ABBV-951	1713.98		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951		32.44	SC / ONCE	[redacted] / 30	
ABBV-951	1649.44		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		32.44	SC / ONCE	[redacted] / 31	
ABBV-951	1692.47		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951		97.32	SC / ONCE	[redacted] / 32	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951		64.88	SC / ONCE	[redacted] / 33	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951		97.32	SC / ONCE	[redacted] / 34	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951		97.32	SC / ONCE	[redacted] / 35	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951		64.88	SC / ONCE	[redacted] / 36	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951		97.32	SC / ONCE	[redacted] / 37	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951		64.88	SC / ONCE	[redacted] / 38	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951		32.44	SC / ONCE	[redacted] / 39	

ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951		32.44	SC / ONCE	[redacted] / 40	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951		64.88	SC / ONCE	[redacted] / 41	
ABBV-951	1663.78		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		32.44	SC / ONCE	[redacted] / 42	
ABBV-951	1678.13		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		32.44	SC / ONCE	[redacted] / 43	
ABBV-951	1685.30		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		64.88	SC / ONCE	[redacted] / 44	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951		64.88	SC / ONCE	[redacted] / 45	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951		64.88	SC / ONCE	[redacted] / 46	
ABBV-951	1699.64		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951		64.88	SC / ONCE	[redacted] / 47	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951		97.32	SC / ONCE	[redacted] / 48	
ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		129.77	SC / ONCE	[redacted] / 49	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951		129.77	SC / ONCE	[redacted] / 50	
ABBV-951	1685.30		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		32.44	SC / ONCE	[redacted] / 51	
ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951		32.44	SC / ONCE	[redacted] / 52	
ABBV-951	1745.23		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		97.32	SC / ONCE	[redacted] / 53	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951		64.88	SC / ONCE	[redacted] / 54	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		64.88	SC / ONCE	[redacted] / 55	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		32.44	SC / ONCE	[redacted] / 56	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951		64.88	SC / ONCE	[redacted] / 57	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57

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ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951		64.88	SC / ONCE	[redacted] / 59	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951		32.44	SC / ONCE	[redacted] / 60	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951		64.88	SC / ONCE	[redacted] / 61	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951		64.88	SC / ONCE	[redacted] / 62	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951		64.88	SC / ONCE	[redacted] / 63	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951		97.32	SC / ONCE	[redacted] / 64	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951		32.44	SC / ONCE	[redacted] / 65	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951		64.88	SC / ONCE	[redacted] / 66	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 66	[redacted] / 66
ABBV-951		97.32	SC / ONCE	[redacted] / 67	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 67	[redacted] / 67
ABBV-951		97.32	SC / ONCE	[redacted] / 68	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 68	[redacted] / 68
ABBV-951		64.88	SC / ONCE	[redacted] / 69	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 69	[redacted] / 69
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ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951		32.44	SC / ONCE	[redacted] / 71	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951		64.88	SC / ONCE	[redacted] / 72	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 72	[redacted] / 72
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ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
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ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
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ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951		64.88	SC / ONCE	[redacted] / 79	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951		32.44	SC / ONCE	[redacted] / 80	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951		32.44	SC / ONCE	[redacted] / 82	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951		97.32	SC / ONCE	[redacted] / 83	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951		97.32	SC / ONCE	[redacted] / 84	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951		64.88	SC / ONCE	[redacted] / 85	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951		64.88	SC / ONCE	[redacted] / 86	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951		32.44	SC / ONCE	[redacted] / 87	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		32.44	SC / ONCE	[redacted] / 88	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		32.44	SC / ONCE	[redacted] / 89	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951		32.44	SC / ONCE	[redacted] / 90	
ABBV-951	1740.11		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	1732.77		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	1710.74		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		64.88	SC / ONCE	[redacted] / 93	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		64.88	SC / ONCE	[redacted] / 94	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951		32.44	SC / ONCE	[redacted] / 95	
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ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339		
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 340			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340		
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341		
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 342			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342		
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 343			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343		
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 344			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344		
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 345			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345		
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 346			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346		
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 347			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347		
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 348			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348		
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 349			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349		
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 350			
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350		

ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 352	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 353	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 354	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 355	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 356	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 357	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 358	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 359	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 360	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 361	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 363	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 364	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 365	
ABBV-951	1853.66		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 366	
ABBV-951	1934.25		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMLODIPINE	5 MG mg	QD	Y-M: 20[redacted]-[redacted]

CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]
LOSARTAN	100 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.500 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
SERTRALINE	100 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.750 mg	TID	Y-M: 20[redacted] / -277
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / -195
ENTACAPONE	100.000 mg	QID	Y-M: 20[redacted] / -187
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted] / -150
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LOSARTAN	100 mg	QD	Y-M: 20[redacted]	ONGOING
AMLODIPINE	5 MG mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / -8
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 299
SERTRALINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / -195	Y-M: 20[redacted] / 110
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 21
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 22
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 49	Y-M: 20[redacted] / 52
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TABLET	BID	Y-M: 20[redacted] / 52	Y-M: 20[redacted] / 58
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 109	ONGOING
HYPROMELLOSE	1 OTHER: DROP	QID	Y-M: 20[redacted] / 109	Y-M: 20[redacted] / 288
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 110	ONGOING
OXYCODONE	5 mg	OTHER: Q6H	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 110
GABAPENTIN	300 mg	TID	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 115
CEFALEXIN	500 mg	OTHER: Q6H	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 117
ATORVASTATIN	10 mg	QD	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 122
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 278

HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: 20[redacted] / 299	ONGOING
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TAB	BID	Y-M: 20[redacted] / 360	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	13 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS　LOWER ABDOMEN AT THE INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22

Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION LOWER ABDOMEN AT THE INFUSION SITE
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DEFINITE EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫

AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT GLAZED IN APPEARANCE AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	65
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHTLY GLAZED APPEARANCE AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	65

Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Polyneuropathy

Event Description	TINGLING IN FINGER TIPS
Preferred term	錯感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	31
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL ILLUSIONS
Preferred term	幻視

AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	52
Duration of AE	10 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 46
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	65
Duration of AE	20 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	106
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SMALL NODULES AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	106
Duration of AE	15 DAYS

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAPULES AT INFUSION SITE
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	106
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MARKED GLAZING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 92

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	106
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	INTRACEREBRAL HEMORRHAGE
Preferred term	脳出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Serious Adverse Event, Event of Interest -Falls And Associated Injuries

Event Description	RIGHT FACE TRAUMA
Preferred term	顔面損傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124] UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	108
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #17: Serious Adverse Event, Event of Interest -Falls And Associated Injuries

Event Description	FALL (ACCIDENTAL)
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124]

UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	108
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #18: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	ACTIVE FACIAL BLEEDING RELATED TO AE [redacted]
Preferred term	出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124] UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	120
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #19: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	LOSS OF CONSCIOUSNESS
Preferred term	意識消失
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124] UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	108
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #20: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	PAIN SURROUNDING EYE RELATED TO AE [redacted]

Preferred term	眼窩周囲痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124] UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	120
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #21: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	RIGHT PERIORBITAL SWELLING
Preferred term	眼窩周囲腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 109): CHOLESTEROL: 3.96 [0 - 5.17] MMOL/L; NPTST138-HEMOGLOBIN A1C: 5.9 [5.6 - 6.5] %; [redacted]20[redacted] (RX DAY 110): CALCIUM: 2.2 [2.12 - 2.62] MMOL/L; CREATININE: 74 [71 - 124] UMOL/L; ERYTHROCYTES: 4 [4.2 - 5.5] 10^12/L; GLUCOSE: 5.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.37 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 130 [134 - 170] G/L; LEUKOCYTES: 4.5 [3.6 - 10.6] 10^9/L; PLATELETS: 183 [150 - 450] 10^9/L; POTASSIUM: 4 [3.5 - 5.5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L; TRIGLYCERIDES: 0.59 [0 - 1.7] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	108
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GAIT DISORDER PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #22: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 185
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	204
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #23: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	REDNESS AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #24: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN PEELING AT THE INFUSION SITE
Preferred term	注入部位皮膚剥脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #25: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RAISED NODULE AT INFUSION SITE
Preferred term	注射部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #26: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN GLAZING AT INFUSION SITE
Preferred term	注射部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #27: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION AT INFUSION SITE
Preferred term	注射部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 360
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，転倒（偶発的），意識消失，右顔面外傷，右眼窩周囲腫脹及び眼周囲痛，並びに活動性顔面出血を発現した。

Event 16，17，18，19，20，及び 21 の臨床経過：

関連する病歴は，不整脈（心房細動），高血圧，便秘（時々），パーキンソン病，軽度白内障，脳回点状出血，脳振とう，高頻度鼻出血，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 108 日目，被験者は転倒（偶発的），意識消失，右顔面外傷，右眼窩周囲腫脹及び眼周囲痛，並びに活動性顔面出血を発現した。同日，転倒（偶発的），意識消失，右顔面外傷，及び右眼窩周囲腫脹は消失した。投与 120 日目，眼周囲痛及び活動性顔面出血は消失した。

投与 108 日目，被験者は疼痛があり，階段から機械的に転落したため入院した。被験者は意識消失だと述べた。被験者はパーキンソン病のため歩行障害があった。被験者は歩行障害のため転落した。被験者は転倒後，活動性出血を伴う右顔面外傷，並びに右眼窩周囲腫脹及び眼周囲痛を発現した。被験者の疼痛の程度は 10 段階中 3 であった。被験者は視力の変化，悪心，嘔吐，及び軽度の意識朦朧／めまいを否定した。被験者はアセチルサリチル酸を服用していた（その他抗凝固薬の服用はなし）。検査により，被験者に右眼浮腫／斑状出血及び両掌擦過傷が認められた。被験者は発熱，悪寒，胸痛及び息切れを否定した。投与 110 日目，被験者は退院した。

治験責任医師によると，被験者は過去にも転倒していたが入院はしていなかった。

被験者にセファレキシン，潤滑剤点眼液，ガバペンチン，及びオキシコドンが投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SELEGILINE for PARKINSON'S DISEASE (Started [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Fall (10016173) (Fall (10016173)) [v.23.1] [10016173]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Loss of consciousness (10024855) (Loss of consciousness (10024855)) [v.23.1] [10024855]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

3) Periorbital swelling (10056647) (Periorbital swelling (10056647)) [v.23.1] [10056647]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

4) Face injury (10050392) (Face injury (10050392)) [v.23.1] [10050392]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

5) Bleeding (10005103) (Haemorrhage (10055798)) [v.23.1] [10005103]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

6) Periorbital pain (10034546) (Periorbital pain (10034546)) [v.23.1] [10034546]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of FALL (ACCIDENTAL), LOSS OF CONSCIOUSNESS, RIGHT FACE TRAUMA, RIGHT PERIORBITAL SWELLING

- Investigator: Gait disorder Parkinson Disease

- AbbVie: More likely related to traumatic injury from an accidental occurrence in an advanced aged patient with a history of Parkinson's disease and concussion

Event of PAIN SURROUNDING EYE, ACTIVE FACIAL BLEEDING

- Investigator: Gait disorder

- AbbVie: More likely related to traumatic injury from an accidental occurrence in an advanced aged patient with a history of Parkinson's disease and concussion

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CALCIUM:** 8.8 mg/dL

[redacted] **20[redacted] CHOLESTEROL:** 153 mg/dL

[redacted] **20[redacted] CREATININE:** 0.84 mg/dL

[redacted] **20[redacted] CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHESTW/ IV CONTRAST:** No acute traumatic findings in the chest. 2.6 x 2.9 x 4.4 cm hypo dense lesion arising from the right lobe of the thyroid, which may represent goiter. recommend non-emergent follow-up thyroid ultrasound for further evaluation. Cardiomegaly. 2.3 x 2.4 cm intermediate density lesion arising from the right kidney, recommend f/u non-emergent renal ultrasound. Mixed sclerotic and lucent multicolor left ischial lesion as described above with features suggesting benign etiology.. Sclerotic lesion within L5 vertebral body, which may represent a bone island. in the setting of enlarged prostate.

[redacted] **20[redacted] CT CERVICAL SPINE:** No definite evidence of a recent fracture involving the cervical vertebrae. No significant central canal compromise at any level of the cervical spine. Grade 1 anterolisthesis at the C4-C5 level, likely degenerative in nature.

[redacted] **20[redacted] CT HEAD W/O IV CONTRAST:** suggestive of ischemic change involving the R perieto-occipital region, of uncertain age, maybe subacute. there is note of adjacent curviclinear hyperattenuation, which may represent gyral petechial hemorrhage, a small amount of subarachnoid hemorrhage would be difficult to exclude, these are not seen on prior study. no significant intracranial mass effect.no definite evidence of calvarial fracture. extensive soft tissue edema overlying the R frontal region the right masticator space, involving the R preseptal soft tissues, w/ note of more discrete hematoma overlying the R lateral orbital wall

[redacted] **20[redacted] CT HEAD W/O IV CONTRAST:** Age related volume loss of findings suggestive of mild to moderate small vessel disease.

[redacted] **20[redacted] CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:** There is a minimally displaced fracture involving the posterolateral wall of the right maxillary sinus. Questionable non-displaced fracture involving the Right Posterior orbital floor. Extensive right-sided facial soft tissue edema as discussed above with note of more discrete hematoma overlying the right lateral orbital wall

[redacted] **20[redacted] CTA NECK:** calcified plaques cause mild narrowing at the origins of both vertebral arteries. No definite evidence of significant stenosis involving the cervical carotid arteries. No definite evidence of a dissection of the cervical carotid or vertebral arteries. There is note of an asymmetrically enlarged right thyroid lobe with a component which extends into the superior mediastinum. this was only partially included in the field of view on the prior study.

[redacted] **20[redacted] GLUCOSE:** 97 mg/dL (normal 60 to 100)

[redacted] **20[redacted] HEMATOCRIT:** 37.4%

[redacted] **20[redacted] HEMOGLOBIN:** 13 G/DL

[redacted] **20[redacted] HEMOGLOBIN A1C:** 5.9% (normal >5.6)

[redacted] **20[redacted] MRI BRAIN/ HEAD WITHOUT CONTRAST:** No acute infarction; abnormality seen on recent head CT likely corresponds to a sub-acute infarction, though new from [redacted]/[redacted]/20[redacted]. Right frontoparietal scalp contusion and thin right frontoparietal subdural hematoma. No significant mass effect. White matter changes of advanced chronic microvascular disease.

[redacted] **20[redacted] PLATELET COUNT:** 183 k/cumm

[redacted] **20[redacted] POTASSIUM:** 4 MMOL/L

[redacted] **20[redacted] RBC:** 4 million/cumm

[redacted] **20[redacted] SODIUM:** 134 MMOL/L

[redacted] **20[redacted] TRIGLYCERIDES:** 52 mg/dL

[redacted] **20[redacted] WBC:** 4.5 k/cumm

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位膿瘍	X			X
注入部位蜂巣炎	X			X
敗血症	X			
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ALLERGY TO PENICILLIN	19[redacted]
HYPOTHYROIDISM	19[redacted]
OVARIAN CYST	19[redacted]
BREAST CANCER	19[redacted]
RESTLESS LEG SYNDROME	19[redacted]
DEGENERATIVE DISC DISEASE	20[redacted]
HYPERTENSION	20[redacted]
ANXIETY	20[redacted]
EXERCISE INDUCED ASTHMA	20[redacted]
OSTEOPOROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
ONSET OF MOTOR FLUCTUATION	19[redacted]
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]

Prior Procedures	Procedure Year
HYSTERECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.17	0.2	0	60	0.11	[redacted]
ABBV-951	0.17	0.2	0	60	0.11	[redacted]
ABBV-951	0.17	0.18	0	660	0.11	[redacted]
ABBV-951	0.2	0.22	0.18	60	0.11	[redacted]
ABBV-951	0.23	0.24	0.22	60	0.11	[redacted]
ABBV-951	0.27	0.28	0.26	60	0.11	[redacted]
ABBV-951	0.3	0.31	0.28	60	0.11	[redacted]
ABBV-951	0.3	0.31	0.24	60	0.11	[redacted]

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	87.08		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	690.85		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	690.85		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	690.85		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	701.09		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		18.78	SC / ONCE	[redacted]	
ABBV-951	690.85		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		37.56	SC / ONCE	[redacted]	
ABBV-951	690.85		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	720.22		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		37.56	SC / ONCE	[redacted]	
ABBV-951	734.56		SC / CONTINUOUS	[redacted]	[redacted]

ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	709.97		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	362.84		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	694.61		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	722.27		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 17	
ABBV-951	791.25		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	812.77		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	814.81		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	728.41		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	716.12		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	854.43		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	917.78		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	895.41		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	934.68		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	891.48		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	695.12		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	917.95		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1017.84		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1101.84		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1118.07		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1142.65		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1128.31		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33

ABBV-951	1137.87		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951		37.56	SC / ONCE	[redacted] / 35	
ABBV-951	1113.97		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	1137.87		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951		18.78	SC / ONCE	[redacted] / 37	
ABBV-951	1099.63		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	1081.53		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	1074.18		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	1101.84		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951		18.78	SC / ONCE	[redacted] / 41	
ABBV-951	1101.84		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		56.34	SC / ONCE	[redacted] / 42	
ABBV-951	1092.62		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		18.78	SC / ONCE	[redacted] / 43	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		37.56	SC / ONCE	[redacted] / 44	
ABBV-951	1194.73		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951		37.56	SC / ONCE	[redacted] / 45	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951		18.78	SC / ONCE	[redacted] / 46	
ABBV-951	1265.08		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	1152.73		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951		18.78	SC / ONCE	[redacted] / 48	
ABBV-951	1188.24		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		18.78	SC / ONCE	[redacted] / 49	
ABBV-951	1142.65		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951	1051.82		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		18.78	SC / ONCE	[redacted] / 51	
ABBV-951	1188.93		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951	1206.51		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		18.78	SC / ONCE	[redacted] / 53	
ABBV-951	1193.88		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	1261.15		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		18.78	SC / ONCE	[redacted] / 55	
ABBV-951	1205.83		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		18.78	SC / ONCE	[redacted] / 56	
ABBV-951	1248.86		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56

ABBV-951	1239.47		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1167.93		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 59	
ABBV-951	1137.87		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 60	
ABBV-951	1133.09		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	1194.56		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 62	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1249.20		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 67	
ABBV-951	1042.77		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 68	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 69	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 70	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 73	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 74	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 77	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 78	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 79	
ABBV-951	1233.32		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80

ABBV-951	1196.95		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	1137.87		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	1137.87		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951		18.78	SC / ONCE	[redacted] / 84	
ABBV-951	1051.82		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951	1047.03		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951	1197.29		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951		18.78	SC / ONCE	[redacted] / 87	
ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		37.56	SC / ONCE	[redacted] / 88	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		18.78	SC / ONCE	[redacted] / 89	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951		56.34	SC / ONCE	[redacted] / 90	
ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	1259.79		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	1259.79		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		37.56	SC / ONCE	[redacted] / 93	
ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		37.56	SC / ONCE	[redacted] / 94	
ABBV-951	1233.32		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951		18.78	SC / ONCE	[redacted] / 95	
ABBV-951	1243.91		SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		75.13	SC / ONCE	[redacted] / 96	
ABBV-951	1238.62		SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		56.34	SC / ONCE	[redacted] / 97	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951		18.78	SC / ONCE	[redacted] / 98	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951		18.78	SC / ONCE	[redacted] / 99	
ABBV-951	1243.91		SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	1230.93		SC / CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	1214.03		SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	1203.78		SC / CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	1208.91		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	1219.15		SC / CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	1224.27		SC / CONTINUOUS	[redacted] / 105	[redacted] / 105

ABBV-951	1198.66		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1198.66		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 113	
ABBV-951	1173.05		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 114	
ABBV-951	1225.81		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	1228.03		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 120	
ABBV-951	1238.62		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1249.20		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 132	
ABBV-951	1249.20		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 133	
ABBV-951	1254.50		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 134	
ABBV-951	1243.91		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 135	
ABBV-951	1259.79		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135

ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1249.20	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1259.79	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1240.66	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	1219.15	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1188.42	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	1214.03	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	1219.15	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1214.03	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	1208.91	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	1214.03	SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HYDROCODONE BITARTRATE;PARACETAMOL	5-325 mg	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
LEVOTHYROXINE	112 ug	QD	Y-M: 20[redacted]-[redacted]
LORAZEPAM	1 mg	PRN	Y-M: 20[redacted]-[redacted]
RALOXIFENE	60 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	145.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	145.000 mg	QID	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
VALSARTAN	80 mg	QD	Y-M: 20[redacted]-[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
HYDROCODONE BITARTRATE;PARACETAMOL	5-325 mg	PRN	Y-M: 20[redacted]	ONGOING
LEVOTHYROXINE	112 ug	QD	Y-M: 20[redacted]-[redacted]	ONGOING
LORAZEPAM	1 mg	PRN	Y-M: 20[redacted]-[redacted]	ONGOING
RALOXIFENE	60 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
VALSARTAN	80 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING

DAPTOMYCIN	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 100
VANCOMYCIN	125 mg	QD	Y-M: 20[redacted] / 83	Y-M: 20[redacted] / 85
CEFALEXIN	50 mg	OTHER: QID	Y-M: 20[redacted] / 95	Y-M: 20[redacted] / 101
CEFTRIAXONE SODIUM	1 g	QD	Y-M: 20[redacted] / 95	Y-M: 20[redacted] / 101
SULFAMETHOXAZOLE	80 mg	BID	Y-M: 20[redacted] / 95	Y-M: 20[redacted] / 101

Event #1: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	ABSCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 81
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	101
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 81
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	101
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Serious Adverse Event

Event Description	SEPSIS
Preferred term	敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 81
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	101
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，敗血症，注入部位蜂巣炎，及び注入部位膿瘍を発現した。

Event 1，2，及び 3 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 81 日目，敗血症，注入部位蜂巣炎，及び注入部位膿瘍を発現した。投与 101 日目，敗血症，注入部位蜂巣炎，及び注入部位膿瘍は消失した。

投与 82 日目，被験者は入院した。被験者に注入部位疼痛及び発赤とともに軽度の発熱が認められた。被験者は小膿瘍を伴う腹壁の蜂巣炎に続発した敗血症と診断された。被験者は抗生物質による治療を受け改善がみられたものの，波動性硬結がいくつか認められた。抗生物質の投与は完了し，投与 101 日目，被験者は安定した状態で退院した。

被験者にダプトマイシン，バンコマイシン，スルファメトキサゾール，ロセフィン，及びセファレキシンが投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

RYTARY for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Sepsis (10040047) (Sepsis (10040047)) [v.23.1] [10040047]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.1] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

3) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.23.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of SEPSIS

- Investigator: Not applicable

- AbbVie: Not applicable

Event of CELLULITIS AT INFUSION SITE, ABSCESS AT INFUSION SITE

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
胸痛	X			
注入部位蜂巣炎				X
注入部位不快感				X
注入部位血腫				X
注入部位結節				X
体重減少				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
FRONTAL POLYPS (SINUSES)	19[redacted]
ABNORMAL UTERINE BLEEDING	19[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
APPENDICITIS	20[redacted]
GALLSTONES	20[redacted]
ANXIETY	20[redacted]
INSOMNIA	20[redacted]
CONSTIPATION	20[redacted]
CATARACT OD	20[redacted]
NEUROPATHIC PAIN	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
GASTROESOPHAGEAL REFLUX	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
POLYPECTOMY SINUS	19[redacted]
CAESAREAN	19[redacted]
CAESAREAN	19[redacted]
HYSTERECTOMY	19[redacted]
APPENDECTOMY	20[redacted]
CHOLECYSTECTOMY	20[redacted]
CATARACT RESECTION, RIGHT EYE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.3	0.22	60	0.11	[redacted]/1
ABBV-951	0.19	0.22	0.16	60	0.11	[redacted]/2
ABBV-951	0.27	0.31	0.22	60	0.11	[redacted]/8
ABBV-951	0.31	0.36	0.26	60	0.11	[redacted]/16
ABBV-951	0.31	0.36	0.26	60	0.11	[redacted]/19
ABBV-951	0.31	0.36	0.26	60	0.11	[redacted]/29
ABBV-951	0.36	0.41	0.3	60	0.15	[redacted]/40
ABBV-951	0.4	0.45	0.32	60	0.15	[redacted]/96
ABBV-951	0.43	0.46	0.34	60	0.11	[redacted]/183
ABBV-951	0.46	0.5	0.37	60	0.11	[redacted]/200
ABBV-951	0.46	0.5	0.37	60	0.15	[redacted]/215
ABBV-951	0.47	0.5	0.4	60	0.15	[redacted]/274
ABBV-951	0.5	0.52	0.42	60	0.19	[redacted]/341
ABBV-951	0.52	0.57	0.46	60	0.19	[redacted]/354
ABBV-951	0.52	0.57	0.46	60	0.19	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		56.34	SC / ONCE	[redacted] / 6	
ABBV-951	518.39		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		93.91	SC / ONCE	[redacted] / 7	
ABBV-951	882.77		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		18.78	SC / ONCE	[redacted] / 8	
ABBV-951	1128.14		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		18.78	SC / ONCE	[redacted] / 14	
ABBV-951	1231.61		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		18.78	SC / ONCE	[redacted] / 15	
ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		18.78	SC / ONCE	[redacted] / 17	
ABBV-951	1238.62		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		18.78	SC / ONCE	[redacted] / 18	
ABBV-951	1366.17		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		18.78	SC / ONCE	[redacted] / 27	
ABBV-951	1308.45		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	476.39		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951		18.78	SC / ONCE	[redacted] / 38	
ABBV-951	1291.04		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38

ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	1335.94		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
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ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
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ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 95	
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ABBV-951	1475.28	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1475.28	SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1475.28	SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1475.28	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1475.28	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
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ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		194.65	SC / ONCE	[redacted]20[redacted] / 363	

ABBV-951	2062.66		SC / CONTINUOUS	[redacted]20[redacted] / 363 [redacted]20[redacted] / 363
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 364
ABBV-951	2243.99		SC / CONTINUOUS	[redacted]20[redacted] / 364 [redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]
PRAMIPEXOLE	0.500 mg	QID	Y-M: 20[redacted]
TRAZODONE	50 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]
MACROGOL 3350	17 g	QD	Y-M: 20[redacted]
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]
CLOZAPINE	25 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted] / -244
PREGABALIN	25 mg	BID	Y-M: 20[redacted] / -244
PREGABALIN	50 mg	QD	Y-M: 20[redacted] / -244
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83
DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted] / -74
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 29
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]	ONGOING

MACROGOL 3350	17 g	QD	Y-M: 20[redacted]	ONGOING
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]	ONGOING
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244	ONGOING
PREGABALIN	25 mg	BID	Y-M: 20[redacted] / -244	Y-M: 20[redacted] / 274
PREGABALIN	50 mg	QD	Y-M: 20[redacted] / -244	Y-M: 20[redacted] / 274
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123	ONGOING
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83	ONGOING
DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83	ONGOING
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41	ONGOING
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 39
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 40	ONGOING
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / 40	ONGOING
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 183	ONGOING
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 275	ONGOING
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 275	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 280	Y-M: 20[redacted] / 284
ACETYLSALICYLIC ACID	325 mg	QD	Y-M: 20[redacted] / 318	Y-M: 20[redacted] / 320
DILTIAZEM	5 mg	QD	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 320
GLYCERYL TRINITRATE	UNKNOWN OTHER: 50 MG PER 500 ML	OTHER: UNKNOWN, CONTINUOUS IV	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 320
HEPARIN	4000 IU	QD	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 320
SODIUM CHLORIDE	UNKNOWN mL	QD	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 320
GLYCERYL TRINITRATE	0.2 mg	OTHER: PER 24 HRS, CONTINUOUS	Y-M: 20[redacted] / 321	ONGOING
ISOSORBIDE DINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 321	ONGOING
MIDODRINE	2.5 mg	BID	Y-M: 20[redacted] / 321	ONGOING
CYCLOBENZAPRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 365	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS NODULARITIES AT OLD INFUSION SITES
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	WITH SUBJECTIVE FEELING BY THE PATIENT THAT IP WAS ACCUMULATING SUBCUTANEOUSLY LEADING TO SOME MASS EFFECT BUT WITHOUT REDNESS NOR PAIN
Preferred term	注入部位不快感
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	4
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 96
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	274
Duration of AE	179 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Weight Loss

Event Description	PT LOST 9 POUNDS IN 3 MONTHS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 96
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	274
Duration of AE	179 DAYS

Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT OLD INFUSION SITE (RIGHT SIDE OF ABDOMEN)
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 279
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	284
Duration of AE	6 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS HEMATOMA AT OLD INFUSION SITE SITE
Preferred term	注入部位血腫

AE Onset Date / Rx Day	[redacted]20[redacted] / 281
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	284
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Serious Adverse Event

Event Description	CHEST PAIN OF UNDETERMINED ETIOLOGY
Preferred term	胸痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 304
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 318): HEMOGLOBIN: 122 [117 - 161] G/L; NPTST131-GLOMERULAR FILTRATION RATE: 89 ML/MIN [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: LESS THAN 2 MG PER L [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	HOSPITAL PHYSICIAN ORDERED A CONSULTATION IN GASTROENTEROLOGY, SO GASTRIC ORIGIN SUSPECTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はカナダの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，原因不明の胸痛を発現した。

Event 7 の臨床経過：

関連する病歴は，起立性低血圧，パーキンソン病，心房細動，胃食道逆流症，及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 304 日目，被験者は原因不明の胸痛を発現した。

被験者の胸痛は 15 日間続いた。被験者は緊急治療室の受診を勧められた。投与 318 日目，被験者は緊急治療室を受診し，不安定狭心症の診断に基づき入院した。投与 320 日目，被験者は緊急冠動脈造影を受けたが正常であった。投与 321 日目，被験者は退院した。

被験者に NITRO DUR が投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA SUSTAINED RELEASE (SINEMET CR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Chest pain (10008479) (Chest pain (10008479)) [v.23.1] [10008479]

Causality asper reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of CHEST PAIN OF UNDETERMINED ETIOLOGY

- Investigator:

- AbbVie: More likely related to a history of gastro-esophageal reflux disease, Parkinson's disease and atrial fibrillation in an advanced aged patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] CORONAROGRAPHY: Results not yet reported

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 5[redacted] kg. Weight at time of event 5[redacted] kg. Weight loss occurred over a period of 3 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced a temporal episode of activity increase/more active since treatment began and a temporal episode of immune disorder.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想				X
転倒				X
幻覚	X			X
注入部位紅斑				X
皮膚損傷				X
** Disc. due to other: other				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	ASIAN

Medical History	Onset Year
NENSTRUATION(MENOPAUSE)	19[redacted]
CONSTIPATION DUE TO PD	20[redacted]
HYPOTENSION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.2	0.24	0.17	180	0.11	[redacted]/1
ABBV-951	0.2	0.24	0.17	180	0.11	[redacted]/2
ABBV-951	0.3	0.36	0.24	180	0.11	[redacted]/7
ABBV-951	0.37	0.44	0.3	180	0.19	[redacted]/9
ABBV-951	0.43	0.52	0.34	180	0.19	[redacted]/16
ABBV-951	0.43	0.52	0.34	180	0.19	[redacted]/23
ABBV-951	0.37	0.44	0.3	180	0.19	[redacted]/24
ABBV-951	0.2	0.24	0.17	180	0.15	[redacted]/31
ABBV-951	0.23	0.28	0.18	180	0.15	[redacted]/45
ABBV-951	0.27	0.32	0.22	180	0.15	[redacted]/73
ABBV-951	0.3	0.36	0.24	180	0.15	[redacted]/94
ABBV-951	0.33	0.4	0.26	180	0.15	[redacted]/122

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	355.16		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	919.31		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		37.56	SC / ONCE	[redacted] / 4	
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		75.13	SC / ONCE	[redacted] / 5	
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		56.34	SC / ONCE	[redacted] / 6	
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		56.34	SC / ONCE	[redacted] / 7	
ABBV-951	1120.80		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		56.34	SC / ONCE	[redacted] / 8	

ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 9	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		194.65	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		227.09	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1359.17		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	1493.20		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1689.91		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1915.81		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1951.16		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1782.80		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	1329.11		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1346.87		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1461.44		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1638.17		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1626.73		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1500.03		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1347.38		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1002.30		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	928.88		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	911.80		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
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ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
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ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
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ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	785.45		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	839.74		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
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ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
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ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
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ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 72	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 73	

ABBV-951	1024.5		SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951		51.22	SC / ONCE	[redacted] / 86	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		51.22	SC / ONCE	[redacted] / 89	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951		25.61	SC / ONCE	[redacted] / 92	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		51.22	SC / ONCE	[redacted] / 93	
ABBV-951	1101.84		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		25.61	SC / ONCE	[redacted] / 94	
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		25.61	SC / ONCE	[redacted] / 96	
ABBV-951	1288.30		SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		25.61	SC / ONCE	[redacted] / 97	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951		51.22	SC / ONCE	[redacted] / 98	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951		25.61	SC / ONCE	[redacted] / 99	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951		76.83	SC / ONCE	[redacted] / 100	

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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 102	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 103	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 106	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 107	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 110	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 113	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 114	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1351.31		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 116	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 117	
ABBV-951	1288.82		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 120	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 121	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 124	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124

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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 128	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 130	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 131	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 134	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 135	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
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ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 138	
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 141	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 142	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
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ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 144	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 145	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 148	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 149	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149

ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 151	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 152	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 156	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 158	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 159	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 162	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 163	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
REBAMIPIDE	100 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted]
DROXIDOPA	200.000 mg	TID	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	40.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
MIDODRINE	4 mg	BID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]

CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted] / -335
CYANOCOBALAMIN	2 OTHER: TAB	QD	Y-M: 20[redacted] / -26

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
REBAMIPIDE	100 mg	TID	Y-M: 20[redacted]	ONGOING
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 68
MIDODRINE	4 mg	BID	Y-M: 20[redacted]	ONGOING
CYANOCOBALAMIN	2 OTHER: TAB	QD	Y-M: 20[redacted] / -26	Y-M: 20[redacted] / 23
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APP	PRN	Y-M: 20[redacted] / 2	Y-M: 20[redacted] / 167
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 57
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	2.6 g	PRN	Y-M: 20[redacted] / 34	ONGOING
PARACETAMOL	200 mg	PRN	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 88
ETIZOLAM	0.5 mg	TID	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 50
SENNOSIDE A+B	12 mg	PRN	Y-M: 20[redacted] / 46	Y-M: 20[redacted] / 83
ETIZOLAM	1 mg	TID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 52
QUETIAPINE	25 mg	TID	Y-M: 20[redacted] / 51	Y-M: 20[redacted] / 53
ETIZOLAM	0.5 mg	TID	Y-M: 20[redacted] / 52	ONGOING
QUETIAPINE	25 mg	QID	Y-M: 20[redacted] / 53	Y-M: 20[redacted] / 56
BROTIZOLAM	0.25 mg	PRN	Y-M: 20[redacted] / 54	Y-M: 20[redacted] / 83

SENNOSIDE A+B	0.5 g	PRN	Y-M: 20[redacted] / 54	Y-M: 20[redacted] / 83
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 56	Y-M: 20[redacted] / 63
QUETIAPINE	37.5 mg	BID	Y-M: 20[redacted] / 56	Y-M: 20[redacted] / 63
QUETIAPINE	37.5 mg	QID	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 68
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted] / 69	ONGOING
QUETIAPINE	37.5 mg	BID	Y-M: 20[redacted] / 69	Y-M: 20[redacted] / 118
QUETIAPINE	50 mg	BID	Y-M: 20[redacted] / 69	Y-M: 20[redacted] / 118
LOXOPROFEN	60 mg	PRN	Y-M: 20[redacted] / 88	ONGOING
REBAMIPIDE	100 mg	PRN	Y-M: 20[redacted] / 88	ONGOING
QUETIAPINE	37.5 mg	QID	Y-M: 20[redacted] / 119	ONGOING
DULOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / 129	Y-M: 20[redacted] / 139
DULOXETINE HYDROCHLORIDE	40 mg	QD	Y-M: 20[redacted] / 140	ONGOING

Event #1: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 18
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	83
Duration of AE	66 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA(INFUSION SITE)
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 24
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	45
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSION
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	83
Duration of AE	54 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 32
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	32
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Falls And Associated Injuries

Event Description	ABRASION WOUND(UPPER LIP,RIGHT CHEEK,UNDER THE NOSE)
Preferred term	皮膚損傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 32
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	36
Duration of AE	5 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Falls And Associated Injuries

Event Description	FALL(SLIPPED.)
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 51
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	51
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 144
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	144
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 146
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	146
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951 の治験で ABBV-951 が投与され，幻覚を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 18 日目，被験者は幻覚を発現した。投与 83 日目，幻覚は消失した。

投与 23 日目，被験者は幻覚のため規定外の来院をしたが，その幻覚は被験者に強く影響を及ぼしていた。したがって，同日被験者は抗パーキンソン病薬の調節目的で入院した。動作困難も認められた。投与 24 日目，症状は改善したが，動作によっては補助が必要であった。

被験者に抑肝散，エチゾラム，及びクエチアピンが投与された。

The patient's past medications include:

MENESIT for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucination (10019063) (Hallucination (10019063)) [v.22.1] [10019063]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATION

- Investigator: Not applicable.

- AbbVie: Not applicable.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
蜂巣炎	X			
転倒				X
注入部位紅斑				X
注入部位発疹				X
肋骨骨折				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	ASIAN

Medical History	Onset Year
CEREBRAL INFARCTION	19[redacted]
CERVICAL SPONDYLOSIS	20[redacted]
CATARACT	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
DYSLIPIDEMIA	20[redacted]
HYPERTENSION	20[redacted]
HYPERURICEMIA	20[redacted]
LOW BACK PAIN	20[redacted]
LOSS OF APPETITE	20[redacted]
INSOMNIA	20[redacted]
CONSTIPATION DUE TO PD	20[redacted]
BENIGN PROSTATIC HYPERPLASIA	20[redacted]
ABDOMINAL DISTENSION	20[redacted]
IMPULSE CONTROL DUE TO PD	20[redacted]
FREQUENT URINATION DUE TO PD	20[redacted]
ALLERGIC RHINITIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
CERVICAL SPINE SURGERY	20[redacted]
CATARACT SURGERY(BOTH EYES)	20[redacted]
ATRIAL FIBRILLATION ABLATION SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	37	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.37	0.44	0.3	240	0.19	[redacted]20[redacted]/1
ABBV-951	0.53	0.64	0.42	240	0.19	[redacted]20[redacted]/2
ABBV-951	0.53	0.64	0.42	240	0.19	[redacted]20[redacted]/6
ABBV-951	0.43	0.52	0.34	240	0.19	[redacted]20[redacted]/12
ABBV-951	0.47	0.56	0.38	240	0.19	[redacted]20[redacted]/15
ABBV-951	0.47	0.56	0.38	120	0.24	[redacted]20[redacted]/23
ABBV-951	0.47	0.56	0.38	120	0.24	[redacted]20[redacted]/29
ABBV-951	0.47	0.56	0.38	120	0.24	[redacted]20[redacted]/43
ABBV-951	0.47	0.56	0.38	120	0.24	[redacted]20[redacted]/92
ABBV-951	0.43	0.52	0.34	120	0.24	[redacted]20[redacted]/135
ABBV-951	0.43	0.52	0.34	120	0.24	[redacted]20[redacted]/183
ABBV-951	0.43	0.47	0.34	120	0.24	[redacted]20[redacted]/208
ABBV-951	0.43	0.47	0.34	120	0.24	[redacted]20[redacted]/273
ABBV-951	0.45	0.49	0.36	120	0.24	[redacted]20[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
ABBV-951	796.03		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 2	
ABBV-951	2219.06		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 3	
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	2254.75		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 6	
ABBV-951	2078.02		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	2155.71		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1557.75		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1597.02		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1781.77		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1871.76		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	1841.36		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1826.17		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25

ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	1898.74		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1851.44		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1869.20		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1953.55		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1862.54		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	2125.83		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57

ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
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ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	1691.27	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	1657.98	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275

ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312

ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349

ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1393.32	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1647.73	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	1607.26	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted]-[redacted]
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	9.000 mg	QD	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	40.000 mg	QD	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX	2.5 g	QD	Y-M: 20[redacted]-[redacted]

GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT			
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted]
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
SILODOSIN	4 mg	BID	Y-M: 20[redacted]
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]
DIMETICONE	40 mg	TID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE	2.5 g	TID	Y-M: 20[redacted]

RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK			
RASAGILINE MESYLATE	0.500 mg	QD	Y-M: 20[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted] / -344
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331
ISTRADEFYLLINE	20.000 mg	QD	Y-M: 20[redacted] / -325
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / -321
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]	ONGOING
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]	ONGOING
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]	ONGOING
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]	ONGOING
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]	ONGOING
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	2.5 g	QD	Y-M: 20[redacted]	ONGOING
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]	ONGOING
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]	ONGOING
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]	ONGOING
SILODOSIN	4 mg	BID	Y-M: 20[redacted]	ONGOING

MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]	ONGOING
DIMETICONE	40 mg	TID	Y-M: 20[redacted]	ONGOING
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted]	ONGOING
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331	ONGOING
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / -321	Y-M: 20[redacted] / 23
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191	ONGOING
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153	ONGOING
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65	ONGOING
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 43
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 44	ONGOING
CAMPHOR;ENOXOLONE;LEVOMENTHOL;METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	ONGOING
CLOBETASONE BUTYRATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	Y-M: 20[redacted] / 92
DIFLUPREDNATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 79	Y-M: 20[redacted] / 92
CLOBETASOL PROPIONATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	BID	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
DIFLUPREDNATE	APPROPRIATE AMOUNT OTHER:	BID	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135

	APPROPRIATE AMOUNT			
EFINACONAZOLE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135	ONGOING
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136	ONGOING
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190	ONGOING
CEFAZOLIN SODIUM	1 g	BID	Y-M: 20[redacted] / 202	Y-M: 20[redacted] / 212
PROCAINE HYDROCHLORIDE	5 mL	OTHER: ONCE	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 203
BACITRACIN;NEOMYCIN SULFATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 205
SODIUM CHLORIDE	20 mL	QD	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 212
GENTAMICIN SULFATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 205	Y-M: 20[redacted] / 212

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA(INFUSION SITE)
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 6
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	273
Duration of AE	268 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RASH(ABDOMEN,INFUSION SITE)
Preferred term	注入部位発疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 51
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	135
Duration of AE	85 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event

Event Description	CELLULITIS(LEFT LOWER LIMB)
Preferred term	蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 199
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 202): NPTST056-C-REACTIVE PROTEIN: 2.51 [0 - 0.3] MG/DL; [redacted]20[redacted] (RX DAY 204): NPTST056-C-REACTIVE PROTEIN: 1.78 [0 - 0.3] MG/DL; [redacted]20[redacted] (RX DAY 208): NPTST056-C-REACTIVE PROTEIN: 1.12 [0 - 0.14] MG/DL; [redacted]20[redacted] (RX DAY 212): NPTST056-C-REACTIVE PROTEIN: 0.33 [0 - 0.14]

MG/DL

Microbiology

NOT REPORTED

AE Stopped Rx Day	219
Duration of AE	21 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	INFECTION.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 288
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	288
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Falls And Associated Injuries

Event Description	RIGHT RIB FRACTURE
Preferred term	肋骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 289
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	364
Duration of AE	76 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，蜂巣炎（左下肢）を発現した。

Event 3 の臨床経過：

関連する病歴は，脳梗塞，心房細動，高血圧，パーキンソン病，元喫煙者（1 日 1 本を 37 年間）及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 199 日目，被験者は蜂巣炎（左下肢）を発現した。

投与 219 日目，蜂巣炎（左下肢）は消失した。

入院前の投与 199 日目，被験者は自宅で転倒し，左膝を打った。その後，腫脹，発赤，及び疼痛が発現した。投与 200 日目，被験者は発赤及び腫脹のため近医を受診した。左膝の内側に局所的な血液の蓄積（血腫）があったため，左膝を部分的に切開した。

投与 202 日目，被験者は「強い腫脹」，発赤及び持続する疼痛があった。また，熱感とともに下肢に腫脹及び発赤が広がっていた。被験者は別の医療機関の皮膚科医を受診した。被験者は膝の周りに「強い皮下出血」があり，炎症が増したため，蜂巣炎と診断された。発熱はなかった。被験者は直ちに治療のため，他の病院に入院した。投与 203 日目，1 日 2 回の注射用セファゾリンの投与が開始された。左膝の周りにいくつかの血腫がみつかり，除去のために部分的な切開を行った。投与 205 日目，血腫の除去後，血腫又は血液の蓄積は観察されなかったが，治験薬の管理が困難であったため，被験者は治験実施医療機関に転院した。左膝に対しゲンタシンによる治療が追加され，弾性包帯で覆われた。投与 212 日目，セファゾリンの投与は中止された。腫脹，疼痛及び膝の周りの炎症は改善し，ゲンタシンによる治療は中止された。投与 219 日目，被験者の蜂巣炎は消失したことが確認され，被験者は退院した。

被験者にセファゾリンナトリウム，生理食塩液，バラマイシン及びゲンタシンが投与された。

The patient's past medications include:

ROPINIROLE for ALZHEIMER'S DISEASE ([redacted])

ROPOLE for PARKINSON’S DISEASE ([redacted])

SELEGILINE for PARKINSON’S DISEASE ([redacted])

MENESIT for PARKINSON’S DISEASE ([redacted])

ROTIGOTINE for PARKINSON’S DISEASE ([redacted])

ISTRADEFYLINE for PARKINSON’S DISEASE ([redacted])

ZONISAMIDE for PARKINSON’S DISEASE ([redacted])

ENTACAPONE for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA BENSERAZIDE HYDROCHLORIDE for ALZHEIMER'S DISEASE ([redacted] [redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Cellulitis of leg (10007912) (Cellulitis (10007882)) [v.23.1] [10007912]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS (LEFT LOWER LIMB)

- Investigator: Infection

- AbbVie: More likely related to reported skin injury due to the fall in an advanced age patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CRP:** 2.51 mg/dL (normal <0.30)

[redacted] **20[redacted] CRP:** 1.78 mg/dL (normal <0.30)

[redacted] **20[redacted] CRP:** 1.12 mg/dL (normal 0.00 to 0.14)

[redacted] **20[redacted] CRP:** 0.33 mg/dL (normal 0.00 to 0.14)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注射部位腫脹				X
嫉妬妄想				X
パーキンソン病	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	ASIAN

Medical History	Onset Year
KINDNEY STONE	19[redacted]
MENOPAUSE	19[redacted]
UTERINE FIBROID	20[redacted]
CONSTIPATION DUE TO PD	20[redacted]
ANXIETY DUE TO PD	20[redacted]
CHRONIC GASTRITIS	20[redacted]
BACK PAIN	20[redacted]
SPINAL CANAL STENOSIS	20[redacted]
RIBFRACTURE(RIGHT 9TH RIB)	20[redacted]
OSTEOPOROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
KINDNEY STONE LITHOTRIPSY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.2	0.24	0.17	60	0.11	[redacted]/1
ABBV-951	0.2	0.24	0.17	60	0.11	[redacted]/2
ABBV-951	0.2	0.22	0.17	60	0.11	[redacted]/8
ABBV-951	0.2	0.22	0.17	60	0.11	[redacted]/14
ABBV-951	0.2	0.22	0.17	60	0.15	[redacted]/21
ABBV-951	0.17	0.2	0	300	0.15	[redacted]/23
ABBV-951	0.2	0.22	0.18	300	0.15	[redacted]/28
ABBV-951	0.2	0.22	0.18	300	0.15	[redacted]/31
ABBV-951	0.2	0.22	0.18	300	0.15	[redacted]/42
ABBV-951	0.23	0.28	0.18	300	0.15	[redacted]/85
ABBV-951	0.27	0.3	0.22	300	0.15	[redacted]/92
ABBV-951	0.27	0.3	0.22	300	0.15	[redacted]/182
ABBV-951	0.27	0.3	0.22	180	0.15	[redacted]/245
ABBV-951	0.27	0.3	0.22	180	0.15	[redacted]/273
ABBV-951	0.3	0.31	0.22	180	0.15	[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	467.85		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	799.11		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6

ABBV-951	795.69		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	437.12		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 12	
ABBV-951	351.74		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	809.35		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	805.94		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	802.52		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	750.44		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	685.04		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	715.61		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	728.41		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40

ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	728.41		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
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ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	737.64		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
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ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	870.82		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	916.92		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	911.12		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	1044.99		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1129.85		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
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ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306

ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343

ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
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ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
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ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1106.46		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1189.44		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	1198.66		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 363	
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 364	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PRAMIPEXOLE	3.000 mg	QD	Y-M: 20[redacted]-[redacted]
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	20.000 mg	QD	Y-M: 20[redacted]-[redacted]
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]-[redacted]
REBAMIPIDE	100 mg	QD	Y-M: 20[redacted]-[redacted]
FLURBIPROFEN	40 mg	BID	Y-M: 20[redacted]-[redacted]

ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]
PREGABALIN	50 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
TIZANIDINE	1 mg	BID	Y-M: 20[redacted]
RISEDRONATE SODIUM	17.5 mg	OTHER: EVERY WEEK	Y-M: 20[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]
VONOPRAZAN FUMARATE	10 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	25.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	1.125 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
RASAGILINE MESYLATE	0.500 mg	QD	Y-M: 20[redacted] / -279
PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted] / -278
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted] / -271
PARACETAMOL	600 mg	BID	Y-M: 20[redacted] / -237
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted] / -229
CYANOCOBALAMIN	2 OTHER: TAB	QD	Y-M: 20[redacted] / -75
MECOBALAMIN	1000 ug	TID	Y-M: 20[redacted] / -28

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 91
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]	ONGOING
REBAMIPIDE	100 mg	QD	Y-M: 20[redacted]	ONGOING
FLURBIPROFEN	40 mg	BID	Y-M: 20[redacted]	ONGOING
PREGABALIN	50 mg	BID	Y-M: 20[redacted]	ONGOING
TIZANIDINE	1 mg	BID	Y-M: 20[redacted]	ONGOING
RISEDRONATE SODIUM	17.5 mg	OTHER: EVERY WEEK	Y-M: 20[redacted]	ONGOING
VONOPRAZAN FUMARATE	10 mg	QD	Y-M: 20[redacted]	ONGOING
PARACETAMOL	600 mg	BID	Y-M: 20[redacted] / -237	ONGOING
MECOBALAMIN	1000 ug	TID	Y-M: 20[redacted] / -28	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 42
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 210

DIFLUCORTOLONE VALERATE;LIDOCAINE	1.45 g	QD	Y-M: 20[redacted] / 76	Y-M: 20[redacted] / 364
INDOMETACIN	70 mg	QD	Y-M: 20[redacted] / 84	Y-M: 20[redacted] / 364
GENTAMICIN	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 205	Y-M: 20[redacted] / 273
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 210	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 245
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 245	ONGOING

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	JEALOUSY DELUSION
Preferred term	嫉妬妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	245
Duration of AE	224 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	WORSENING OF PARKINSON'S DISEASE
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 70

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	94
Duration of AE	25 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	DUE TO THE SPREAD OF COVID-19 INFECTION, THE USUAL REHABILITATION COULD NOT BE PERFORMED, AND THE PATIENT WAS HOSPITALIZED FOR IMPROVEMENT OF MOTOR SYMPTOMS.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SWELLING AT THE INJECTION SITE(UPPER RIGHT ABDOMEN)
Preferred term	注射部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 195
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	273
Duration of AE	79 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病の悪化を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，パーキンソン病による不安，パーキンソン病の悪化であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 70 日目，被験者はパーキンソン病の悪化を発現した。投与 94 日目，パーキンソン病の悪化は消失した。被験者は別の病院でリハビリテーションを受けていた。COVID-19 感染の蔓延により，他の施設で定期的に行われていたリハビリテーションができなくなり，パーキンソン病の運動症状が悪化した。徴候及び症状には，すくみ足が含まれていた。投与 70 日目，被験者は定期的な検査で診察を受けた。投与 83 日目，被験者は運動症状を改善する目的で入院した。投与 95 日目，被験者は退院した。

治験責任医師によると，被験者は投与 5 年前，投与 4 年前，投与 3 年前，投与 2 年前，及び投与 1 年前にパーキンソン病の悪化を発現した。

被験者にインドメタシンが投与された。

The patient's past medications include:

QUETIAPINE for JEALOUSY DELUSION ([redacted] 20[redacted] - [redacted] 20[redacted], Started [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.23.1] [10034006]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF PARKINSON’S DISEASE

- Investigator: Due to the spread of covid-19 infection, the usual rehabilitation could not be performed, and the patient was hospitalized for improvement of motor symptoms.

- AbbVie: More likely related to history of Parkinson's disease and reported the usual rehabilitation could not be performed.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想	X			X
転倒				X
幻覚	X			X
注入部位蜂巣炎				X
注入部位皮膚炎				X
注入部位紅斑				X
靭帯捻挫				X
筋肉痛				X
肋骨骨折				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	ASIAN

Medical History	Onset Year
RIGHT CATARACT	20[redacted]
HYPER URICEMIA	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
REM SLEEP BEHAVIOR DISORDER	20[redacted]
FREQUENCY URINARY	20[redacted]
CRASH SYNDROME	20[redacted]
FILMY VISION	20[redacted]
HEADACHES	20[redacted]
ANTI-HCV POSITIVE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.31	0.23	120	0.19	[redacted]/1
ABBV-951	0.27	0.31	0.23	120	0.19	[redacted]/2
ABBV-951	0.29	0.31	0.25	120	0.24	[redacted]/7
ABBV-951	0.29	0.31	0.25	120	0.24	[redacted]/14
ABBV-951	0.31	0.33	0.27	120	0.24	[redacted]/21
ABBV-951	0.33	0.35	0.29	120	0.24	[redacted]/22
ABBV-951	0.37	0.39	0.33	120	0.24	[redacted]/23
ABBV-951	0.37	0.39	0.3	120	0.24	[redacted]/27
ABBV-951	0.34	0.37	0.27	120	0.24	[redacted]/28
ABBV-951	0.3	0.32	0.24	120	0.24	[redacted]/29
ABBV-951	0.25	0.3	0.2	120	0.19	[redacted]/42
ABBV-951	0.26	0.31	0.21	120	0.19	[redacted]/49
ABBV-951	0.27	0.32	0.22	120	0.19	[redacted]/57
ABBV-951	0.28	0.33	0.23	120	0.19	[redacted]/63
ABBV-951	0.29	0.34	0.24	120	0.19	[redacted]/70
ABBV-951	0.27	0.32	0.22	120	0.19	[redacted]/76
ABBV-951	0.29	0.34	0.24	120	0.19	[redacted]/82
ABBV-951	0.3	0.36	0.24	120	0.19	[redacted]/89
ABBV-951	0.32	0.38	0.25	120	0.19	[redacted]/99
ABBV-951	0.33	0.4	0.26	120	0.19	[redacted]/104
ABBV-951	0.37	0.44	0.3	120	0.19	[redacted]/111

ABBV-951	0.4	0.48	0.32	120	0.3	[redacted]/135
ABBV-951	0.4	0.48	0.32	60	0.3	[redacted]/153
ABBV-951	0.43	0.52	0.34	60	0.3	[redacted]/182
ABBV-951	0.52	0.56	0.34	60	0.3	[redacted]/275
ABBV-951	0.52	0.56	0.34	60	0.3	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		32.44	SC / ONCE	[redacted] / 1	
ABBV-951	548.61		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
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ABBV-951	1934.25		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 261	
ABBV-951	1949.96		SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 263	
ABBV-951	1823.61		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 264	
ABBV-951	1823.61		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 265	
ABBV-951	1765.55		SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 266	
ABBV-951	1740.62		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 267	
ABBV-951	1786.04		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 268	
ABBV-951	1851.27		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 269	
ABBV-951	1734.13		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 270	
ABBV-951	1777.50		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 271	
ABBV-951	1818.14		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 272	
ABBV-951	1796.29		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 273	
ABBV-951	1769.65		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 274	
ABBV-951	1808.24		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 275	
ABBV-951	1768.97		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 276	
ABBV-951	1931.18		SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	2095.44		SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 278	
ABBV-951	1919.23		SC / CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 279	
ABBV-951	1709.54		SC / CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 280	

ABBV-951	1775.11		SC / CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 281	
ABBV-951	1778.87		SC / CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 282	
ABBV-951	1937.32		SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 283	
ABBV-951	1962.60		SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 284	
ABBV-951	1721.84		SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 285	
ABBV-951	1943.47		SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 288	
ABBV-951	1957.13		SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 289	
ABBV-951	1931.18		SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 290	
ABBV-951	1931.52		SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 291	
ABBV-951	1814.04		SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 292	
ABBV-951	1710.23		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 293	
ABBV-951	1915.81		SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 294	
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 295	
ABBV-951	1685.98		SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 297	
ABBV-951	1766.23		SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 298	
ABBV-951	1728.33		SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 299	
ABBV-951	1719.79		SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 300	

ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 301	
ABBV-951	1744.38		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 302	
ABBV-951	1814.38		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 303	
ABBV-951	1709.89		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 304	
ABBV-951	1823.61		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 305	
ABBV-951	1762.82		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 306	
ABBV-951	1736.86		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 307	
ABBV-951	1800.04		SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 308	
ABBV-951	1763.16		SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 309	
ABBV-951	1792.87		SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1798.68		SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 311	
ABBV-951	1998.79		SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 312	
ABBV-951	1909.66		SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 314	
ABBV-951	1921.62		SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 315	
ABBV-951	1766.23		SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 316	
ABBV-951	1735.50		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 317	
ABBV-951	1722.18		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 318	
ABBV-951	1726.62		SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 319	
ABBV-951	1683.93		SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 320
ABBV-951	1735.50		SC / CONTINUOUS	[redacted]20[redacted] / 320 [redacted]20[redacted] / 320
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 321
ABBV-951	1792.87		SC / CONTINUOUS	[redacted]20[redacted] / 321 [redacted]20[redacted] / 321
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 322
ABBV-951	1744.38		SC / CONTINUOUS	[redacted]20[redacted] / 322 [redacted]20[redacted] / 322
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 323
ABBV-951	1765.21		SC / CONTINUOUS	[redacted]20[redacted] / 323 [redacted]20[redacted] / 323
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 324
ABBV-951	1888.15		SC / CONTINUOUS	[redacted]20[redacted] / 324 [redacted]20[redacted] / 324
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 325
ABBV-951	2011.09		SC / CONTINUOUS	[redacted]20[redacted] / 325 [redacted]20[redacted] / 325
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 326
ABBV-951	1717.40		SC / CONTINUOUS	[redacted]20[redacted] / 326 [redacted]20[redacted] / 326
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 327
ABBV-951	1684.96		SC / CONTINUOUS	[redacted]20[redacted] / 327 [redacted]20[redacted] / 327
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 328
ABBV-951	1752.23		SC / CONTINUOUS	[redacted]20[redacted] / 328 [redacted]20[redacted] / 328
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 329
ABBV-951	1723.20		SC / CONTINUOUS	[redacted]20[redacted] / 329 [redacted]20[redacted] / 329
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 330
ABBV-951	1808.24		SC / CONTINUOUS	[redacted]20[redacted] / 330 [redacted]20[redacted] / 330
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 331
ABBV-951	1781.26		SC / CONTINUOUS	[redacted]20[redacted] / 331 [redacted]20[redacted] / 331
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 332
ABBV-951	1735.50		SC / CONTINUOUS	[redacted]20[redacted] / 332 [redacted]20[redacted] / 332
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 333
ABBV-951	1745.06		SC / CONTINUOUS	[redacted]20[redacted] / 333 [redacted]20[redacted] / 333
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 334
ABBV-951	1684.96		SC / CONTINUOUS	[redacted]20[redacted] / 334 [redacted]20[redacted] / 334
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 335
ABBV-951	1792.87		SC / CONTINUOUS	[redacted]20[redacted] / 335 [redacted]20[redacted] / 335
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 336
ABBV-951	1721.84		SC / CONTINUOUS	[redacted]20[redacted] / 336 [redacted]20[redacted] / 336
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 337
ABBV-951	1721.84		SC / CONTINUOUS	[redacted]20[redacted] / 337 [redacted]20[redacted] / 337
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 338

ABBV-951	1805.85		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 339	
ABBV-951	1741.99		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 340	
ABBV-951	1744.72		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 341	
ABBV-951	1814.38		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 342	
ABBV-951	1745.74		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 343	
ABBV-951	1766.23		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 344	
ABBV-951	1754.28		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 345	
ABBV-951	1823.61		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 346	
ABBV-951	1772.04		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 347	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 348	
ABBV-951	1786.38		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 349	
ABBV-951	1746.08		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 350	
ABBV-951	1804.82		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 351	
ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 352	
ABBV-951	1802.77		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 353	
ABBV-951	1726.62		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 354	
ABBV-951	1732.42		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 355	
ABBV-951	1750.52		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 356	
ABBV-951	1744.38		SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 357	
ABBV-951	1766.23		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 358	
ABBV-951	1722.18		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 359	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 360	
ABBV-951	1792.87		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 361	
ABBV-951	1733.11		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	1358.48		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 363	
ABBV-951	1811.31		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 364	
ABBV-951	1560.65		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 365	
ABBV-951	1946.55		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LIMAPROST ALFADEX	5 ug	TID	Y-M: 20[redacted]-[redacted]
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted]-[redacted]
APOMORPHINE HYDROCHLORIDE	3.000 mg	PRN	Y-M: 20[redacted]-[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]-[redacted]
CABERGOLINE	2.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
BORIC ACID;EPHEDRINE HYDROCHLORIDE;MAFENIDE HYDROCHLORIDE;TAURINE;ZINC SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]
UNSPECIFIED HERBAL	5 OTHER: TABLET	PRN	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]-[redacted] / -357

ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -294
CARBIDOPA;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted] / -210
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	6.8523 g	TID	Y-M: 20[redacted] / -49
CLONAZEPAM	1.0 mg	PRN	Y-M: 20[redacted] / -15

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LIMAPROST ALFADEX	5 ug	TID	Y-M: 20[redacted]	ONGOING
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted]	ONGOING
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]	ONGOING
UNSPECIFIED HERBAL	5 OTHER: TABLET	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / -7
BORIC ACID;EPHEDRINE HYDROCHLORIDE;MAFENIDE HYDROCHLORIDE;TAURINE;ZINC SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 62
ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -294	ONGOING
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	6.8523 g	TID	Y-M: 20[redacted] / -49	ONGOING
CLONAZEPAM	1.0 mg	PRN	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -2
SENNOSIDE A+B	24 mg	PRN	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 84
ZOLPIDEM TARTRATE	5 mg	PRN	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 84
QUETIAPINE	12.5 mg	PRN	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 15
LOXOPROFEN	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 15	Y-M: 20[redacted] / 71
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 25
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 27
QUETIAPINE	100 mg	QD	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 76
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 43

INFLUENZA VACCINE	0.5 mL	QD	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 37
SUVOREXANT	20 mg	QD	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 83
RAMELTEON	8 mg	QD	Y-M: 20[redacted] / 48	ONGOING
HYALURONATE SODIUM	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 62	ONGOING
SODIUM PICOSULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 63	ONGOING
QUETIAPINE	125 mg	QD	Y-M: 20[redacted] / 77	Y-M: 20[redacted] / 153
LEMBOREXANT	5 mg	QD	Y-M: 20[redacted] / 89	ONGOING
OXYBUTYNIN HYDROCHLORIDE	73.5 mg	QD	Y-M: 20[redacted] / 94	ONGOING
KETOPROFEN	30 mg	PRN	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
HEPARIN SODIUM	10 mL	QD	Y-M: 20[redacted] / 121	Y-M: 20[redacted] / 121
AMOXICILLIN TRIHYDRATE	250 mg	TID	Y-M: 20[redacted] / 137	Y-M: 20[redacted] / 137
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted] / 141	Y-M: 20[redacted] / 222
REBAMIPIDE	100 mg	PRN	Y-M: 20[redacted] / 141	Y-M: 20[redacted] / 222
QUETIAPINE	125 mg	QD	Y-M: 20[redacted] / 154	Y-M: 20[redacted] / 209
QUETIAPINE	25 mg	PRN	Y-M: 20[redacted] / 210	ONGOING
QUETIAPINE	75 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 243
DIPHENHYDRAMINE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 246
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 274
QUETIAPINE	37.5 mg	QD	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 350
BROMFENAC SODIUM	1 OTHER: DROP	BID	Y-M: 20[redacted] / 302	ONGOING
BETAMETHASONE SODIUM PHOSPHATE	1 OTHER: DROP	OTHER: 6 TIMES A DAY	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305
CEFDITOREN PIVOXIL	100 mg	TID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305
GATIFLOXACIN	1 OTHER: DROP	OTHER: 6 TIMES A DAY	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305
BETAMETHASONE SODIUM PHOSPHATE	1 OTHER: DROP	BID	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 316
GATIFLOXACIN	1 OTHER: DROP	QID	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 330
CLOBETASOL	APPLICATION	PRN	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 330

PROPIONATE	OTHER: APPLICATION			
GENTAMICIN SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 330
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 351	ONGOING
QUETIAPINE	37.5 mg	QD	Y-M: 20[redacted] / 351	ONGOING

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSION
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	153
Duration of AE	146 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

AE Stopped Rx Day	153
Duration of AE	146 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	4[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	13
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	MUSCLE PAIN(NECK AND SHOULDER)
Preferred term	筋肉痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	76
Duration of AE	62 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF DELUSION
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 28
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	42
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 28
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	42
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 46
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	46
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 48
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	48
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 49
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	49
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 64
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	64
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 67
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	67
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 70
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	70
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 81
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	81
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 99
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	99
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 99
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	99
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #17: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 99
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	99
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #18: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 102
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	102
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #19: Event of Interest -Falls And Associated Injuries

Event Description	FOOT SPRAIN
Preferred term	靭帯捻挫
AE Onset Date / Rx Day	[redacted]20[redacted] / 104
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	106
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #20: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	108
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #21: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 113
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	113
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #22: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 132
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	132
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #23: Event of Interest -Falls And Associated Injuries

Event Description	FRACTURED RIBS(RIGHT)
Preferred term	肋骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 132
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	222
Duration of AE	91 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #24: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 230
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	230
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #25: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REDNESS
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 243
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	246
Duration of AE	4 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #26: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 313
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	330
Duration of AE	18 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #27: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	CONTACT DERMATITIS AT INFUSION SITE
Preferred term	注入部位皮膚炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 316
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	330
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #28: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 351
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 4[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，妄想の悪化，幻覚の悪化を発現した。

Event 6 及び 7 の臨床経過：

関連する病歴は，パーキンソン病，不眠症，レム睡眠行動障害，クラッシュ症候群，かすみ目，頭痛，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 28 日目，被験者は妄想の悪化，幻覚の悪化を発現した。

投与 42 日目，妄想の悪化，幻覚の悪化は消失した。

本事象の発現前，投与 8 日目，被験者は妄想及び幻覚を自覚したが，それは非持続的であった。投与 9 日目，セレギリンの投与を中止し，クエチアピン 12.5 mg/日の投与を開始した。投与 10 日目から投与 13 日目まで，アマンタジンの投与量を 100 mg 1 日 2 回から 50 mg 1 日 1 回に減量した。投与 14 日目，幻覚及び妄想は夜から夜明けまでみられなかった。投与 16 日目，精神症状が悪化し，クエチアピンの投与量を 25 mg/日に増量した。投与 21 日目から投与 25 日目までの間，精神症状は治まったが，長時間の wearing-off 現象に関連する精神的ストレスを和らげるために ABBV-951 の投与量を増量した。投与 26 日目，幻覚及び妄想は夜から夜明けにかけて悪化した。

投与 28 日目，被験者は日中に発現した妄想及び幻覚の悪化のため，入院した。クエチアピンの投与量を 100 mg に増量した。入院の延長が決定された。投与 29 日目，幻覚妄想は夜から夜明けまで続いた。投与 30 日目，被験者及び家族との打ち合わせが行われた。治験薬投与は中止され，精神症状の治療が優先された。治験薬投与の中止期間中，ドパコール 750 mg/日 の投与を開始した。投与 32 日目，幻覚及び妄想が続き，クエチアピンの投与量を 25 mg に再び減量した。投与 35 日目，幻覚及び妄想は軽快した。

被験者にクエチアピンが投与された。

The patient's past medications include:

APOMORPHINE HYDROCHLORIDE HYDRATE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CABERGOLINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Delusion (10012239) (Delusion (10012239)) [v.23.1] [10012239]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Hallucinations aggravated (10019078) (Hallucination (10019063)) [v.23.1] [10019078]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF DELUSION, WORSENING OF HALLUCINATION

- Investigator: Not applicable

- AbbVie: Not applicable

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
幻覚	X	X		X
パーキンソン病	X	X		
穿刺部位内出血				X
横紋筋融解症	X	X		
** Disc. due to adverse event				X
** Disc. due to lack of efficacy				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	ASIAN

Medical History	Onset Year
ALLERGY	NOT REPORTED
CONSTIPATION	NOT REPORTED
DEPRESSION	NOT REPORTED
DIABETES MELLITUS	NOT REPORTED
FALL	NOT REPORTED
MENOPAUSE	NOT REPORTED
OVERACTIVE BLADDER	NOT REPORTED

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.17	0	0	0	0	[redacted]/1
ABBV-951	0.22	0	0.17	0	0	[redacted]/2
ABBV-951	0.22	0	0.17	0	0	[redacted]/3
ABBV-951	0.27	0	0.17	0	0	[redacted]/4
ABBV-951	0.3	0	0.22	0	0	[redacted]/7
ABBV-951	0.36	0	0.22	0	0	[redacted]/8
ABBV-951	0.36	0	0.22	0	0	[redacted]/10
ABBV-951	0.36	0	0.22	0	0	[redacted]/16

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	403.48		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	727.05		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	780.32		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	873.89		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	873.89		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	876.11		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	954.49		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1144.02		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1193.20		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1386.83		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1112.94		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	751.3		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12

ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1366	SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1343.46	SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1295.65	SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	10 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.375 mg	TID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.500 mg	BID	Y-M: 20[redacted]-[redacted]
SITAGLIPTIN PHOSPHATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]-[redacted]
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted]-[redacted] / -257
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted] / -257
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -82
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -82
CARBIDOPA MONOHYDRATE;LEVODOPA	75.000 mg	BID	Y-M: 20[redacted]-[redacted] / -82
MECOBALAMIN	0.5 mg	TID	Y-M: 20[redacted]-[redacted] / -14

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PAROXETINE HYDROCHLORIDE HEMIHYDRATE	10 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
SITAGLIPTIN PHOSPHATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted]-[redacted] / -257	ONGOING
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted] / -257	ONGOING
MECOBALAMIN	0.5 mg	TID	Y-M: 20[redacted]-[redacted] / -14	ONGOING
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	2.6 g	PRN	Y-M: 20[redacted]-[redacted] / 9	ONGOING
METFORMIN HYDROCHLORIDE	250 mg	BID	Y-M: 20[redacted]-[redacted] / 14	ONGOING

GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	500 mL	QD	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 15
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 15
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted] / 15	Y-M: 20[redacted] / 15
QUETIAPINE FUMARATE	12.5 mg	BID	Y-M: 20[redacted] / 16	ONGOING
QUETIAPINE FUMARATE	50 mg	QD	Y-M: 20[redacted] / 16	ONGOING
LUBIPROSTONE	24 ug	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 16
GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	500 mL	BID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 25
LUBIPROSTONE	24 ug	BID	Y-M: 20[redacted] / 17	ONGOING
SODIUM PICOSULFATE	15 gtt	PRN	Y-M: 20[redacted] / 21	ONGOING
BROTIZOLAM	0.25 mg	PRN	Y-M: 20[redacted] / 22	ONGOING
NUTRIENTS NOS	250 mL	PRN	Y-M: 20[redacted] / 22	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PUNCTURE SITE BRUISE
Preferred term	穿刺部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	2
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	5
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	84 (66 DAYS AFTER LAST TREATMENT)

Duration of AE	71 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	RHABDOMYOLYSIS
Preferred term	横紋筋融解症
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 1): NPTST079-CK: 58 [26 - 192] U/L; NPTST167-LDH: 230 [53 - 234] U/L; [redacted]20[redacted] (RX DAY 9): NPTST093-CPK: 438 [41 - 153] U/L; NPTST167-LDH: 177 [124 - 222] U/L; [redacted]20[redacted] (RX DAY 14): NPTST093-CPK: 5810 [41 - 153] U/L; NPTST167-LDH: 329 [124 - 222] U/L; [redacted]20[redacted] (RX DAY 17): NPTST093-CPK: 900 [41 - 153] U/L; NPTST167-LDH: 382 [124 - 222] U/L; [redacted]20[redacted] (RX DAY 22): NPTST093-CPK: 94 [41 - 153] U/L; NPTST167-LDH: 239 [124 - 222] U/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	22 (4 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	16
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	WORSENING OF PARKINSON'S SYMPTOMS
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 18
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	84 (66 DAYS AFTER LAST TREATMENT)
Duration of AE	67 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 19 (1 day after last treatment)
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	19 (1 DAY AFTER LAST TREATMENT)
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，幻覚，横紋筋融解症及びパーキンソン病の症状の悪化を発現した。

Event 3，4 及び 6 の臨床経過：

関連する病歴は，パーキンソン病，糖尿病，過活動膀胱及びうつ病であった。

投与 14 日目，被験者は幻覚及び横紋筋融解症を発現した。投与 18 日目，被験者はパーキンソン病の症状の悪化を発現した。投与 22 日目，横紋筋融解症は消失した。投与 84 日目，幻覚及びパーキンソン病の症状の悪化は消失した。

本事象の発現前，投与から 7 日前，被験者はスクリーニング来院 2 のため，入院した。被験者は治験薬投与の開始のため入院を継続した。

入院中，被験者はパーキンソン病の症状の悪化を発現した。徴候及び症状には，1 日中持続するオフ状態が含まれていた。被験者はクレアチンキナーゼ値の上昇及び幻覚妄想とみなされた精神症状も発現した。被験者は点滴及び薬物による治療を受けた。被験者の精神症状は改善した。投与 22 日目，被験者のクレアチンキナーゼ値は正常範囲内であった。被験者はリハビリテーションを受け，投与 84 日目に退院した。被験者は本試験への参加を完全に中止した。

被験者にブロチゾラム，ソルデム，sinemet，レボドパ，ルビプロストン，プラミペキソール，オランザピン及びクエチアピンフマル酸塩が投与された。

The patient's past medications include:

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucination (10019063) (Hallucination (10019063)) [v.22.1] [10019063]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

2) Rhabdomyolysis (10039020) (Rhabdomyolysis (10039020)) [v.22.1] [10039020]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

3) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.22.1] [10034006]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATION

- Investigator: Not applicable.

- AbbVie: Not applicable.

Event of RHABDOMYOLYSIS

- Investigator: Not applicable.

- AbbVie: More likely related to history of diabetes and concomitant medication pramipexole.

Event of WORSENING OF PARKINSON'S SYMPTOMS

- Investigator: Not applicable

- AbbVie: More likely related to stopping study drug and changing concomitant antiparkinsonian drugs in 6[redacted] year old patient with Parkinson's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CK:** 58 U/L (normal 26 to 192)

[redacted] **20[redacted] CPK:** 438 U/L (normal 41 to 153)

[redacted] **20[redacted] CPK:** 5810 U/L (normal 41 to 153)

[redacted] **20[redacted] CPK:** 900 U/L (normal 41 to 153)

[redacted] **20[redacted] CPK:** 94 U/L (normal 41 to 153)

[redacted] **20[redacted] LDH:** 230 U/L (normal 53 to 234)

[redacted] **20[redacted] LDH:** 177 U/L (normal 124 to 222)

[redacted] **20[redacted] LDH:** 329 U/L (normal 124 to 222)

[redacted] **20[redacted] LDH:** 382 U/L (normal 124 to 222)

[redacted] **20[redacted] LDH:** 239 U/L (normal 124 to 222)

[redacted] **20[redacted] MINI MENTAL STATUS EXAM:** 28 no units

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位腫瘤				X
パーキンソン病	X	X		
** Disc. due to adverse event				X
** Disc. due to lack of efficacy				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	ASIAN

Medical History	Onset Year
CONSTIPATION	NOT REPORTED
INSOMNIA	20[redacted]
ACNE	20[redacted]
CELLULITIS(LOWER LIMB)	20[redacted]
DIARRHEA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			

PIPES NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.26	0	0.23	0	0	[redacted]/1
ABBV-951	0.26	0	0.23	0	0	[redacted]/2
ABBV-951	0.35	0	0.29	0	0	[redacted]/5
ABBV-951	0.38	0	0.35	0	0	[redacted]/6
ABBV-951	0.38	0	0.35	0	0	[redacted]/9
ABBV-951	0.38	0	0.31	0	0	[redacted]/13
ABBV-951	0.33	0	0.28	0	0	[redacted]/15

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	621.53		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	992.91		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1017.67		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	984.37		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1225.13		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1321.43		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1452.91		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1433.44		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1451.71		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1459.40		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1465.88		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1523.94		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
FLUNITRAZEPAM	2 mg	QD	Y-M: [redacted]
LORAZEPAM	0.5 mg	BID	Y-M: [redacted]

MAGNESIUM OXIDE	500 mg	TID	Y-M: 20[redacted] / -286
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -62
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted] / -62
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted] / -27
ENTACAPONE	100.000 mg	BID	Y-M: 20[redacted] / -27
ROPINIROLE	4.000 mg	QD	Y-M: 20[redacted] / -27
TRIHEXYPHENIDYL	1.000 mg	BID	Y-M: 20[redacted] / -27

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]	ONGOING
LORAZEPAM	0.5 mg	BID	Y-M: 20[redacted]	ONGOING
MAGNESIUM OXIDE	500 mg	TID	Y-M: 20[redacted] / -286	ONGOING
ANTIBIOTICS-RESISTANT LACTIC ACID BACTERIAE	1 g	TID	Y-M: 20[redacted] / 1	Y-M: 20[redacted] / 2
NADIFLOXACIN	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 2	ONGOING
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	2.6 g	PRN	Y-M: 20[redacted] / 5	ONGOING
GLYCEROL	60 mg	PRN	Y-M: 20[redacted] / 8	ONGOING
SODIUM PICOSULFATE	15 gtt	PRN	Y-M: 20[redacted] / 8	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE MASS
Preferred term	注入部位腫瘤
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15

Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	WORSENING OF PARKINSON'S SYMPTOMS
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	91 (75 DAYS AFTER LAST TREATMENT)
Duration of AE	77 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病の症状の悪化を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者及び非飲酒者であった。

投与 15 日目，被験者はパーキンソン病の症状の悪化を発現した。投与 91 日目，パーキンソン病の症状の悪化は消失した。

投与 27 日前に同意書に署名された。投与 3 日前，被験者は治験薬投与開始のため入院した。入院中の投与初日，被験者は治験薬投与を開始した。治験薬は数回増量されたが，症状は悪化した。治験薬投与は投与 16 日目に完全に中止された。投与 91 日目，被験者は退院した。

被験者に短時間作用型の CD/LD が投与された。

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.22.1] [10034006]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF PARKINSON'S SYMPTOMS

- Investigator: Causal relationship.

- AbbVie: More likely related to a history of Parkinson's disease.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想				X
幻覚				X
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位硬結				X
意識消失	X			
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	ASIAN

Medical History	Onset Year
MENOPAUSE	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
SKIN RASH	20[redacted]
PAIN(LUMBAR)	20[redacted]
OPTEOPOROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.32	0.22	60	0.19	[redacted]/1
ABBV-951	0.27	0.32	0.22	60	0.19	[redacted]/2
ABBV-951	0.33	0.4	0.26	60	0.19	[redacted]/7
ABBV-951	0.43	0.52	0.34	60	0.19	[redacted]/14
ABBV-951	0.43	0.52	0.34	60	0.19	[redacted]/21
ABBV-951	0.5	0.6	0.4	60	0.19	[redacted]/31
ABBV-951	0.5	0.6	0.4	60	0.19	[redacted]/42
ABBV-951	0.5	0.55	0.4	60	0.19	[redacted]/91

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	410.31		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1088.01		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1046.52		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1092.62		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1137.70		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1174.76		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1304.01		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1384.61		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1474.59		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1454.10		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1611.88		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1618.71		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12

ABBV-951	1591.39	SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1686.32	SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1740.11	SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1681.37	SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1688.71	SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1747.45	SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1712.11	SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1765.55	SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1875.85	SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2139.83	SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2003.58	SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1998.79	SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2051.04	SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2068.80	SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2078.02	SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2054.12	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1915.81	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2014.85	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2031.92	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1997.77	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2031.92	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2149.74	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2219.75	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2139.49	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1835.56	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	163.92	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1938.01	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1878.25	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1857.76	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1854.34	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1605.05	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70

ABBV-951	1827.02	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1821.90	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1797.99	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1886.78	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1963.62	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1878.25	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1982.40	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1639.2	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1797.99	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1929.47	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1625.54	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1886.78	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1864.59	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1929.47	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	2014.85	SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	2055.83	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1929.47	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1639.2	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1924.35	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1873.12	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	1900.44	SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2009.72	SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1960.21	SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1972.16	SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1932.03	SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1955.08	SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1849.22	SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	1666.52	SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1507.72	SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PRAMIPEXOLE	1.500 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	50.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	27.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]-[redacted]
ASCORBIC ACID;CALCIUM PANTOTHENATE	200 mg	TID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	BID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	22.500 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]-[redacted]
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted]-[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
LOXOPROFEN SODIUM	100 mg	PRN	Y-M: 20[redacted]-[redacted]
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	13.500 mg	QD	Y-M: 20[redacted]-[redacted]
SODIUM PICOSULFATE	APPLICATION OTHER: DROPS	PRN	Y-M: 20[redacted]-[redacted]
BETAMETHASONE BUTYRATE PROPIONATE	5 g	PRN	Y-M: 20[redacted]-[redacted]

ROTIGOTINE	11.250 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	13.500 mg	QD	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	QID	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	QID	Y-M: 20[redacted]
ISTRADEFYLLINE	20.000 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	13.500 mg	QD	Y-M: 20[redacted]
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
HEPARINOID	0.3%	PRN	Y-M: 20[redacted]
ROTIGOTINE	22.500 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	27.000 mg	QD	Y-M: 20[redacted]
SUVOREXANT	20 mg	QD	Y-M: 20[redacted] / -363
ZOLPIDEM TARTRATE	5 mg	QD	Y-M: 20[redacted] / -363
MINODRONIC ACID	50 mg	OTHER: PER MONTH	Y-M: 20[redacted] / -338
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted] / -328
ROTIGOTINE	22.500 mg	QD	Y-M: 20[redacted] / -271
RASAGILINE	0.500 mg	QD	Y-M: 20[redacted] / -197
CARBIDOPA;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -72
ENTACAPONE	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -65
ELOBIXIBAT	5 mg	QD	Y-M: 20[redacted] / -64
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	2 OTHER: DROP	TID	Y-M: 20[redacted] / -63
ROTIGOTINE	27.000 mg	QD	Y-M: 20[redacted] / -58
LINACLOTIDE	0.25 mg	QD	Y-M: 20[redacted] / -57
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -56
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted] / -55
ENTACAPONE	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted] / -55
ROTIGOTINE	31.500 mg	QD	Y-M: 20[redacted] / -54
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / -53

ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -50
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -28
ENTACAPONE	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -28

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ASCORBIC ACID;CALCIUM PANTOTHENATE	200 mg	TID	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted]	ONGOING
LOXOPROFEN SODIUM	100 mg	PRN	Y-M: 20[redacted]	ONGOING
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]	ONGOING
SODIUM PICOSULFATE	APPLICATION OTHER: DROPS	PRN	Y-M: 20[redacted]	ONGOING
BETAMETHASONE BUTYRATE PROPIONATE	5 g	PRN	Y-M: 20[redacted]	ONGOING
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]	ONGOING
HEPARINOID	0.3%	PRN	Y-M: 20[redacted]	ONGOING
SUVOREXANT	20 mg	QD	Y-M: 20[redacted] / -363	ONGOING
MINODRONIC ACID	50 mg	OTHER: PER MONTH	Y-M: 20[redacted] / -338	ONGOING
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	2 OTHER: DROP	TID	Y-M: 20[redacted] / -63	ONGOING
LINACLOTIDE	0.25 mg	QD	Y-M: 20[redacted] / -57	ONGOING
ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -50	ONGOING
BETAMETHASONE VALERATE;GENTAMICIN SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 34
BETAMETHASONE BUTYRATE PROPIONATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 34	ONGOING
FUSIDATE SODIUM	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 36	ONGOING
GENTAMICIN SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 42	ONGOING

CEFCAPENE PIVOXIL HYDROCHLORIDE	100 mg	TID	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 48

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA BARELY PERCEPTIBLE AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 7
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	13
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INDURATION AT INFUSION SITE
Preferred term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 16

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Infections

Event Description	RIGHT LOWER ABDOMEN CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONS
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 71
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 71
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INDURATION AT INFUSION SITE
Preferred term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 87
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Serious Adverse Event

Event Description	LOSS OF CONSCIOUSNESS ATTACK
Preferred term	意識消失
AE Onset Date / Rx Day	[redacted]20[redacted] / 102
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	103
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は日本の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，意識消失発作を発現した。

Event 9 の臨床経過：

関連する病歴は，パーキンソン病，不眠症，非喫煙者及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 102 日目，被験者は意識消失発作を発現した。投与 103 日目，意識消失発作は消失した。

投与 102 日目，被験者は午後 9 時頃に自宅で気を失い，転倒した。その後，被験者は観察のため入院した。CT 検査が実施され，結果は正常であった。投与 103 日目，被験者は退院した。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted])

MENESIT for PARKINSON'S DISEASE ([redacted])

ZONISAMIDE for PARKINSON'S DISEASE ([redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted])

ISTRADEFYLINE for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Loss of consciousness (10024855) (Loss of consciousness (10024855)) [v.23.0] [10024855]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of LOSS OF CONSCIOUSNESS ATTACK

- Investigator: Not Applicable

- AbbVie: More likely related to a history of Parkinson's disease in an advanced aged patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT SCAN:** Normal

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位膿瘍	X	X		X
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位炎症				X
注入部位損傷	X			X
注入部位疼痛				X
注入部位膿疱				X
注入部位反応				X
注入部位腫脹				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	8[redacted]	MALE	ASIAN

Medical History	Onset Year
ISCHAEMIC HEART DISEASE	20[redacted]
MYOCARDIAL INFARCT	20[redacted]
PARKINSON'S DISEASE	20[redacted]
CATARACTS	20[redacted]
IMPULSE CONTROL BEHAVIOURS/DISORDER	20[redacted]
HEMARROIDS	20[redacted]
CONGESTIVE HEART DISEASE	20[redacted]
ADDISON'S DISEASE	20[redacted]
IDIOPATHIC COUGH	20[redacted]
RIGHT KNEE RECONSTRUCTION	20[redacted]
EJECTION MURMUR	20[redacted]
LEFT CATARACT REMOVAL	20[redacted]
UMBILICAL HERNIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RIGHT KNEE RECONSTRUCTION	20[redacted]
LEFT CATARACT REMOVAL	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	5 CIGARETTE	10	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.4	0.32	0.48	60	0.15	[redacted]20[redacted]/1
ABBV-951	0.36	0.29	0.43	60	0.15	[redacted]20[redacted]/2
ABBV-951	0.36	0.29	0.43	60	0.24	[redacted]20[redacted]/8
ABBV-951	0.4	0.24	0.48	60	0.24	[redacted]20[redacted]/15
ABBV-951	0.43	0.36	0.5	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/29
ABBV-951	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/44
ABBV-951	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/59
ABBV-951	0.6	0.48	0.72	60	0.3	[redacted]20[redacted]/63

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	848.28		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1466.05		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1385.12		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		40.98	SC / ONCE	[redacted] / 8	
ABBV-951	1396.39		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		40.98	SC / ONCE	[redacted] / 13	
ABBV-951	1468.79		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		40.98	SC / ONCE	[redacted] / 14	
ABBV-951	1468.10		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		122.94	SC / ONCE	[redacted] / 20	
ABBV-951	1669.42		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		40.98	SC / ONCE	[redacted] / 21	
ABBV-951	1531.28		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1747.11		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		102.45	SC / ONCE	[redacted] / 27	
ABBV-951	1859.29		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		102.45	SC / ONCE	[redacted] / 28	
ABBV-951	1720.81		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	125.000 mg	BID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted]
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]
SPIRONOLACTONE	25 mg	QD	Y-M: 20[redacted]
ASCORBIC ACID	2 OTHER: TAB	QD	Y-M: 20[redacted]
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted]
GLUCOSAMINE	1 OTHER: TABLET	QD	Y-M: 20[redacted]
VITAMIN D NOS	3 OTHER: TABLETS	QD	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]	ONGOING
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted]	ONGOING
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]	ONGOING
SPIRONOLACTONE	25 mg	QD	Y-M: 20[redacted]	ONGOING
ASCORBIC ACID	2 OTHER: TAB	QD	Y-M: 20[redacted]	ONGOING
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted]	ONGOING
GLUCOSAMINE	1 OTHER: TABLET	QD	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	3 OTHER: TABLETS	QD	Y-M: 20[redacted]	ONGOING
CEFALEXIN	500 mg	TID	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 19
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 65
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 68
CEFAZOLIN	2 g	TID	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 69
ALFENTANIL	0.15 mg	PRN	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 66
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 69	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 80	ONGOING
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 81	ONGOING

CEFAZOLIN	2 g	TID	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 87
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 87	Y-M: 20[redacted] / 88
CEFAZOLIN	2 g	BID	Y-M: 20[redacted] / 87	Y-M: 20[redacted] / 89
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	1 OTHER: TABLET	BID	Y-M: 20[redacted] / 89	Y-M: 20[redacted] / 93

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE INFLAMMATION
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	59
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE SORE TO THE TOUCH
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

AE Stopped Rx Day	59
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	8[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	59
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE SWELLING
Preferred term	注入部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	59
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	SUPERFICIAL CELLULITIS RIGHT ABDOMEN AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 55
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 65): ERYTHROCYTES: 3.4 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 107 [122 - 170] G/L; LEUKOCYTES: 4.5 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.49 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 36 [0 - 5] MG/L; NPTST307-UREA: 13.6 [3 - 9.2] MMOL/L; [redacted]20[redacted] (RX DAY 66): ERYTHROCYTES: 3.6 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.34 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 112 [122 - 170] G/L; LEUKOCYTES: 4.3 [4.6 - 10.5] 10^9/L; [redacted]20[redacted] (RX DAY 67): ERYTHROCYTES: 3.7 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.35 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 112 [122 - 170] G/L; NPTST097-CRP: 24 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 68): ERYTHROCYTES: 3.1 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 97 [122 - 170] G/L; NPTST097-CRP: 15 [5 - 5] MG/L; [redacted]20[redacted] (RX DAY 69): ERYTHROCYTES: 3.1 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 97 [122 - 170] G/L; NPTST097-CRP: 10 [0 - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 65): WOUND CULTURE: NEGATIVE-HEAVY GROWTH OF MIXED SKIN AND ENTERIC FLOR; [redacted]20[redacted] (RX DAY 66): WOUND CULTURE: POSITIVE-POLYMORPHS 2+

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	FROM HITTING ABDOMEN/INFUSION SITE ON TABLE
Preferred term	注入部位損傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 55
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 65): ERYTHROCYTES: 3.4 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 107 [122 - 170] G/L; LEUKOCYTES: 4.5 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.49 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 36 [0 - 5] MG/L; NPTST307-UREA: 13.6 [3 - 9.2] MMOL/L; [redacted]20[redacted] (RX DAY 66): ERYTHROCYTES: 3.6 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.34 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 112 [122 - 170] G/L; LEUKOCYTES: 4.3 [4.6 - 10.5] 10^9/L; [redacted]20[redacted] (RX DAY 67): ERYTHROCYTES: 3.7 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.35 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 112 [122 - 170] G/L; NPTST097-CRP: 24 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 68): ERYTHROCYTES: 3.1 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 97 [122 - 170] G/L; NPTST097-CRP: 15 [5 - 5] MG/L; [redacted]20[redacted] (RX DAY 69): ERYTHROCYTES: 3.1 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 97 [122 - 170] G/L; NPTST097-CRP: 10 [0 - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 65): WOUND CULTURE: NEGATIVE-HEAVY GROWTH OF MIXED SKIN AND ENTERIC FLOR; [redacted]20[redacted] (RX DAY 66): WOUND CULTURE: POSITIVE-POLYMORPHS 2+

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE INFLAMMATION
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 80
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE PAIN
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 80
Age at AE Onset	8[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE WHITE PUSTULES PRESENT FOR 24 HOURS, SELF RESOLVED
Preferred term	注入部位膿疱
AE Onset Date / Rx Day	[redacted]20[redacted] / 80
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE REACTION L SIDE OF ABDOMEN,
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 80
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE ABSCESS L SIDE ABDOMEN
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 83
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 86): ERYTHROCYTES: 3.3 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; LEUKOCYTES: 6.1 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.54 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 63 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 87): HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 99 [120 - 170] G/L; NPTST097-CRP: 49 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 88): HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; NPTST097-CRP: 34 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 89): HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; LEUKOCYTES: 5.5 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.56 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 24 [0 - 5] MG/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #13: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE ABSCESS LEFT ABDOMEN.
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted] / 86
Age at AE Onset	8[redacted]

Laboratory Testing

[redacted] (RX DAY 86): ERYTHROCYTES: 3.3 [4 - 5.7] 10^12/L; HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; LEUKOCYTES: 6.1 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.54 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 63 [0 - 5] MG/L; [redacted] (RX DAY 87): HEMATOCRIT: 0.29 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 99 [120 - 170] G/L; NPTST097-CRP: 49 [0 - 5] MG/L; [redacted] (RX DAY 88): HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; NPTST097-CRP: 34 [0 - 5] MG/L; [redacted] (RX DAY 89): HEMATOCRIT: 0.31 [0.36 - 0.49] FRACTION OF 1; HEMOGLOBIN: 102 [122 - 170] G/L; LEUKOCYTES: 5.5 [4.6 - 10.5] 10^9/L; LYMPHOCYTES: 0.56 [0.9 - 3.3] 10^9/L; NPTST097-CRP: 24 [0 - 5] MG/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，腹部穿刺部 / 骨盤上の注入部位から右腹部注入部位の表面の蜂巣炎を発現した。

Event 6 及び 7 の臨床経過：

関連する病歴は，虚血性心疾患，心筋梗塞，パーキンソン病，うっ血性心疾患，高血圧（アジソン病），元喫煙者（1 日 5 本を 10 年間）及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 55 日目，腹部穿刺部 / 骨盤上の注入部位から右腹部注入部位の表面の蜂巣炎を発現した。

投与 65 日目，被験者は皮下注入部位から右下腹壁の 4 × 4 cm の貯留物，及び中央部が波動性の 5 × 5 mm の壊死を調べるために救急診療部を介して入院した。切開及び排膿による治療を行い，感染性の血腫がみつかった。被験者に発熱はなかったが，採取部位に腹部不快感があった。投与 67 日目，被験者には持続する出血が認められ，腹壁血腫の除去，前腹壁創傷の創面切除，及び小さな皮下穿孔出血のジアテルミーのため再手術を受けた。投与 69 日目，被験者は自宅で創傷被覆管理を実施するため，退院した。

被験者にイブプロフェン，セファレキシン，フルクロキサシリン，セファゾリン，アルフェンタニル，エノキサパリン及びパラセタモールが投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.0] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Infusion site injury (10076070) (Infusion site injury (10076070)) [v.23.0] [10076070]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUPERFICIAL CELLULITIS RIGHT ABDOMEN AT INFUSION SITE FROM HITTING ABDOMEN/INFUSION SITE ON TABLE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CRP:** 48 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 24 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 15 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 10 MG/L (normal 0 to 5)

[redacted] **20[redacted] CULTURE:** Negative -Heavy growth of mixed skin and enteric flora.

[redacted] **20[redacted] CULTURE:** Positive- POLYMORPHS 2+

[redacted] **20[redacted] HEMATOCRIT:** 0.33 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMATOCRIT:** 0.35 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMATOCRIT:** 0.29 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMOGLOBIN:** 112 G/L (normal 122 to 170)

[redacted] **20[redacted] HEMOGLOBIN:** 112 G/L (normal 122 to 170)

[redacted] **20[redacted] HEMOGLOBIN:** 97 G/L (normal 122 to 170)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.56 X10**9/L (normal 0.9 to 3.30)

[redacted] 20[redacted] **RED BLOOD CELLS:** 3.56 X10**12/L (normal 4.00 to 5.70)

[redacted] 20[redacted] **RED BLOOD CELLS:** 3.69 X10**12/L (normal 4.00 to 5.70)

[redacted] 20[redacted] **RED BLOOD CELLS:** 3.08 X10**12/L (normal 4.00 to 5.70)

[redacted] 20[redacted] **ULTRASOUND ABDOMINAL WALL:** In the region of concern in the right lower abdomen there was a subcutaneous 41x12x28 mm elongated fluid collection with surrounding echogenic fat and hyperemia. It is superficial to the rectus abdominis and is an overlaying 3x2 mm punctum at the skin surface connects to this small collection via a thin fluid. The collection is most likely related to subcutaneous injections. There is no drainable collection.

[redacted] 20[redacted] **UREA:** 13.1 MMOL/L (normal 3.0 to 9.2)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 4.54 X10**9/L (normal 4.60 to 10.50)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 4.26 X10**9/L (normal 4.60 to 10.50)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左側腹部及び左腹部の注入部位膿瘍を発現した。

Event 12 及び 13 の臨床経過：

関連する病歴は，虚血性心疾患，心筋梗塞，パーキンソン病，うっ血性心疾患，元喫煙者（1 日 5 本を 10 年間）及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 83 日目，被験者は左側腹部の注入部位膿瘍を発現した。投与 86 日目，被験者は左腹部の注入部位膿瘍を発現した。

投与 86 日目，被験者は左側腹部に 2 つの膿瘍を認め，緊急治療室を受診した。1 つ目はより内側にあり，紅斑及び硬さを伴う直径 6 cm の膿瘍であった。2 つ目は左下腹部にあり，より小さく，紅斑はより軽度であった。両方の部位に疼痛及び炎症があった。被験者は抗生物質の静脈内投与を開始し，腹部超音波検査を受けた。投与 87 日目，被験者は治療に対して良好な反応を示し，外科的ドレナージをする必要はなかった。被験者は更に 24 時間，抗生物質の静脈内投与を続けた。投与 89 日目，被験者は経口抗生物質投与下で，退院した。

被験者にパラセタモール，イブプロフェン，セファゾリン，及び augmentin duo が投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.23.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

2) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.23.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of INFUSION SITE ABSCESS LEFT SIDE ABDOMEN

- Investigator: Not Applicable.

- AbbVie: Not applicable

Event of INFUSION SITE ABSCESS LEFT ABDOMEN

- Investigator: Not Applicable.

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Small subcutaneous hypoechoic collection within the left upper abdominal wall measuring 2.98 cm x 0.796 cm containing several hyper-echoic foci which are likely to represent locules of gas. Appearance of the collection favours haematoma. Superficial to this is an area of subcutaneous oedema.

[redacted] **20[redacted] CRP:** 63 MG/L (normal 0 to 5)

[redacted] **20[redacted] CRP:** 24 MG/L (normal 0 to 5)

[redacted] **20[redacted] HEMATOCRIT:** 0.31 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMATOCRIT:** 0.29 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMATOCRIT:** 0.31 L/L (normal 0.36 to 0.49)

[redacted] **20[redacted] HEMOGLOBIN:** 102 G/DL (normal 120 to 170)

[redacted] **20[redacted] HEMOGLOBIN:** 99 G/L (normal 120 to 170)

[redacted] **20[redacted] HEMOGLOBIN:** 102 G/L (normal 120 to 170)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.54 X10**9/L (normal 0.90 to 3.30)

[redacted] **20[redacted] RED BLOOD CELLS:** 3.32 X10**12/L (normal 4 to 5.70)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 6.07 X10**9/L (normal 4.60 to 10.50)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 5.45 X10**9/L (normal 4.60 to 10.50)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
カテーテル留置部位炎症				X
注入部位膿瘍	X			X
注入部位蜂巣炎	X	X		X
注入部位炎症				X
注入部位結節				X
末梢性ニューロパチー				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
DEPRESSION/ANXIETY	20[redacted]
INSOMNIA	20[redacted]
OBSTRUCTIVE SLEEP APNOEA	20[redacted]
BILIARY COLIC	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
DIVERTICULAR DISEASE	20[redacted]
HYPERTENSION	20[redacted]
MORTONS METATARSALGIA	20[redacted]
ACTINIC SKIN DAMAGE	20[redacted]
REM BEHAVIOUR DISORDER	20[redacted]
LEFT ROTATOR CUFF INJURY	20[redacted]
FACIAL LACERATION	20[redacted]
FALL	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]

PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
CHOLECYSTECTOMY	20[redacted]
DEEP BRAIN STIMULATION	20[redacted]
EXCISION BENIGN MELANOTIC LESION LEFT FOOT FIRST WEBSPACE	20[redacted]
6 SUTURES TO PALM OF LEFT HAND	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.86	0	0	120	0.15	[redacted]20[redacted]/1
ABBV-951	0.86	0	0	120	0.15	[redacted]20[redacted]/2
ABBV-951	1	0	0.95	120	0.15	[redacted]20[redacted]/8
ABBV-951	1	0	0.95	120	0.15	[redacted]20[redacted]/15
ABBV-951	1	0	0.95	120	0.15	[redacted]20[redacted]/22
ABBV-951	1	0	0.95	120	0.15	[redacted]20[redacted]/29
ABBV-951	1	0	0.95	120	0.15	[redacted]20[redacted]/48
ABBV-951	1	0	0.7	240	0.11	[redacted]20[redacted]/91
ABBV-951	1	0	0.95	240	0.11	[redacted]20[redacted]/142
ABBV-951	1	0	0.95	240	0.11	[redacted]20[redacted]/149
ABBV-951	1	0	0.7	240	0.11	[redacted]20[redacted]/191

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1791.50		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		51.22	SC / ONCE	[redacted] / 2	
ABBV-951	3494.91		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		25.61	SC / ONCE	[redacted] / 3	
ABBV-951	3450.85		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	3524.28		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	3524.28		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	3524.28		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	3524.28		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		51.22	SC / ONCE	[redacted] / 8	
ABBV-951	3524.28		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	3903.00		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	4063.85		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	3978.47		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	4098		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		51.22	SC / ONCE	[redacted] / 13	
ABBV-951	4080.92		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		76.83	SC / ONCE	[redacted] / 14	
ABBV-951	4063.85		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		25.61	SC / ONCE	[redacted] / 15	
ABBV-951	4098		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	4098		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	4098		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		76.83	SC / ONCE	[redacted] / 18	
ABBV-951	4063.85		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		25.61	SC / ONCE	[redacted] / 19	
ABBV-951	4063.85		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		51.22	SC / ONCE	[redacted] / 20	
ABBV-951	4046.77		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	3995.55		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		25.61	SC / ONCE	[redacted] / 22	
ABBV-951	4080.92		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	4098		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	4029.7		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24

ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	4063.85		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	4063.85		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 46	

ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	4012.62	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
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ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
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ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
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ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
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ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
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ABBV-951	4098	SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
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ABBV-951	4098	SC / CONTINUOUS	[redacted] / 111	[redacted] / 111
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ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	4046.77	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	3995.55	SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	4046.77	SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	3961.4	SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	4046.77	SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156

ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	4029.7		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	4029.7		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	4063.85		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 167	
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	4046.77		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 175	
ABBV-951	4063.85		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 176	
ABBV-951	4080.92		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	4098		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] /

ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 179
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 180
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 181
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 182
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 183
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 184
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 185
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 186
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 187
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 188
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 189
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 190
ABBV-951	4098	SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 191
ABBV-951	3923.83	SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 192
ABBV-951	3671.12	SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 193
ABBV-951	3560.13	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 194
ABBV-951	3635.26	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
MELATONIN	10 mg	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]

ZOPICLONE	22.5 mg	QD	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	4.000 mg	QD	Y-M: 20[redacted]-[redacted]
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	ONE SACHET13.8G g	BID	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	3.750 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]
APOMORPHINE	7.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	10 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	10 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -172
PAROXETINE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -44

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
MELATONIN	10 mg	PRN	Y-M: 20[redacted]	ONGOING
ZOPICLONE	22.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 142
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	ONE SACHET13.8G g	BID	Y-M: 20[redacted]-[redacted]	ONGOING
PAROXETINE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -44	Y-M: 20[redacted]-[redacted] / 51
TRIAMCINOLONE ACETONIDE	200MICROGRAM/GRAM ug	PRN	Y-M: 20[redacted]-[redacted] / 12	Y-M: 20[redacted]-[redacted] / 64
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted]-[redacted] / 33	Y-M: 20[redacted]-[redacted] / 43
PARACETAMOL	1000 mg	QID	Y-M: 20[redacted]-[redacted] / 43	ONGOING
CEFAZOLIN	2 g	QD	Y-M: 20[redacted]-[redacted] / 48	Y-M: 20[redacted]-[redacted] / 50
CIPROFLOXACIN	200 mg	QD	Y-M: 20[redacted]-[redacted] / 48	Y-M: 20[redacted]-[redacted] / 50
CLINDAMYCIN	450 mg	TID	Y-M: 20[redacted]-[redacted] / 50	Y-M: 20[redacted]-[redacted] / 59
CIPROFLOXACIN	500 mg	QD	Y-M: 20[redacted]-[redacted] / 59	Y-M: 20[redacted]-[redacted] / 88

CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / 142	ONGOING
CEFAZOLIN	2 g	QD	Y-M: 20[redacted] / 195	Y-M: 20[redacted] / 197
CIPROFLOXACIN	200 mg	QD	Y-M: 20[redacted] / 195	Y-M: 20[redacted] / 197
CIPROFLOXACIN HYDROCHLORIDE	500 mg	BID	Y-M: 20[redacted] / 198	Y-M: 20[redacted] / 202
CLINDAMYCIN	300 mg	QID	Y-M: 20[redacted] / 198	Y-M: 20[redacted] / 202
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/400 mg	BID	Y-M: 20[redacted] / 202	Y-M: 20[redacted] / 208

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT INFLAMMATION AT CANNULA INSERTION SITE
Preferred term	カテーテル留置部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFLAMMATION AT CANNULA SITE, SAME SITE AS [redacted] 20[redacted]
Preferred term	カテーテル留置部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	142
Duration of AE	121 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFLAMMATION AT INFUSION SITE.
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 27
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	32
Duration of AE	6 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	AND NODULES AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 27
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	32
Duration of AE	6 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	MULTIPLE SMALL NO DRAINABLE POST INFLAMMATORY ABSCESSES (INFUSION SITE ABSCESSES)
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 33
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 33): HEMOGLOBIN: 125 [135 - 180] G/L; LEUKOCYTES: 15.7 [4 - 11] 10^9/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	120
Duration of AE	88 DAYS
Severity	SEVERE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #6: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	ABCESS OF ABDOMINAL WALL (BILATERAL) AT INFUSION SITE THIS DIAGNOSIS HAS BEEN TAKEN DIRECTLY FROM THE DISCHARGE SUMMARY.
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 48
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 48): BILIRUBIN: 21 [0 - 20] UMOL/L; EOSINOPHILS: 0 [0 - 0.5] 10^9/L; ERYTHROCYTES: 3.8 [4.5 - 5.5] 10^12/L; HEMATOCRIT: 0.35 [0.4 - 0.54] FRACTION OF 1; HEMOGLOBIN: 115 [135 - 180] G/L; LEUKOCYTES: 11.1 [4 - 11] 10^9/L; LYMPHOCYTES: 0.34 [1.2 - 4] 10^9/L; MONOCYTES: 0.06 [0.2 - 1] 10^9/L; NPTST097-CRP: 130 [0 - 5] MG/L; NEUTROPHILS: 10.71 [2 - 7.5] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 50): OTHER ABDOMINAL ABSCESS SWAB WOUND SWAB M/C/S/: POSITIVE-ABUDANT GROWTH OF CITROBACTER FREUNDII

AE Stopped Rx Day	120
Duration of AE	73 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #7: Event of Interest - Polyneuropathy

Event Description	PERIPHERAL NEUROPATHY
Preferred term	末梢性ニューロパチー
AE Onset Date / Rx Day	[redacted]20[redacted] / 74
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	THE PERIPHERAL NEUROPATY WAS CONSIDERED RELATED TO THE ANTIBIOTIC CIPROFLOXACIN HE WAS PRESCRIBED FOR PREVIOUS INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFLAMMATION AT SUBCUTANEOUS INFUSION SITE
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 178
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	191
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 195
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 195): LEUKOCYTES: 30 [4 - 11] 10^9/L; NEUTROPHILS: 27.2 [2 - 7.5] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	205 (9 DAYS AFTER LAST TREATMENT)
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，複数の小さな非排出性炎症後膿瘍（注入部位膿瘍）及び注入部位での腹壁膿瘍（両側）を発現した。

Event 5 及び 6 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 33 日目，被験者は複数の小さな非排出性炎症後膿瘍（注入部位膿瘍）を発現した。投与 48 日目，被験者は注入部位での腹壁膿瘍（両側）を発現した。投与 120 日目，複数の小さな非排出性炎症後膿瘍（注入部位膿瘍）及び注入部位での腹壁膿瘍（両側）は消失した。

本事象発現前，投与の約 1 ヵ月後に被験者は注入部位炎症（非重篤）を発現した。被験者は経口抗生物質の投与を開始し，炎症を起こした結節の 1 つをランセットで切開し，被覆した。投与 32 日目，被験者は気分が悪くなり始めた。

投与 33 日目，被験者は注入部位の周囲 3 か所に発赤，硬結，及び結節を認め，救急診療部を受診した。被験者は全身の具合が悪く，痛みがあったが，発熱や悪寒はなかった。ベッドサイドでの超音波検査では，注入部位領域に複数の小さな非排出性炎症後膿瘍が認められた。その後，被験者は入院し，抗生物質の静脈内投与を開始した。投与 35 日目，被験者は改善し，退院した。

投与 48 日目，被験者は分泌物を伴わない波動性，紅斑性で，圧痛のある 2 つの両側腹壁膿瘍の疑いで，再入院した。入院時の臨床検査では，WBC 及び CRP の上昇を認めた。抗生物質の静脈内投与を開始し，創傷のスワブ検査を実施した。投与 50 日目，被験者は両側腹壁膿瘍の切開及び排膿のための外科的処置を受け，傷は治癒していた。被験者に発熱はなく，WBC は正常化しており，CRP は下降傾向にあった。投与 51 日目，被験者は経口抗生物質投与の状態で，退院した。

被験者にアセトアミノフェン，トリアムシノロン，シプロフロキサシン，クリンダマイシン及びセファゾリンが投与された。

The patient's past medications include:

CARBIDOPA/ LEVODOPA for PARKINSON'S DISEASE (20[redacted] - 20[redacted], 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/ BENSERAZID for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CODEINE for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of MULTIPLE SMALL NON DRAINABLE POST INFLAMMATORY ABSCESSES (INFUSION SITE ABSCESSES)

- Investigator: Not applicable

- AbbVie: Not applicable

Event of ABSCESS OF ABDOMINAL WALL (BILATERAL) AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABSOLUTE LYMPHOCYTES:** 0.34 X10**9/L (normal 1.20 to 4.00)

[redacted] **20[redacted] ABSOLUTE LYMPHOCYTES:** 0.64 X10**9/L (normal 1.20 to 4.00)

[redacted] **20[redacted] ABSOLUTE LYMPHOCYTES:** 0.52 X10**9/L (normal 1.20 to 4.00)

[redacted] **20[redacted] ABSOLUTE MONOCYTES:** 0.06 X10**9/L (normal 0.20 to 1.00)

[redacted] **20[redacted] ABSOLUTE MONOCYTES:** 0.77 X10**9/L (normal 0.20 to 1.00)

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 10.71 X10**9/L (normal 2.00 to 7.50)

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 14.96 X10**9/L (normal 2.00 to 7.50)

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 9.35 X10**9/L (normal 2.00 to 7.50)

[redacted] **20[redacted] ALBUMIN:** 38 G/L (normal 35 to 50)

[redacted] **20[redacted] ALBUMIN:** 33 G/L (normal 35 to 50)

[redacted] **20[redacted] ALPHA 1 GLOBULINS:** 5 G/L (normal 2 to 4)

[redacted] **20[redacted] ALPHA 2 GLOBULINS:** 8 G/L (normal 5 to 9)

[redacted] **20[redacted] ALT:** < 6 U/L (0-40 U/L)

[redacted] **20[redacted] BETA GLOBULINS:** 9 G/L (normal 6 to 10)

[redacted] **20[redacted] BODY TEMPERATURE:** 38.3 Degrees C

[redacted] **20[redacted] BODY WEIGHT:** 7[redacted].[redacted] KG

[redacted] **20[redacted] CD 16/56 (NK CELLS):** 8% (normal 6 to 28)

[redacted] **20[redacted] CD16/56 ABSOLUTE COUNT:** 48 X10**6/MCL (normal 93 to 575)

[redacted] 20[redacted] **CD19 (B CELLS):** 5% (normal 6 to 22)

[redacted] 20[redacted] **CD19 ABSOLUTE COUNT:** 30 X10**6/MCL (normal 93 to 480)

[redacted] 20[redacted] **CD3 (T CELLS):** 86% (normal 58 to 84)

[redacted] 20[redacted] **CD3 ABSOLUTE COUNT:** 516 X10**6/MCL (normal 805 to 2332)

[redacted] 20[redacted] **CD4:** 79% (normal 30 to 61)

[redacted] 20[redacted] **CD4 ABSOLUTE COUNT:** 474 X10**6/MCL (normal 457 to 1498)

[redacted] 20[redacted] **CD4/CD8 RATIO:** 13.17 no units (normal 0.72 to 4.18)

[redacted] 20[redacted] **CD8:** 7% (normal 12 to 45)

[redacted] 20[redacted] **CD8 ABSOLUTE COUNT:** 36 X10**6/MCL (normal 205 to 1013)

[redacted] 20[redacted] **CHEST ULTRASOUND:** Below both erythematous swellings are collection. These contain echogenic shadow casting elements consistent with microbubbles (often seen with infection). They also contain anechoic fluid tracking within the subcutaneous tissues. The area on the left is larger and measures 30 x 35x 6 mm. That on the right only 20 x 22x 5 mm. Ultrasounds cannot differentiate the nature of these collections- they may represent the infused fluid or could represent early abscess formation.

[redacted] 20[redacted] **CHEST X RAY:** There is a medical device projected over the left side of the chest. The cardiomediastinal contours outline satisfactorily. The visualized lungs are clear. Left mid zone is partially obscured by the metallic device. No significant pleural effusion.

[redacted] 20[redacted] **COMPLEMENT C3:** 1.21 G/L (normal 0.88 to 1.98)

[redacted] 20[redacted] **COMPLEMENT C4:** 0.36 G/L (normal 0.16 to 0.52)

[redacted] 20[redacted] **CREATININE:** 51 umol/L (normal 60 to 110)

[redacted] 20[redacted] **CRP:** 130 MG/L (normal 0 to 5.0)

[redacted] 20[redacted] **CRP:** 220 MG/L (normal 0 to 5.0)

[redacted] 20[redacted] **CRP:** 150 MG/L (normal 0 to 5.0)

[redacted] 20[redacted] **EGFR:** >90 (>60 mL/min/1.73 m^2)

[redacted] 20[redacted] **EGFR:** >90 (>60 mL/min/1.73 m^2)

[redacted] 20[redacted] **FREE KAPPA:** 17.4 MG/L (normal 3.3 to 19.4)

[redacted] 20[redacted] **FREE LAMBDA:** 16.2 MG/L (normal 5.7 to 26.3)

[redacted] **20[redacted] GAMMA GLOBULINS:** 10 G/L (normal 8 to 16)

[redacted] **20[redacted] GLOBULINS:** 32 G/L (normal 25 to 42)

[redacted] **20[redacted] HEMATOCRIT:** 0.35% (normal 0.40 to 0.54)

[redacted] **20[redacted] HEMATOCRIT:** 0.30% (normal 0.40 to 0.54)

[redacted] **20[redacted] HEMATOCRIT:** 0.29% (normal 0.40 to 0.54)

[redacted] **20[redacted] HEMOGLOBIN:** 115 G/L (normal 135 to 180)

[redacted] **20[redacted] HEMOGLOBIN:** 99 G/L (normal 135 to 180)

[redacted] **20[redacted] HEMOGLOBIN:** 92 G/L (normal 135 to 180)

[redacted] **20[redacted] IGA:** 2.70 G/L (normal 0.60 to 3.40)

[redacted] **20[redacted] IGG:** 9.5 G/L (normal 5.8 to 13.7)

[redacted] **20[redacted] IGM:** 0.42 G/L (normal 0.30 to 1.70)

[redacted] **20[redacted] KAPPA/LAMBDA RATIO:** 1.07 NO UNITS (normal 0.26 to 1.65)

[redacted] **20[redacted] LYMPHOCYTE COUNT:** 0.6 X10**9/L (normal 1.2 to 4.0)

[redacted] **20[redacted] MCV:** 93 FL (normal 80 to 100)

[redacted] **20[redacted] MEAN PLATELET VOLUME:** 9 G (normal 8 to 12)

[redacted] **20[redacted] NOSTRIL SWAB:** Methicillin-resistant Staphylococcus aureus not isolated

[redacted] **20[redacted] PLATELET:** 347 X10**9/L (normal 150 to 400)

[redacted] **20[redacted] PLATELET:** 277 X10**9/L (normal 150 to 400)

[redacted] **20[redacted] PLATELET:** 290 X10**9/L (normal 150 to 400)

[redacted] **20[redacted] POTASSIUM:** 3.9 MMOL/L (normal 3.5 to 5.2)

[redacted] **20[redacted] RED BLOOD CELL:** 3.27 X10**12/L (normal 4.50 to 5.50)

[redacted] **20[redacted] RED CELL DISTRIBUTION WIDTH:** 14.4% (normal 9.0 to 15.0)

[redacted] **20[redacted] SODIUM:** 141 MMOL/L (normal 135 to 145)

[redacted] **20[redacted] SWAB FROM ABDOMINAL ABSCESS:** WOUND SWAB M/C/S: Many leucocytes, moderate gram-negative bacilli, abundant growth of citrobacter freundii This isolate may become readily resistant to extended spectrum cephalosporins. Amoxycillin- resistant, Ciprofloxacin- susceptible,

Cotrimoxazole- susceptible, Gentamicin- susceptible.

[redacted] **20[redacted] THROAT SWAB:** Methicillin-resistant Staphylococcus aureus not isolated

[redacted] **20[redacted] TOTAL BILIRUBIN:** 21 umol/L (normal 0 to 20)

[redacted] **20[redacted] TOTAL PROTEIN:** 70 G/L (normal 60 to 80)

[redacted] **20[redacted] TOTAL PROTEIN:** 65 G/L (normal 60 to 80)

[redacted] **20[redacted] ULTRASOUND:** multiple small not drainable post inflammatory abscesses with one measuring 1x1x1.5 cm

[redacted] **20[redacted] UREA:** 6.1 MMOL/L (normal 3.0 to 8.0)

[redacted] **20[redacted] URINE ANALYSIS:** pH 6.0 protein 2+, nitrite- negative, glucose-negative, leucocyte esterase-negative, blood 2+ Preliminary screening is not suggestive of infection

[redacted] **20[redacted] WHITE BLOOD CELLS:** 11.12 X10**9/L (normal 4.00 to 11.00)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.51 X10**9/L (normal 4.00 to 11.00)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 10.71 X10**9/L (normal 4.00 to 11.00)

[redacted] **20[redacted] WOUND CULTURE:** RIGHT abdominal wound- moderate leucocytes, no bacteria seen. Methicillin-resistant Staphylococcus aureus not isolated.

[redacted] **20[redacted] WOUND CULTURE:** LEFT abdominal wound- Insufficient material to perform microscopy. Methicillin-resistant Staphylococcus aureus not isolated.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位蜂巣炎を発現した。

Event 9 の臨床経過：

関連する病歴は，パーキンソン病，高血圧，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 195 日目，被験者は注入部位蜂巣炎を発現した。投与 205 日目，注入部位蜂巣炎は消失した。

本事象の発現前，投与 189 日目，被験者の注入部位の評価では，明確な浮腫及び顕著な光沢を認めた。

投与 195 日目，被験者は治験薬投与に続発した腹壁の蜂巣炎で入院した。周囲に紅斑を伴う 2 cm × 2 cm の痛みを伴う硬結を認めた。被験者に発熱はなかった。被験者は膿瘍を伴わない表在性腹部蜂巣炎と診断された。被験者は抗生物質の静脈内投与で治療された。表面の領域は治療により改善した。超音波検査では排出可能な貯留物は認められず，保存的な管理が続けられた。投与 202 日目，被験者は炎症マーカーが減少し，紅斑が減少し，臨床的に安定している間に退院した。

被験者にクリンダマイシン，セファゾリン，シプロフロキサシン及び bactrim が投与された。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

TRIAMCINOLONE for SKIN INFLAMMATION AT CANNULA SITE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.0] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** No drainable collection

[redacted] **20[redacted] INFLAMMATORY MARKER:** Declining

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Neuropathy Peripheral: Onset is chronic, more than 4 weeks. Subject experienced pain, pins and needles and numbness; which EMG reported as axonal peripheral neuropathy. Reflexes: Patellar reduced bilaterally, Achilles absent at ankles, both reported as axonal peripheral neuropathy by EMG, Sensory: vibration, proprioception, pain, coordination abnormal EMG reported as axonal peripheral neuropathy, Sensmoto: sensorimotor, Axondemy: axonal, Pattern of involvement: Polyneuropathy: abnormal, Symmetric: abnormal. EMG performed on [redacted] 20[redacted] showed changes consistent with a crural predominant distal sensory motor axonopathy.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻聴				X
注入部位膿瘍				X
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位結節				X
注入部位浮腫				X
自殺企図	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
HAY FEVER	20[redacted]
ANXIETY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.23	0.28	0.18	60	0.11	[redacted]/1
ABBV-951	0.23	0.28	0.18	60	0.11	[redacted]/2
ABBV-951	0.23	0.28	0.18	60	0.11	[redacted]/8
ABBV-951	0.23	0.28	0.18	60	0.11	[redacted]/15
ABBV-951	0.28	0.37	0.23	60	0.11	[redacted]/23
ABBV-951	0.28	0.37	0.23	60	0.11	[redacted]/30
ABBV-951	0.28	0.31	0.25	60	0.11	[redacted]/43
ABBV-951	0.31	0.34	0.28	60	0.11	[redacted]/94
ABBV-951	0.33	0.34	0.3	60	0.11	[redacted]/184
ABBV-951	0.33	0.34	0.3	60	0.11	[redacted]/239
ABBV-951	0.33	0.34	0.3	60	0.11	[redacted]/275
ABBV-951	0.32	0.34	0.3	60	0.11	[redacted]/288
ABBV-951	0.32	0.34	0.3	60	0.11	[redacted]/304
ABBV-951	0.34	0.35	0.3	60	0.11	[redacted]/368

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		56.34	SC / ONCE	[redacted] / 6	
ABBV-951	651.92		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		18.78	SC / ONCE	[redacted] / 7	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		93.91	SC / ONCE	[redacted] / 10	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		112.69	SC / ONCE	[redacted] / 11	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		93.91	SC / ONCE	[redacted] / 12	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		112.69	SC / ONCE	[redacted] / 13	

ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 17	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38

ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
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ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
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ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	1270.38	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272

ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 273	
ABBV-951	1315.79		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 274	
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 367	
ABBV-951	1323.99		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 368	
ABBV-951	1371.12		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]
MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted]-[redacted] / -223
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]-[redacted] / -223
SERTRALINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted]-[redacted] / -223

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]	ONGOING
MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]	ONGOING
SERTRALINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / -223	Y-M: 20[redacted] / 284
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted] / 72	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 83	Y-M: 20[redacted] / 90
DOXYCYCLINE	100 mg	QD	Y-M: 20[redacted] / 125	Y-M: 20[redacted] / 132
CHARCOAL, ACTIVATED	100 g	PRN	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 284
VENLAFAXINE HYDROCHLORIDE	37.5 mg	QD	Y-M: 20[redacted] / 288	Y-M: 20[redacted] / 304
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 20[redacted] / 305	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE EDEMA
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	4
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA TO INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA TO ABDOMEN AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	42
Duration of AE	13 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA TO INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	45
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL NODULES TO INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	4[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO ABDOMEN AT INFUSION SITE.
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 80
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	90
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Infections

Event Description	ABDOMINAL ABCESS TO INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 125
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	132
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Serious Adverse Event

Event Description	SUICIDE ATTEMPT
Preferred term	自殺企図
AE Onset Date / Rx Day	[redacted]20[redacted] / 284
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	284
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	DEPRESSIVE EPISODE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	LIFE THREATENING

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	AUDITORY HALLUCINATIONS
Preferred term	幻聴
AE Onset Date / Rx Day	[redacted]20[redacted] / 286
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	302
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，自殺企図を発現した。

Event 8 の臨床経過：

関連する病歴は，パーキンソン病，不安，非喫煙者及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 284 日目，被験者は自殺企図を発現した。投与 284 日目，自殺企図は消失した。

投与 284 日目，被験者は COVID-19，息子の健康状態，仕事量の増加，及びパーキンソン病の診断を含む人生における複数のストレス要因に圧倒されたと報告した。被験者は夫と口論になり，セルトラリン 100 mg 錠（錠数不明）を衝動的に服用した。被験者はすぐに自責の念に駆られ，夫に知らせ，救急搬送された。被験者は薬物の吸収を促進するために救急診療部で活性炭を投与された。被験者は救急診療部の心理士の診察を受け，メンタルヘルスクライシスチームによる自宅でのフォローアップのため，6 時間後に退院した。治験責任医師によると，投与 288 日目，被験者は適切な神経精神医学的フォローアップが予定されていた。

被験者に薬用炭及びベンラファキシン塩酸塩が投与された。

The patient's past medicas include:

RASAGILINE for UNKNOWN INDICATION (Started [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE DISPERSIBLE (MADOPAR RAPID TABLET) for UNKNOWN INDICATION ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE STANDARD (MADOPAR) for UNKNOWN INDICATION ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Suicide attempt (10042464) (Suicide attempt (10042464)) [v.23.0] [10042464]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUICIDE ATTEMPT

- Investigator: Depressive episode

- AbbVie: More likely related to a history of anxiety and Parkinson's disease in a 4[redacted] year old patient with a report of increased life stressors.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
感覚鈍麻				X
注入部位膿瘍				X
注入部位損傷				X
注入部位結節				X
心因性発作	X			
感覚障害				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	ASIAN

Medical History	Onset Year
FRACTURED L5	19[redacted]
LEFT FOOT DYSTONIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.67	0.74	0.6	60	0.3	[redacted]/1
ABBV-951	0.67	0.74	0.6	60	0.3	[redacted]/2
ABBV-951	0.7	0.74	0.67	60	0.3	[redacted]/11
ABBV-951	0.74	0.76	0.7	60	0.3	[redacted]/18
ABBV-951	0.74	0.76	0.7	60	0.3	[redacted]/24
ABBV-951	0.8	0.84	0.76	60	0.3	[redacted]/32
ABBV-951	0.8	0.84	0.76	60	0.3	[redacted]/46
ABBV-951	0.8	0.84	0.76	60	0.3	[redacted]/93
ABBV-951	0.84	0.85	0.8	60	0.3	[redacted]/184
ABBV-951	0.84	0.85	0.8	60	0.3	[redacted]/274
ABBV-951	0.84	0.85	0.8	60	0.3	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		102.45	SC / ONCE	[redacted] / 1	
ABBV-951	1407.15		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		102.45	SC / ONCE	[redacted] / 2	
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		102.45	SC / ONCE	[redacted] / 3	
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2745.66		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13

ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	2799.44		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
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ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
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ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
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ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
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ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
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ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	3032.52		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49

ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
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ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	3032.52	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86

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ABBV-951	3037.98		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	3357.62		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	1673.35		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 92	
ABBV-951	3292.74		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2837.18		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 182	
ABBV-951	3318.69		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 183	
ABBV-951	3284.54		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
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ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
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ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
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ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
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ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	3442.32		SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207

ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	3442.32	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
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Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]-[redacted] / -353

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PYRIDOXINE	25 mg	QD	Y-M: 20[redacted]-[redacted] / 22	Y-M: 20[redacted]-[redacted] / 32
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted]-[redacted] / 33	ONGOING
LEVETIRACETAM	1 g	QD	Y-M: 20[redacted]-[redacted] / 72	Y-M: 20[redacted]-[redacted] / 72
MIDAZOLAM	5 mg	QD	Y-M: 20[redacted]-[redacted] / 72	Y-M: 20[redacted]-[redacted] / 72
VALPROATE SODIUM	800 mg	QD	Y-M: 20[redacted]-[redacted] / 72	Y-M: 20[redacted]-[redacted] / 72
VALPROATE SODIUM	400 mg	BID	Y-M: 20[redacted]-[redacted] / 72	Y-M: 20[redacted]-[redacted] / 73
EPINEPHRINE BITARTRATE;LIDOCAINE	5 mL	OTHER: ONCE ONLY	Y-M: 20[redacted]-[redacted] / 247	Y-M: 20[redacted]-[redacted] / 247

HYDROCHLORIDE				
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 261	Y-M: 20[redacted] / 276
CHLORHEXIDINE	2%	OTHER: SECOND DAILY	Y-M: 20[redacted] / 261	Y-M: 20[redacted] / 289
CHLORHEXIDINE GLUCONATE	2%	OTHER: TWICE WEEKLY	Y-M: 20[redacted] / 290	ONGOING
MUPIROCIN	2%	BID	Y-M: 20[redacted] / 290	Y-M: 20[redacted] / 297

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL NODULES AT PREVIOUS INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 11
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	23
Duration of AE	13 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	WORSENING OF ABDOMINAL NODULES AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 24
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Polyneuropathy

Event Description	ALTERED SENSATION TO LIMBS
Preferred term	感覚障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 64
Age at AE Onset	4[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	75
Duration of AE	12 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	PSEUDOSEIZURE
Preferred term	心因性発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 71
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	72
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	DOPAMINE AGONIST WITHDRAWAL SYNDROME
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest - Polyneuropathy

Event Description	NUMBNESS TO TOES
Preferred term	感覚鈍麻
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL WOUNDS AT PREVIOUS INFUSION SITE
Preferred term	注入部位損傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 235
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	289
Duration of AE	55 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Infections

Event Description	ABDOMINAL ABCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 247
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	276
Duration of AE	30 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，偽発作を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 71 日目，被験者は偽発作を発現した。投与 72 日目，偽発作は消失した。

投与 71 日目，被験者は反応がなく，歯を食いしばって震えているところを発見された。5 分後，被験者は意識を取り戻した。被験者は救急診療部に搬送された。救急診療部にいる間，被験者は 3～5 分間持続した別の発作様エピソードを認めた。その後，被験者は発作を起こしていたと診断され，それに応じて治療された。脳の CT 検査では，急性の異常は認められなかった。

被験者は偽発作の診断で入院した。徴候及び症状には，胸痛，不安，手足の感覚の変化，過換気及び息切れなどがあった。被験者は神経学的に評価された。偽発作及び関連する徴候や症状はオフ期が関連していると評価された。症状が始まったとき，被験者はABBV-951の追加用量の投与について指導を受けていた。被験者は心理士に紹介された。投与 75 日目，被験者は退院した。

被験者に epilim，ミダゾラム及び keppra が投与された。

The patient's past medications include:

STALEVO for PARKINSON’S DISEASE (20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Pseudoseizure (10037148) (Psychogenic seizure (10058895)) [v.23.1] [10037148]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PSEUDOSEIZURE

- Investigator: Dopamine agonist withdrawal syndrome.

- AbbVie: More likely related to tapering doses of Pramipexole in a patient with history of Parkinson's Disease.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
幻覚	X			X
注入部位紅斑				X
注入部位結節				X
起立性低血圧	X			
皮膚裂傷				X
傾眠				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	ASIAN

Medical History	Onset Year
ASPIRIN ALLERGY	NOT REPORTED
ASTHMA	19[redacted]
MIGRAINE	19[redacted]
DEPRESSION	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
CONSTIPATION	20[redacted]
POST MENOPAUSAL	20[redacted]
INFLAMMATORY ARTHRITIS	20[redacted]
CHRONIC OBSTRUCTIVE PULMONARY DISORDER	20[redacted]
GASTRO ESOPHOGEAL REFLUX DISEASE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
LEFT KNEE ARTHROSCOPY	20[redacted]
COLONOSCOPY AND ENDOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	25 CIGARETTE	28	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.35	0.31	60	0.15	[redacted]/1
ABBV-951	0.34	0.35	0.31	60	0.15	[redacted]/2
ABBV-951	0.36	0.37	0.32	60	0.19	[redacted]/8
ABBV-951	0.38	0.4	0.32	60	0.19	[redacted]/15
ABBV-951	0.36	0.37	0.32	60	0.19	[redacted]/22
ABBV-951	0.34	0.35	0.28	60	0.19	[redacted]/23
ABBV-951	0.36	0.37	0.32	60	0.19	[redacted]/26
ABBV-951	0.32	0.33	0.26	60	0.19	[redacted]/29
ABBV-951	0.3	0.32	0.25	60	0.19	[redacted]/43
ABBV-951	0.3	0.32	0.25	60	0.19	[redacted]/91
ABBV-951	0.32	0.33	0.25	60	0.19	[redacted]/182
ABBV-951	0.37	0.38	0.25	60	0.19	[redacted]/238
ABBV-951	0.39	0.4	0.24	60	0.19	[redacted]/273
ABBV-951	0.38	0.4	0.15	60	0.19	[redacted]/357
ABBV-951	0.34	0.4	0.15	60	0.19	[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		64.88	SC / ONCE	[redacted] / 13	

ABBV-951	448.73		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1014.25		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1518.30		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
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ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1477.32		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
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ABBV-951	1408.00		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1182.61		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
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ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353

ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1557.24	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1167.93	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]
IPRATROPIUM BROMIDE	500 ug	PRN	Y-M: 20[redacted]
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	BID	Y-M: 20[redacted]
PANTOPRAZOLE SODIUM SESQUIHYDRATE	20 mg	QD	Y-M: 20[redacted]
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
DESVENLAFAXINE SUCCINATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	25 mL	QD	Y-M: 20[redacted] / -225
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted]-[redacted] / -73

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]	ONGOING
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]	ONGOING
IPRATROPIUM BROMIDE	500 ug	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 322
PANTOPRAZOLE SODIUM SESQUIHYDRATE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 258
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]	ONGOING
DESVENLAFAXINE SUCCINATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 195
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 2	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 28
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 57
FLUDROCORTISONE	100 ug	QD	Y-M: 20[redacted] / 43	Y-M: 20[redacted] / 49
FLUDROCORTISONE	100 ug	BID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 55
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted] / 56	ONGOING
QUETIAPINE	12.5 mg	PRN	Y-M: 20[redacted] / 57	Y-M: 20[redacted] / 113
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 113
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 113
RIVASTIGMINE	4.6 mg	QD	Y-M: 20[redacted] / 77	Y-M: 20[redacted] / 104
RIVASTIGMINE HYDROGEN TARTRATE	4.5 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 91
RIVASTIGMINE	9.6 mg	QD	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 110
BETAMETHASONE	0.02%	PRN	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 109
DOMPERIDONE	20 mg	TID	Y-M: 20[redacted] / 106	Y-M: 20[redacted] / 115
RIVASTIGMINE HYDROGEN TARTRATE	4.5 mg	QD	Y-M: 20[redacted] / 111	Y-M: 20[redacted] / 114
QUETIAPINE	50 mg	BID	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 176
DONEPEZIL HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / 119	Y-M: 20[redacted] / 162
DONEPEZIL HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 163	Y-M: 20[redacted] / 173
CLOZAPINE	6.25 mg	QD	Y-M: 20[redacted] / 173	Y-M: 20[redacted] / 174

DONEPEZIL HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / 174	Y-M: 20[redacted] / 174
CLOZAPINE	12.5 mg	BID	Y-M: 20[redacted] / 175	Y-M: 20[redacted] / 175
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	50 mL	QD	Y-M: 20[redacted] / 175	Y-M: 20[redacted] / 180
CLOZAPINE	12.5 mg	QD	Y-M: 20[redacted] / 176	Y-M: 20[redacted] / 180
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 176	Y-M: 20[redacted] / 180
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 177	Y-M: 20[redacted] / 178
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 177	Y-M: 20[redacted] / 179
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 177	Y-M: 20[redacted] / 181
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 180	Y-M: 20[redacted] / 180
CLOZAPINE	25 mg	BID	Y-M: 20[redacted] / 181	Y-M: 20[redacted] / 188
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	25 mL	QD	Y-M: 20[redacted] / 181	Y-M: 20[redacted] / 237
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 183	Y-M: 20[redacted] / 188
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 189	Y-M: 20[redacted] / 209
CLOZAPINE	37.5 mg	QD	Y-M: 20[redacted] / 189	Y-M: 20[redacted] / 209
DESVENLAFAXINE SUCCINATE MONOHYDRATE	100 mg	QD	Y-M: 20[redacted] / 196	Y-M: 20[redacted] / 209
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 230
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 265
DESVENLAFAXINE SUCCINATE MONOHYDRATE	200 mg	QD	Y-M: 20[redacted] / 231	ONGOING
CLOZAPINE	75 mg	QD	Y-M: 20[redacted] / 231	Y-M: 20[redacted] / 251
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	TID	Y-M: 20[redacted] / 238	ONGOING
METFORMIN	1000 mg	QD	Y-M: 20[redacted] / 245	ONGOING
CLOZAPINE	100 mg	QD	Y-M: 20[redacted] / 252	Y-M: 20[redacted] / 362
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted] / 259	ONGOING
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 266	Y-M: 20[redacted] / 293

FAMOTIDINE	20 mg	QD	Y-M: 20[redacted] / 285	ONGOING
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 285	ONGOING
INDACATEROL	150 ug	QD	Y-M: 20[redacted] / 293	ONGOING
CLOZAPINE	75 mg	QD	Y-M: 20[redacted] / 294	Y-M: 20[redacted] / 362
FLUDROCORTISONE	150 ug	QD	Y-M: 20[redacted] / 350	ONGOING
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 357	ONGOING
CLOZAPINE	175 mg	QD	Y-M: 20[redacted] / 363	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS NODULES AT OLD INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	21
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	6 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	28
Duration of AE	13 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	WORSENING OF SUBCUTANEOUS NODULES AT OLD INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Hallucinations/Psychosis

Event Description	FURTHER WORSENING OF HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	171
Duration of AE	143 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Falls And Associated Injuries

Event Description	FALL FROM BED
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 155
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	155
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Falls And Associated Injuries

Event Description	LACERATION TO FOREHEAD
Preferred term	皮膚裂傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 155
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	155
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	FURTHER WORSENING OF HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 172
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	183
Duration of AE	12 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #9: Event of Interest - Somnolence

Event Description	DAYTIME SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 175
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	183
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 184
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO PREVIOUS INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 272
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	280
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Serious Adverse Event

Event Description	WORSENING OF ORTHOSTATIC HYPOTENSION
Preferred term	起立性低血圧
AE Onset Date / Rx Day	[redacted]20[redacted] / 357
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	REFLUX OESOPHAGITIS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，幻覚の更なる悪化を発現した。

Event 8 の臨床経過：

関連する病歴は，片頭痛，うつ病，パーキンソン病，閉経後，元喫煙者（1 日 25 本を 28 年間）及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 172 日目，被験者は幻覚の更なる悪化を発現した。投与 183 日目，幻覚の更なる悪化は消失した。

本事象の発現前，投与 10 日目，被験者は幻覚（非重篤）を発現した。被験者はクエチアピンの投与を開始するも，効果はごくわずかであった。幻覚は続き，被験者は投与 16 日目から投与

28 日目まで，幻覚の悪化（非重篤）を発現した。それから，被験者はイクセロンパッチの貼付を開始したが，非重篤の皮膚反応事象により中止し，その後，イクセロン錠の投与を開始したが，非重篤の悪心及び嘔吐によりこれも中止した。投与 29 日目，投与 171 日目まで，被験者は幻覚の更なる悪化（非重篤）を発現した。また，被験者はアリセプトに対する効果は不十分であった。

投与 172 日目，被験者は幻覚の更なる悪化に対しクロザピンの投与を開始するため，入院した。被験者は 1 日 24 時間，幻視を発現していた。クロザピンは 6.25 mg で開始し，25 mg まで漸増した。被験者は副作用なくクロザピンの開始が忍容されたため，退院する上で安全であった。幻覚は退院後も継続していた。投与 183 日目，被験者は退院した。

被験者にクロザピン，クエチアピン，マクロゴール 4000 及び pristiq が投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted])

MADOPAR HBS for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

EXELON PATCH for HALLUCINATIONS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

EXELON TABLET for HALLUCINATIONS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ASPIRIN for DRUG USED FOR UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Hallucinations aggravated (10019078) (Hallucination (10019063)) [v.23.1] [10019078]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of FURTHER WORSENING OF HALLUCINATIONS

- Investigator: Not applicable

- AbbVie: Not applicable

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，起立性低血圧の悪化を発現した。

Event 12 の臨床経過：

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 357 日目，被験者は起立性低血圧の悪化を発現した。

本事象の発現前，投与 15 日目，被験者は非重篤の起立性低血圧を発現した（投与 356 日目に消失）。

投与 357 日目，被験者は起立性低血圧の悪化を訴えて入院し，逆流性食道炎の二次診断，クロザピン療法に抵抗性の進行中の幻覚及びうつ病に対処した。更に，被験者は起立性低血圧の悪化について，自宅で立ったり歩いたりしているときのめまいを訴えた。被験者は逆流性食道炎による悪心及び嘔吐に悩まされており，経口摂取が不十分であった。被験者は輸液を静脈内投与され，綿密にモニターされた。経口レボドパによる治療開始時，被験者は入院中であり，悪心及び嘔吐は消失し，経口摂取量がモニターされていた。被験者の記録から，起立時血圧は改善し，幻視は継続していたが顕著な改善を認めた。投与 373 日目，被験者は退院した。

治験責任医師によると，パーキンソン病の病歴が起立性低血圧の悪化のリスク因子とみなされた。

被験者にレボドパが投与された。

Causality for ABBV-951 (Open Label)

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1) Orthostatic hypotension (10031127) (Orthostatic hypotension (10031127)) [v.24.1] [10031127]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF ORTHOSTATIC HYPOTENSION

- Investigator: Reflux oesophagitis

- AbbVie: More likely related to reported nausea, reflux esophagitis and history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **BODY WEIGHT:** 6[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位感染				X
注入部位結節				X
仙腸関節機能障害	X			
傾眠				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
RECURRING TONSIL INFECTIONS	19[redacted]
CHRONIC VAGINAL BLEEDING	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
HEADACHES	20[redacted]
CHRONIC MIGRAINE	20[redacted]
CONSTIPATION	20[redacted]
FRACTURED 5TH METATARSAL	20[redacted]
LOW VITAMIN B6	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
TONSILLECTOMY	19[redacted]
CAESARIAN SECTION	20[redacted]
UTERINE ABLATION	20[redacted]
CAESARIAN SECTION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	5	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.29	0.31	0.27	60	0.19	[redacted]/1
ABBV-951	0.27	0.28	0.25	60	0.19	[redacted]/2
ABBV-951	0.22	0.21	0.19	60	0.11	[redacted]/10
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/16
ABBV-951	0.21	0.22	0.19	60	0.19	[redacted]/23
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/28
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/30
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/44
ABBV-951	0.19	0.21	0.18	60	0.11	[redacted]/93
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/183
ABBV-951	0.21	0.22	0.19	60	0.11	[redacted]/274
ABBV-951	0.21	0.22	0.19	60	0.15	[redacted]/293
ABBV-951	0.21	0.22	0.19	60	0.15	[redacted]/371

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	628.87		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1068.04		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1003.15		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		32.44	SC / ONCE	[redacted] / 7	

ABBV-951	1034.06		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	1042.77		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 9	
ABBV-951	1068.89		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	921.02		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	878.85		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	813.62		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	821.30		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	810.03		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	835.13		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	823.52		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	802.01		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	819.94		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	865.70		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	869.45		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	813.45		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	815.33		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37

ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	838.04		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	873.72		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	818.23		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	813.28		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
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ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
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ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
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ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
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ABBV-951	778.62	SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
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ABBV-951	778.62	SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	778.62	SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
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ABBV-951	778.62	SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
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ABBV-951	778.62	SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
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ABBV-951	291.98	SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	586.18	SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
ABBV-951	801.84	SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
ABBV-951	838.72	SC / CONTINUOUS	[redacted] / 183	[redacted] / 183
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 184	[redacted] / 184
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ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 215	[redacted] / 215
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ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 220	[redacted] / 220
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 221	[redacted] / 221
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 222	[redacted] / 222
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 223	[redacted] / 223
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 224	[redacted] / 224
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 225	[redacted] / 225
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 226	[redacted] / 226
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 227	[redacted] / 227
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 228	[redacted] / 228
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 229	[redacted] / 229
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 230	[redacted] / 230
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 231	[redacted] / 231
ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 232	[redacted] / 232
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ABBV-951	901.56	SC / CONTINUOUS	[redacted] / 235	[redacted] / 235

ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
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ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
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ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
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ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
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ABBV-951	827.28		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 273	
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ABBV-951	817.03		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
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ABBV-951	811.23		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	798.93		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	833.08		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 369	
ABBV-951	810.55		SC / CONTINUOUS	[redacted]20[redacted] / 369	[redacted]20[redacted] / 369
ABBV-951	806.79		SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	8 TIMES PER DAY	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]
BOTULINUM TOXIN TYPE A	UNKNOWN IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]-[redacted] / -231

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]	ONGOING
BOTULINUM TOXIN TYPE A	UNKNOWN IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]-[redacted]	ONGOING
DICLOFENAC	50 mg	TID	Y-M: 20[redacted]-[redacted] / 26	Y-M: 20[redacted]-[redacted] / 26
MORPHINE	2.5 mg	PRN	Y-M: 20[redacted]-[redacted] / 26	Y-M: 20[redacted]-[redacted] / 26
DIAZEPAM	5 mg	PRN	Y-M: 20[redacted]-[redacted] / 26	Y-M: 20[redacted]-[redacted] / 181
MELOXICAM	15 mg	PRN	Y-M: 20[redacted]-[redacted] / 72	ONGOING

CEFALEXIN	250 mg	QID	Y-M: 20[redacted] / 164	Y-M: 20[redacted] / 174

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL NODULES TO PREVIOUS INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	LEFT SACROILIAC JOINT INCOMPETENCE .
Preferred term	仙腸関節機能障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 25
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	27
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	STRUCTURAL DEGENERATIVE CHANGES TO SACROILIAC JOINT ASSOCIATED WITH SEVERAL TENDON ENTHESOPATHIES AND HIP IMPINGEMENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest - Somnolence

Event Description	DAYTIME SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	ABDOMINAL WOUND INFECTION TO PREVIOUS INFUSION SITE
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 164

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	175
Duration of AE	12 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左仙腸関節機能障害を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，元喫煙者（1 日 1 本を 5 年間）及び飲酒者（1 日 2 杯未満）であった。

投与 25 日目，被験者は左仙腸関節機能障害を発現した。投与 27 日目，左仙腸関節機能障害は消失した。

投与 25 日目，被験者は突発的に腰痛を発現し，痛みは胸部に放射状に広がり，歩行及び移動中に増強した。被験者は多少の排尿困難を訴えたが，下肢の脱力感は否定した。投与 26 日目，

被験者は重度の腰痛で入院した。骨盤の超音波検査及び腎臓の CT 検査で，腎臓結石は除外された。投与 27 日目，被験者は退院した。
　被験者にジアゼパム，メロキシカム，モルヒネ及びジクロフェナクが投与された。

The patient's past medications include:

STALEVO for PARKINSON'S (20[redacted] - [redacted] 20[redacted])

MADOPAR HBS for PARKINSON'S ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR RAPID TABLET for PARKINSON'S ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Sacroiliac joint dysfunction (10084449) (Sacroiliac joint dysfunction (10084449)) [v.23.1] [10084449]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of LEFT SACROILIAC JOINT INCOMPETENCE

- Investigator: Structural degenerative changes to sacroiliac joint associated with several tendon enthesopathies and hip impingement.

- AbbVie: More likely related to reported several tendon enthesopathies and hip impingement in a 5[redacted] year old female with increased BMI

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **BMI:** 35.32 kg/m2

[redacted] **20[redacted] BODY WEIGHT:** 9[redacted] KG

[redacted] **20[redacted] BONE SCAN:** Result = Left sacroiliac joint incompetence associated with several tendon enthesopathies and hip impingement.

[redacted] **20[redacted] CT SCAN:** RENAL: Normal CT scan

[redacted] **20[redacted] MRI:** SPINE: LEFT SACROILIAC JOINT INCOMPETENCE ASSOCIATED WITH SEVERAL TENDON ENTHESOPATHIES AND HIP IMPINGEMENT.

[redacted] **20[redacted] PELVIC ULTRASOUND:** Normal ultrasound

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位結節				X
腰仙部神経根障害	X			
筋力低下				X
傾眠				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	WHITE

Medical History	Onset Year
FRACTURED SKULL	19[redacted]
MIGRAINE	19[redacted]
TORN LIGAMENT RIGHT ANKLE	19[redacted]
BIPOLAR AFFECTIVE DISORDER	20[redacted]
DEPRESSION	20[redacted]
LUMBAR DISC HERNIATION	20[redacted]
LOW VITAMIN B12	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RIGHT ANKLE LIGAMENT REPAIR	19[redacted]
LUMBAR DISCECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	FORMER			
CIGARETTES	FORMER	20 CIGARETTE	3	20[redacted]
CIGARS	FORMER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	More than 4 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.51	0.52	0.41	60	0.24	[redacted]/1
ABBV-951	0.52	0.53	0.42	60	0.24	[redacted]/2
ABBV-951	0.53	0.54	0.43	60	0	[redacted]/6
ABBV-951	0.53	0.54	0.43	60	0.24	[redacted]/13
ABBV-951	0.54	0.55	0.44	60	0.24	[redacted]/20
ABBV-951	0.55	0.56	0.44	60	0.24	[redacted]/27
ABBV-951	0.55	0.56	0.44	60	0.24	[redacted]/42
ABBV-951	0.57	0.58	0.44	60	0.24	[redacted]/72
ABBV-951	0.57	0.58	0.45	60	0.24	[redacted]/91
ABBV-951	0.58	0.59	0.45	60	0.24	[redacted]/182
ABBV-951	0.59	0.6	0.45	60	0.24	[redacted]/199
ABBV-951	0.6	0.61	0.47	60	0.24	[redacted]/275
ABBV-951	0.62	0.63	0.47	60	0.24	[redacted]/342
ABBV-951	0.62	0.63	0.47	60	0.24	[redacted]/363

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		81.96	SC / ONCE	[redacted] / 2	
ABBV-951		81.96	SC / ONCE	[redacted] / 3	
ABBV-951		0	SC / ONCE	[redacted] / 6	
ABBV-951		0	SC / ONCE	[redacted] / 8	
ABBV-951		0	SC / ONCE	[redacted] / 9	
ABBV-951		0	SC / ONCE	[redacted] / 10	
ABBV-951		0	SC / ONCE	[redacted] / 11	
ABBV-951		40.98	SC / ONCE	[redacted] / 13	
ABBV-951		81.96	SC / ONCE	[redacted] / 14	
ABBV-951		81.96	SC / ONCE	[redacted] / 15	

ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 16
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 17
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 18
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 19
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 20
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 21
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 23
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 24
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 25
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 27
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 28
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 29
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 30
ABBV-951	122.94	SC / ONCE	[redacted]20[redacted] / 31
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 32
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 33
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 35
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 36
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 38
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 39
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 40
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 44
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 47
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 49
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 51
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 52
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 53
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 54
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 55
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 56
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 59
ABBV-951	122.94	SC / ONCE	[redacted]20[redacted] / 60
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 62
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 65
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 68
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 73
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 74

ABBV-951		40.98	SC / ONCE	[redacted] / 85	
ABBV-951		40.98	SC / ONCE	[redacted] / 88	
ABBV-951	2280.36		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	2182.69		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	2105.00		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951		122.94	SC / ONCE	[redacted] / 102	
ABBV-951		40.98	SC / ONCE	[redacted] / 103	
ABBV-951		81.96	SC / ONCE	[redacted] / 105	
ABBV-951		40.98	SC / ONCE	[redacted] / 106	
ABBV-951		81.96	SC / ONCE	[redacted] / 107	
ABBV-951		122.94	SC / ONCE	[redacted] / 108	
ABBV-951		122.94	SC / ONCE	[redacted] / 109	
ABBV-951		40.98	SC / ONCE	[redacted] / 110	
ABBV-951		40.98	SC / ONCE	[redacted] / 111	
ABBV-951		40.98	SC / ONCE	[redacted] / 114	
ABBV-951		40.98	SC / ONCE	[redacted] / 119	
ABBV-951		40.98	SC / ONCE	[redacted] / 123	
ABBV-951		81.96	SC / ONCE	[redacted] / 124	
ABBV-951		81.96	SC / ONCE	[redacted] / 125	
ABBV-951		81.96	SC / ONCE	[redacted] / 127	
ABBV-951		40.98	SC / ONCE	[redacted] / 132	
ABBV-951		40.98	SC / ONCE	[redacted] / 140	
ABBV-951		40.98	SC / ONCE	[redacted] / 142	
ABBV-951		40.98	SC / ONCE	[redacted] / 148	
ABBV-951		40.98	SC / ONCE	[redacted] / 150	
ABBV-951		40.98	SC / ONCE	[redacted] / 151	
ABBV-951		40.98	SC / ONCE	[redacted] / 152	
ABBV-951		40.98	SC / ONCE	[redacted] / 156	
ABBV-951		40.98	SC / ONCE	[redacted] / 157	
ABBV-951		40.98	SC / ONCE	[redacted] / 158	
ABBV-951		122.94	SC / ONCE	[redacted] / 159	
ABBV-951		40.98	SC / ONCE	[redacted] / 160	
ABBV-951		40.98	SC / ONCE	[redacted] / 161	
ABBV-951		40.98	SC / ONCE	[redacted] / 165	
ABBV-951		40.98	SC / ONCE	[redacted] / 166	
ABBV-951		40.98	SC / ONCE	[redacted] / 168	
ABBV-951		40.98	SC / ONCE	[redacted] / 171	

ABBV-951	40.98	SC / ONCE	[redacted] / 172
ABBV-951	40.98	SC / ONCE	[redacted] / 173
ABBV-951	40.98	SC / ONCE	[redacted] / 174
ABBV-951	40.98	SC / ONCE	[redacted] / 176
ABBV-951	40.98	SC / ONCE	[redacted] / 177
ABBV-951	40.98	SC / ONCE	[redacted] / 179
ABBV-951	40.98	SC / ONCE	[redacted] / 180
ABBV-951	40.98	SC / ONCE	[redacted] / 181
ABBV-951	40.98	SC / ONCE	[redacted] / 182
ABBV-951	81.96	SC / ONCE	[redacted] / 183
ABBV-951	40.98	SC / ONCE	[redacted] / 184
ABBV-951	40.98	SC / ONCE	[redacted] / 185
ABBV-951	40.98	SC / ONCE	[redacted] / 186
ABBV-951	40.98	SC / ONCE	[redacted] / 188
ABBV-951	81.96	SC / ONCE	[redacted] / 190
ABBV-951	40.98	SC / ONCE	[redacted] / 191
ABBV-951	81.96	SC / ONCE	[redacted] / 192
ABBV-951	81.96	SC / ONCE	[redacted] / 193
ABBV-951	40.98	SC / ONCE	[redacted] / 194
ABBV-951	40.98	SC / ONCE	[redacted] / 199
ABBV-951	81.96	SC / ONCE	[redacted] / 200
ABBV-951	40.98	SC / ONCE	[redacted] / 201
ABBV-951	40.98	SC / ONCE	[redacted] / 203
ABBV-951	81.96	SC / ONCE	[redacted] / 204
ABBV-951	40.98	SC / ONCE	[redacted] / 207
ABBV-951	40.98	SC / ONCE	[redacted] / 211
ABBV-951	40.98	SC / ONCE	[redacted] / 212
ABBV-951	81.96	SC / ONCE	[redacted] / 215
ABBV-951	81.96	SC / ONCE	[redacted] / 216
ABBV-951	40.98	SC / ONCE	[redacted] / 217
ABBV-951	40.98	SC / ONCE	[redacted] / 218
ABBV-951	40.98	SC / ONCE	[redacted] / 219
ABBV-951	40.98	SC / ONCE	[redacted] / 220
ABBV-951	40.98	SC / ONCE	[redacted] / 221
ABBV-951	122.94	SC / ONCE	[redacted] / 222
ABBV-951	122.94	SC / ONCE	[redacted] / 224
ABBV-951	81.96	SC / ONCE	[redacted] / 227

ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 231
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 233
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 234
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 235
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 236
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 237
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 238
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 239
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 240
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 242
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 243
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 246
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 248
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 249
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 250
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 252
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 253
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 256
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 257
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 259
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 266
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 267
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 268
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 270
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 271
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 272
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 274
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 276
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 277
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 278
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 279
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 280
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 282
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 283
ABBV-951	81.96	SC / ONCE	[redacted]20[redacted] / 284
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 285
ABBV-951	40.98	SC / ONCE	[redacted]20[redacted] / 286

ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 287	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 288	
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 289	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 290	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 292	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 293	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 295	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 296	
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 297	
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 298	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 299	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 300	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 301	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 302	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 303	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 304	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 311	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 312	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 314	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 318	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 320	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 321	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 323	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 330	
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 331	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 338	
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 341	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 345	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 347	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 348	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 349	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 354	
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 361	
ABBV-951	2351.22		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	2098.51		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LAMOTRIGINE	150 mg	BID	Y-M: 20[redacted]
VALPROATE SODIUM	1000 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
DULOXETINE	90 mg	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / -224
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	8 TIMES PER DAY	Y-M: 20[redacted] / -162
VITAMIN B12 NOS	1 mg	QD	Y-M: 20[redacted] / -20

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LAMOTRIGINE	150 mg	BID	Y-M: 20[redacted]	ONGOING
VALPROATE SODIUM	1000 mg	BID	Y-M: 20[redacted]	ONGOING
DULOXETINE	90 mg	QD	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / -224	ONGOING
VITAMIN B12 NOS	1 mg	QD	Y-M: 20[redacted] / -20	Y-M: 20[redacted] / -20
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 339
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 339
PREGABALIN	75 mg	QD	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 49
PREGABALIN	75 mg	BID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 71
PREGABALIN	75 mg	PRN	Y-M: 20[redacted] / 72	Y-M: 20[redacted] / 295

Event #1: Event of Interest - Somnolence

Event Description	DAYTIME SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 6
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	363
Duration of AE	358 DAYS

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL NODULES TO PREVIOUS INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Polyneuropathy

Event Description	LEFT LEG WEAKNESS
Preferred term	筋力低下
AE Onset Date / Rx Day	[redacted]20[redacted] / 264

Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	317
Duration of AE	54 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	WORSENING L5 AND S1 COMPRESSIVE RADICULOPATHY
Preferred term	腰仙部神経根障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 315
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	339
Duration of AE	25 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	LUMBAR DISC HERNIATION

Discontinued Study Drug Due to the Event NO

SAE Criteria REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，L5 及び S1 の圧迫性神経根障害の悪化を発現した。

Event 4 の臨床経過：

関連する病歴は，腰椎椎間板ヘルニア，腰椎椎間板切除術，元喫煙者（紙巻きタバコ 1 日 20 本を 3 年間と噛みタバコ）及び元飲酒者（1 日 4 杯以上）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 315 日目，被験者は L5 及び S1 の圧迫性神経根障害の悪化を発現した。投与 339 日目，L5 及び S1 の圧迫性神経根障害の悪化は消失した。

投与 51 日目，被験者は MRI 検査で左 L5 及び S1 の圧迫性神経根障害と診断された。被験者は診断後に保存療法を選択した。直近（日付不明）で，被験者は多少の左下肢の脱力感を発現し，脳神経外科のレビューが手配された。

投与 315 日目，被験者は L4～5 及び L5～S1 レベルでの減圧のため，入院を手配した。被験者の徴候及び症状には背部痛があった。同日，被験者は左 L4～5 及び L5～S1 の減圧/椎間孔拡大術及び部分的椎間関節切除術を再度受けた。投与 317 日目，被験者は退院した。

Causality for ABBV-951 (Open Label)

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1) Lumbosacral radiculopathy (10076578) (Lumbosacral radiculopathy (10076578)) [v.24.1] [10076578]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING L5 AND S1 COMPRESSIVE RADICULOPATHY

- Investigator: Lumbar disc herniation

- AbbVie: More likely related to worsening of reported history of left L5 and S1 compressive radiculopathy, history of lumbar disc herniation and Parkinson Disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] MRI SPINE:** L5 and S1 compressive radiculopathy

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位蜂巣炎	X			X
注入部位感染				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
HYPERLIPIDAEMIA	20[redacted]
ISCHAEMIC HEART DISEASE	20[redacted]
HYPERURICEMIA	20[redacted]
CARPAL TUNNEL SYNDROME LEFT SIDE	20[redacted]
FROZEN LEFT SHOULDER	20[redacted]
RIGHT KNEE PAIN	20[redacted]
OVERWEIGHT	20[redacted]
CORONARY ARTERY DISEASE	20[redacted]
ANAEMIA	20[redacted]
HELICOBACTOR PYLORI GASTRITIS	20[redacted]
COMMUNITY ACQUIRED PNEUMONIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
STENT INSERTION TO RIGHT CORONARY ARTERY (RCA)	20[redacted]
GASTROSCOPY OF UPPER GASTRO-INTESTINE	20[redacted]
UPPER GASTROINTESTINAL ENDOSCOPY	20[redacted]
CHEST XRAY	20[redacted]
CHEST XRAY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	3 CIGARETTE	20	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.23	0.26	0.2	60	0.24	[redacted]/1
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/2
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/9
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/16
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/23
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/28
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/42
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/99
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/182
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/275
ABBV-951	0.26	0.28	0.23	60	0.24	[redacted]/366

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		40.98	SC / ONCE	[redacted] / 7	
ABBV-951	846.92		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		40.98	SC / ONCE	[redacted] / 9	
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		40.98	SC / ONCE	[redacted] / 12	

ABBV-951	1090.06		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		40.98	SC / ONCE	[redacted] / 13	
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1099.63		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	458.97		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	769.74		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	1128.31		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]

BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted]
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	BID	Y-M: 20[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
APOMORPHINE	3.000 mg	PRN	Y-M: 20[redacted] / -272

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]	ONGOING
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]	ONGOING
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	BID	Y-M: 20[redacted]	ONGOING
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 44
FLUCLOXACILLIN	2 g	OTHER: 4 TIMES PER DAY	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 46
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 46	Y-M: 20[redacted] / 59
CEFAZOLIN SODIUM	2 g	BID	Y-M: 20[redacted] / 270	Y-M: 20[redacted] / 276
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 276	Y-M: 20[redacted] / 286
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 298	Y-M: 20[redacted] / 308

Event #1: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 44): NEUTROPHILS: 5.8 [2 - 7.5] 10^9/L; PLATELETS: 156 [150 - 350] 10^9/L; [redacted]20[redacted] (RX DAY 45): CREATININE: 59 [60 - 110] UMOL/L; ERYTHROCYTES: 5.9 [4.2 - 5.6] 10^12/L; LYMPHOCYTES: 0.9 [0.96 - 4.75] 10^9/L; NPTST053-C REACTIVE PROTEIN: 183.0 [NOT REPORTED - 5] MG/L; NPTST181-MCH: 25.9

[NOT REPORTED - NOT REPORTED] PG; NPTST183-MCV: 79.9 [NOT REPORTED - NOT REPORTED] FL; NPTST273-RDW: 15.9 [NOT REPORTED - NOT REPORTED] %

Microbiology

NOT REPORTED

AE Stopped Rx Day	59
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #2: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF INFUSION SITE ON RIGHT LOWER ABDOMEN
Preferred term	注射部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 270
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	286
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION AT INFUSION SITE
Preferred term	注射部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 283
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	287
Duration of AE	5 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF INFUSION SITE LEFT LOWER ABDOMEN
Preferred term	注射部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 298
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	307
Duration of AE	10 DAYS
Severity	MODERATE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位蜂巣炎を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，過体重，胃潰瘍出血による貧血，虚血性心疾患，喫煙者（1 日 3 本を 20 年間）及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 43 日目，被験者は注入部位蜂巣炎を発現した。投与 59 日目，注入部位蜂巣炎は消失した。

被験者は気分が悪く，投与 43 日目，39.3°C の発熱があった。注入部位は柔らかく，赤く腫れていたが，分泌物はなかった。治験薬の投与は中止された。投与 44 日目，被験者はまだ発熱があったため，救急診療部を受診した。被験者は観察のため，入院した。同日，治験薬の注入が再開された。被験者は投与 44 日目から投与 46 日目まで，6 時間ごとにフルクロキサシリン 2 g の静脈内投与を受けた。投与 46 日目，6 時間ごとのフルクロキサシリン 500 mg 経口投与下で，被験者は退院した。入院中の創傷部スワブ検査及び血液検査では，蜂巣炎の原因となる病原体は特定されなかった。

退院報告書によると，入院時，右下腹部の注入部位に紅斑及び腫脹を認め，蜂巣炎と一致していた。抗生物質の静脈内投与開始後，被験者は入院中ずっと発熱がなかった。退院時，注入部位に疼痛はなく，腫脹は減少していたが，依然として紅斑が認められた。退院の 3 日目，注入部位の状態は著しく改善した。
被験者にイブプロフェン及びフルクロキサシリンが投与された。

The patient's past medications include:

MADOPAR for PARKINSON'S DISEASE ([redacted])

STALEVO for PARKINSON'S DISEASE ([redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.23.1] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **ABDOMINAL ULTRASOUND:** Cellulitis equivocal 1.7 mL collection, no deep extension is demonstrated. No foreign bodies were noted on the result.

[redacted] 20[redacted] **BLOOD CULTURE:** negative

[redacted] 20[redacted] **BODY TEMPERATURE:** 39.3 Degrees C

[redacted] 20[redacted] **CREATININE:** 59 MMOL/L (normal 60 to 110)

[redacted] 20[redacted] **CRP:** 139.5 MG/L (normal <5.0)

[redacted] 20[redacted] **CRP:** 183.0 MG/L (normal <5.0)

[redacted] 20[redacted] **CRP:** 79.1 MG/L (normal <5.0)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.9 X10**9/L

[redacted] 20[redacted] **MCH:** 25.9 PG

[redacted] 20[redacted] **MCV:** 79.9 FL

[redacted] 20[redacted] **NEUTROPHILS ABS:** 5.8 X10**9/L (normal 2.0 to 7.5)

[redacted] 20[redacted] **PLATELET COUNT:** 156 X10**9/L (normal 150 to 350)

[redacted] 20[redacted] **RDW:** 15.9 %

[redacted] 20[redacted] **RED BLOOD CELLS:** 5.88 X10**12/L

[redacted] 20[redacted] **TEMPERATURE:** 39.3 Degrees C

[redacted] 20[redacted] **WOUND CULTURE:** swab of infusion site : negative. no growth [redacted] 20[redacted]

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
認知障害	X	X		
注入部位びらん				X
注入部位紅斑				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
BREAST CYST	19[redacted]
MENOPAUZE	19[redacted]
VIT B 12 DEFFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RESECTION BREAST CYST	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.83	0.91	0.75	120	0.3	[redacted]/1
ABBV-951	0.83	0.91	0.75	120	0.3	[redacted]/2
ABBV-951	0.91	1	0.82	120	0.3	[redacted]/8
ABBV-951	1	1.09	0.91	120	0.3	[redacted]/15
ABBV-951	0.95	1	0.91	120	0.3	[redacted]/22
ABBV-951	0.95	1	0.91	120	0.3	[redacted]/29
ABBV-951	0.95	1	0.91	120	0.3	[redacted]/43
ABBV-951	1.02	1.04	1	120	0.3	[redacted]/92

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1842.39		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	3573.45		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	150.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted]

SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	3.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	QD	Y-M: 20[redacted]
CYANOCOBALAMIN	1000 ug	OTHER: ONCE	Y-M: 20[redacted] / -40

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
NOT REPORTED				

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SMALL EROSIONS ON INFUSION SITE
Preferred term	注入部位びらん
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	21
Duration of AE	7 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE EVALUATION , GRADE 2, LETTER A - MINIMAL ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 43

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	107
Duration of AE	65 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	COGNITIVE DECLINE
Preferred term	認知障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 108): NPTST162-LACTATE: 5.8 [0.5 - 1.6] MMOL/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	COGNITIVE DECLINE > DIFFICULTIES HANDLING THE PUMP >

	DRUG WITHDRAWN
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はベルギーの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，認知機能の低下を発現した。

Event 3 の臨床経過：

関連する病歴は，閉経，パーキンソン病，ビタミン B12 欠乏症，非喫煙者及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 107 日目，被験者は認知機能の低下を発現した。

投与 108 日目，被験者は認知機能の低下のため，入院した。被験者の認知機能は，試験を継続するにはあまりにも悪化していた。被験者は注入ポンプの取扱いが困難であった。投与 114 日目，被験者は退院した。

The patient's past medications include:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA HBS for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

VITAMIN B12 for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Cognitive deterioration (10009843) (Cognitive disorder (10057668)) [v.23.1] [10009843]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of COGNITIVE DECLINE

- Investigator: Cognitive decline - difficulties handling the pump - drug withdrawn.

- AbbVie: More likely related to advanced age and medical history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] LACTATE:** 5.8 MMOL/L (normal 0.5 to 1.6)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻覚	X			X
注入部位紅斑				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	8[redacted]	MALE	WHITE

Medical History	Onset Year
GROIN RUPTURE RIGHT	20[redacted]
BENING HYPERTROPHY PROSTATE	20[redacted]
DIVERTICULAR BLEEDING	20[redacted]
VIT B DEFFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
TRANSVESICAL PROSTATECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	20	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.47	0.51	0.43	120	0.3	[redacted]/1
ABBV-951	0.47	0.51	0.43	120	0.3	[redacted]/2
ABBV-951	0.47	0.51	0.43	120	0.3	[redacted]/9
ABBV-951	0.45	0.5	0.4	120	0.3	[redacted]/16
ABBV-951	0.44	0.46	0.42	120	0.3	[redacted]/23
ABBV-951	0.43	0.44	0.42	120	0.3	[redacted]/30
ABBV-951	0.43	0.44	0.42	120	0.3	[redacted]/44
ABBV-951	0.43	0.44	0.42	120	0.3	[redacted]/92
ABBV-951	0.43	0.44	0.42	120	0.3	[redacted]/160
ABBV-951	0.43	0.44	0.42	120	0.3	[redacted]/174
ABBV-951	0.44	0.43	0.45	120	0.3	[redacted]/264
ABBV-951	0.45	0.46	0.44	120	0.3	[redacted]/362

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	963.03		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1884.05		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	TID	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	2.100 mg	QD	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	62.500 mg	BID	Y-M: 20[redacted] / -216
CYANOCOBALAMIN	1000 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted] / -40

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 154	ONGOING
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 161	Y-M: 20[redacted] / 165

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE MODERATE ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	23
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE MODERATE ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	44
Duration of AE	15 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 158
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA ON INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 174
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	176
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，幻覚を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，ビタミン B 欠乏症，元喫煙者（1 日 20 本を 20 年間）及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 158 日目，被験者は幻覚を発現した。投与 535 日目，幻覚は消失した。

投与 158 日目，被験者は幻覚のため入院した。被験者は被験者の家に居ない人々の幻覚を見た。被験者の家族は被験者の状況を心配した。投与 161 日目，被験者は退院した。

同時に，被験者は非重篤の尿路感染の治療を受けた。

被験者にクエチアピンが投与された。

The patient's past medications include:

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA HBS for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PROLOPA DISPERSIBLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

VIT B 12 INJECTION for VIT B 12 DEFFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucinations (10019077) (Hallucination (10019063)) [v.24.0] [10019077]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATIONS

- Investigator: Not applicable

- AbbVie: More likely related to reported urinary tract infection in a 8[redacted] year old male with Parkinson's disease.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
胸痛				X
転倒				X
幻覚				X
注入部位血腫	X			X
注入部位感染	X			X
注入部位炎症				X
注入部位結節				X
注射部位炎症				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
MOTION SICKNESS.	19[redacted]
DIABETES.	19[redacted]
POSTMENOPAUSAL CONDITION	20[redacted]
G209 PARKINSON'S DISEASE	20[redacted]
HYPERTENSION.	20[redacted]
HAY FEVER ALLERGY.	20[redacted]
CONSTIPATION.	20[redacted]
NAIL FUNGUS.	20[redacted]
RECES STONOSIS LUMBER.	20[redacted]
HALLUCINATIONS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
KABC 56. DEKOMPRESSION OF LUMBAL MEDULLA.	20[redacted]
KNAG 76. SPONDYLODESE I COL. LUMBALIS L2-S1.	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.47	0.52	0.42	60	0.15	[redacted]/1
ABBV-951	0.47	0.52	0.42	60	0.15	[redacted]/4
ABBV-951	0.58	0.69	0.47	60	0.15	[redacted]/9
ABBV-951	0.54	0.58	0.47	60	0.15	[redacted]/18
ABBV-951	0.6	0.65	0.55	60	0.15	[redacted]/22
ABBV-951	0.65	0.69	0.6	60	0.15	[redacted]/29
ABBV-951	0.65	0.69	0.6	60	0.15	[redacted]/43
ABBV-951	0.69	0.73	0.65	60	0.19	[redacted]/49
ABBV-951	0.73	0.75	0.69	60	0.15	[redacted]/92
ABBV-951	0.76	0.78	0.73	60	0.11	[redacted]/124
ABBV-951	0.76	0.78	0.73	60	0.11	[redacted]/183
ABBV-951	0.71	0.75	0.69	60	0.15	[redacted]/194
ABBV-951	0.75	0.78	0.7	60	0.15	[redacted]/271
ABBV-951	0.78	0.8	0.75	60	0.15	[redacted]/362

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1035.25		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2

ABBV-951	1810.80		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1768.11		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 8	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	2211.55		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2233.92		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2198.91		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2021.68		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
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ABBV-951	3196.44		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 358	
ABBV-951	3023.29		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	3169.80		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	3169.80		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	3169.80		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INSULIN	0.3-0.6 OTHER: I.E/H	OTHER: SUBCUTANEOUS PUMP	Y-M: 19[redacted]
FLUTICASONE PROPIONATE	50 ug	PRN	Y-M: 20[redacted]
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	1 OTHER: TABLET.	QD	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	12.000 mg	QD	Y-M: 20[redacted]
SIMVASTATIN	40 mg	QD	Y-M: 20[redacted]
BISACODYL	10 mg	QD	Y-M: 20[redacted]
VITAMINS NOS	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]
CALCIUM	1 OTHER: TABLET.	QD	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	9 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
MAGNESIUM HYDROXIDE	500 mg	PRN	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]-[redacted]
ESTRADIOL	10 ug	OTHER: BIS	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.520 mg	QID	Y-M: 20[redacted]-[redacted] / -110
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -35

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INSULIN	0.3-0.6 OTHER: I.E/H	OTHER: SUBCUTANEOUS PUMP	Y-M: 19[redacted]	ONGOING
FLUTICASONE PROPIONATE	50 ug	PRN	Y-M: 20[redacted]	ONGOING
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	1 OTHER: TABLET.	QD	Y-M: 20[redacted]-[redacted]	ONGOING
SIMVASTATIN	40 mg	QD	Y-M: 20[redacted]	ONGOING
BISACODYL	10 mg	QD	Y-M: 20[redacted]	ONGOING
VITAMINS NOS	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]	ONGOING
CALCIUM	1 OTHER: TABLET.	QD	Y-M: 20[redacted]	ONGOING
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]	ONGOING

MAGNESIUM HYDROXIDE	500 mg	PRN	Y-M: 20[redacted]	ONGOING
ESTRADIOL	10 ug	OTHER: BIS	Y-M: 20[redacted]-[redacted]	ONGOING
DOMPERIDONE	10 mg	PRN	Y-M: 20[redacted]-[redacted] / 4	ONGOING
DOCUSATE;SORBITOL	1 mL	OTHER: SD	Y-M: 20[redacted]-[redacted] / 7	Y-M: 20[redacted]-[redacted] / 7
INFLUENZA VACCINE	1 OTHER: NOT SPECIFIED.	OTHER: SD	Y-M: 20[redacted]-[redacted] / 8	Y-M: 20[redacted]-[redacted] / 8
ONDANSETRON	2 mg	PRN	Y-M: 20[redacted]-[redacted] / 35	Y-M: 20[redacted]-[redacted] / 35
TERBINAFINE HYDROCHLORIDE	250 mg	QD	Y-M: 20[redacted]-[redacted] / 64	Y-M: 20[redacted]-[redacted] / 71
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted]-[redacted] / 103	Y-M: 20[redacted]-[redacted] / 111
LOSARTAN	50 mg	QD	Y-M: 20[redacted]-[redacted] / 106	ONGOING
PIVMECILLINAM	400 mg	TID	Y-M: 20[redacted]-[redacted] / 147	Y-M: 20[redacted]-[redacted] / 152
MELATONIN	2 mg	QD	Y-M: 20[redacted]-[redacted] / 153	Y-M: 20[redacted]-[redacted] / 163
DONEPEZIL	5 mg	QD	Y-M: 20[redacted]-[redacted] / 161	Y-M: 20[redacted]-[redacted] / 163
DONEPEZIL	5 mg	QD	Y-M: 20[redacted]-[redacted] / 165	Y-M: 20[redacted]-[redacted] / 192
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 244	Y-M: 20[redacted]-[redacted] / 283
QUETIAPINE FUMARATE	50 mg	QD	Y-M: 20[redacted]-[redacted] / 284	ONGOING
RIVASTIGMINE	4.6 mg	QD	Y-M: 20[redacted]-[redacted] / 313	Y-M: 20[redacted]-[redacted] / 362
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted]-[redacted] / 322	Y-M: 20[redacted]-[redacted] / 329
RIVASTIGMINE	9.5 mg	QD	Y-M: 20[redacted]-[redacted] / 362	ONGOING

Event #1: Serious Adverse Event, Event of Interest - Infusion Site Related Non Infection Reactions

Event Description HEMATOMA AT INFUSION SITE.

Preferred term 注入部位血腫

AE Onset Date / Rx Day [redacted]20[redacted] / 34

Age at AE Onset 7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 34): ALBUMIN: 30 [34 - 45] G/L; GLUCOSE: 13.5 [4.2 - 7.8] MMOL/L; GLUCOSE: 7.8 [4.2 - 7.8] MMOL/L; NPTST009-ALANINE AMINOTRANSFERASE (ALAT): 7 [10 - 45] U/L; NPTST057-C-REACTIVE PROTEIN (CRP): 27.7 [NOT REPORTED - 8] MG/L; NPTST064-CARBAMIDE: 11.8 [3.1 - 7.9] MMOL/L; NPTST156-INR: 1.4 [NOT REPORTED - 1.2] RATIO; NPTST170-LEUCOCYTE: 10.8 [3.5 - 10] 10^9/L; NPTST192-MONOCYTES: 0.92 [0.2 - 0.7] 10^9/L; NPTST197-NEUTROPHILOCYTES: 8 [2 - 7] 10^9/L; NPTST208-PANCREATIC AMYLASE: 7 [10 - 65] U/L

Microbiology

[redacted]20[redacted] (RX DAY 34): OTHER SWAP ABDOMINAL: NEGATIVE-NO GROWTH.; OTHER SWAP THROAT: NEGATIVE-WITHOUT SYMPTOMS OF COVID-19 - ACUTE HOSPITALIZATION.

AE Stopped Rx Day 49

Duration of AE	16 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	INFECTION AT INFUSION SITE.
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 34
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 34): ALBUMIN: 30 [34 - 45] G/L; GLUCOSE: 13.5 [4.2 - 7.8] MMOL/L; GLUCOSE: 7.8 [4.2 - 7.8] MMOL/L; NPTST009-ALANINE AMINOTRANSFERASE (ALAT): 7 [10 - 45] U/L; NPTST057-C-REACTIVE PROTEIN (CRP): 27.7 [NOT REPORTED - 8] MG/L; NPTST064-CARBAMIDE: 11.8 [3.1 - 7.9] MMOL/L; NPTST156-INR: 1.4 [NOT REPORTED - 1.2] RATIO; NPTST170-LEUCOCYTE: 10.8 [3.5 - 10] 10^9/L; NPTST192-MONOCYTES: 0.92 [0.2 - 0.7] 10^9/L; NPTST197-NEUTROPHILOCYTES: 8 [2 - 7] 10^9/L; NPTST208-PANCREATIC AMYLASE: 7 [10 - 65] U/L

Microbiology

[redacted]20[redacted] (RX DAY 34): OTHER SWAP ABDOMINAL: NEGATIVE-NO GROWTH.; OTHER SWAP THROAT: NEGATIVE-WITHOUT SYMPTOMS OF COVID-19 - ACUTE HOSPITALIZATION.

AE Stopped Rx Day	49
Duration of AE	16 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO

SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS.
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 56
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	146
Duration of AE	91 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	THORACAL PAIN.
Preferred term	胸痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	92
Duration of AE	25 DAYS
Severity	MILD

Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Falls And Associated Injuries

Event Description	DUE TO ACCIDENTIAL FALL.
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	92
Duration of AE	25 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Falls And Associated Injuries

Event Description	SUBJECT HAS FALLEN ACCIDENTIAL.
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 68
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	68
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS INFLAMMATION AT INJECTION SITE.
Preferred term	注射部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 103
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	124
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULUS AT INFUSION SITE.
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 124
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	131
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS - WORSENING
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 147
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	283
Duration of AE	137 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS - FURTHER WORSENING
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 284
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEUS RIGHT THIGH INFUSION SITE INFLAMMATION.
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 322
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はデンマークの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位感染及び注入部位血腫を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，糖尿病，パーキンソン病，高血圧，非喫煙者及び飲酒者（1 日 2 杯未満）であった。

投与 34 日目，被験者は注入部位感染及び注入部位血腫を発現した。投与 49 日目，注入部位感染及び注入部位血腫は消失した。

投与 34 日目，被験者は気分が悪く，歩くことができず，腹部の腫脹，疼痛，発赤，及び持続皮下注入の注射部位の疼痛があり，緊急治療室を受診した。検査の結果，被験者に発熱，咳嗽及び息切れはなかった。被験者は感染症及び便秘について評価された。緊急治療室で下腹部の

感染性血腫が特定され，その後ドレナージし，空洞を洗い流した。創部領域を覆うため絆創膏を貼布した。処置後，被験者は悪心を発現したが，血糖値は安定していた。投与 35 日目，被験者は退院した。

The patient's past medications include:

ROTIGOTINE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ZONISAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR RAPID TABLET for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site infection (10054997) (Infusion site infection(10054997)) [v.23.1] [10054997]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

2) Infusion site hematoma (10065469) (Infusion site haematoma (10065463)) [v.23.1] [10065469]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of INFECTION AT INFUSION SITE

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

Event of HEMATOMA AT INFUSION SITE

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL SWAB:** No growth

[redacted] **20[redacted] ALANINE AMINOTRANSFERASE:** 7 U/L (normal 10 to 45)

[redacted] **20[redacted] ALBUMIN:** 30 G/L (normal 34 to 45)

[redacted] **20[redacted] BLOOD GLUCOSE:** 13.5 MMOL/L (normal 4.2 to 7.8)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 27.7 MG/L (normal <8)

[redacted] **20[redacted] CARBAMIDE:** 11.8 MMOL/L (normal 3.1 to 7.9)

[redacted] **20[redacted] INR:** 1.4 RATIO (normal <1.2)

[redacted] **20[redacted] LEUCOCYTE:** 10.8 X10**9/L (normal 3.50 to 10.0)

[redacted] **20[redacted] MONOCYTES:** 0.92 X10**9/L (normal 0.20 to 0.70)

[redacted] **20[redacted] NEUTROPHILOCYTES:** 8.00 X10**9/L (normal 2.00 to 7.00)

[redacted] **20[redacted] PANCREATIC AMYLASE:** 7 U/L (normal 10 to 65)

[redacted] **20[redacted] THROAT SWAB:** WITHOUT SYMPTOMS OF COVID-19

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
反応性関節炎	X			
ジスキネジア		X		
注入部位膿瘍				X
注入部位炎症				X
注射部位炎症				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
PARKINSON'S DISEASE	20[redacted]
STROKE	20[redacted]
POSTMENOPAUSE.	20[redacted]
HYPERTENSION	20[redacted]
REUMATOID ARTRIT	20[redacted]
DEPRESSION.	20[redacted]
ROSACEA IN FACE	20[redacted]
SLEEP APNEA	20[redacted]
LEG EDEMA.	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	6 CIGARETTE	40	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.2	0.25	0.15	60	0.15	[redacted]/1
ABBV-951	0.17	0.22	0.12	60	0.15	[redacted]/3
ABBV-951	0.12	0.14	0.1	60	0.11	[redacted]/4
ABBV-951	0.17	0.19	0.15	60	0.15	[redacted]/10
ABBV-951	0.19	0.21	0.17	60	0.19	[redacted]/18
ABBV-951	0.17	0.19	0.15	60	0.19	[redacted]/25
ABBV-951	0.18	0.19	0.17	60	0.19	[redacted]/32
ABBV-951	0.18	0.19	0.17	60	0.24	[redacted]/43
ABBV-951	0.18	0.19	0.17	60	0.15	[redacted]/92
ABBV-951	0.19	0.2	0.18	60	0.15	[redacted]/162
ABBV-951	0.2	0.21	0.19	60	0.15	[redacted]/183
ABBV-951	0.21	0.23	0.19	60	0.24	[redacted]/281
ABBV-951	0.19	0.21	0.17	60	0.15	[redacted]/305

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	368.82		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	491.76		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		18.78	SC / ONCE	[redacted] / 7	
ABBV-951	459.31		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7

ABBV-951		37.56	SC / ONCE	[redacted] / 8	
ABBV-951	409.8		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		75.13	SC / ONCE	[redacted] / 9	
ABBV-951	450.78		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
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ABBV-951	809.35		SC / CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	795.69		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 206	
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 207	
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	849.99		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209

ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	791.25		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 212	
ABBV-951	830.01		SC / CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 213	
ABBV-951	842.82		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 214	
ABBV-951	825.40		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 215	
ABBV-951	803.20		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 216	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 217	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 218	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 219	
ABBV-951	806.79		SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 220	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 221	
ABBV-951	849.82		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	849.82		SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 224	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 225	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 226	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 228	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 229	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231

ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 232	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 233	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 234	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	847.77		SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 236	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 238	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 239	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 241	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	842.65		SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 243	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 244	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 246	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 249	
ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 250	
ABBV-951	842.65		SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 251	
ABBV-951	842.65		SC / CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 252	
ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 253	
ABBV-951	627.50		SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253

ABBV-951	179.28		SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	849.82		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 258	
ABBV-951	821.13		SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 260	
ABBV-951	828.30		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 261	
ABBV-951	817.55		SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	831.89		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	849.82		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	835.13		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 275	
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 276	
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 277	
ABBV-951	816.18		SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 278	
ABBV-951	734.56		SC / CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 279	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 280	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 281	

ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 282	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 284	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 289	
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 290	
ABBV-951	821.13		SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 291	
ABBV-951	856.99		SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 292	
ABBV-951	853.40		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 293	
ABBV-951	506.95		SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 294	
ABBV-951	838.38		SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 295	
ABBV-951	499.10		SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	775.37		SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 297	
ABBV-951	681.29		SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	772.13		SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	480.14		SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	528.81		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 301	
ABBV-951	357.20		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	340.64		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 305	
ABBV-951	98.69		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	29.02		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	232.22		SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308

ABBV-951	510.88		SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 310	
ABBV-951	406.38		SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	197.38		SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	264.15		SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	171.26		SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	554.42		SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 316	
ABBV-951	647.31		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	696.66		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 318	
ABBV-951	685.04		SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	467.34		SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
ENALAPRIL	20 mg	QD	Y-M: 20[redacted]-[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]-[redacted]
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]-[redacted]
METHOTREXATE	2.5 mg	QD	Y-M: 20[redacted]-[redacted]
AMITRIPTYLINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted]-[redacted]
METRONIDAZOLE	0.75%	BID	Y-M: 20[redacted]-[redacted] / -314
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]-[redacted] / -283
CALCIUM	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted] / -70
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]-[redacted] / -70
POTASSIUM CHLORIDE	750 mg	QD	Y-M: 20[redacted]-[redacted] / -70
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -50
ATORVASTATIN	40 mg	QD	Y-M: 20[redacted]-[redacted] / -32
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -28
RASAGILINE	1.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -28

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ENALAPRIL	20 mg	QD	Y-M: 20[redacted]	ONGOING
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	ONGOING
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]	ONGOING
METHOTREXATE	2.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 210
AMITRIPTYLINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 92
METRONIDAZOLE	0.75%	BID	Y-M: 20[redacted] / -314	ONGOING
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -283	ONGOING
CALCIUM	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -70	ONGOING
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / -70	ONGOING
POTASSIUM CHLORIDE	750 mg	QD	Y-M: 20[redacted] / -70	ONGOING
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted] / -50	Y-M: 20[redacted] / 34
ATORVASTATIN	40 mg	QD	Y-M: 20[redacted] / -32	ONGOING
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 25
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 40
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 149	Y-M: 20[redacted] / 156
METHOTREXATE	20 mg	OTHER: WEEKLY	Y-M: 20[redacted] / 239	Y-M: 20[redacted] / 316
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted] / 262	ONGOING
PIPERACILLIN;TAZOBACTAM	4 g	TID	Y-M: 20[redacted] / 262	ONGOING
TRIAMCINOLONE ACETONIDE	40 mg	QD	Y-M: 20[redacted] / 270	Y-M: 20[redacted] / 270
PREDNISOLONE	15 mg	QD	Y-M: 20[redacted] / 274	Y-M: 20[redacted] / 280
PREDNISOLONE	10 mg	QD	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 287
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted] / 288	ONGOING
METHOTREXATE	15 mg	OTHER: QW	Y-M: 20[redacted] / 316	ONGOING
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 352

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANOUS INJECTION SITE INFLAMMATION.
Preferred term	注射部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 18
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	32
Duration of AE	15 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANOUS INJECTION SITE INFLAMMATION.
Preferred term	注射部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	15 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS INJECTION SITE INFLAMMATION
Preferred term	注射部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 149
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	162
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	REACTIVE ARTHRITIS IN RIGHT KNEE
Preferred term	反応性関節炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 262
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 262): LEUKOCYTES: 16.3 [3.5 - 10] 10^9/L; NPTST097-CRP: 187.6 [0 - 8] MG/L; NEUTROPHILS: 14.4 [2 - 7] 10^9/L; PLATELETS: 411 [165 - 400] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 262): SPUTUM COVID-19: NEGATIVE; OTHER SYNOVIAL FLUID CULTURE: NEGATIVE-HIGH CELL COUNT WHICH WAS A SIGN OF INFLAMMATION IN SYNOVIAL FLUID.

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING

Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	P.I SUSPECT THIS AE IS CAUSED AND DUE TO INFLAMMATION (AE [redacted])
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANOUS ABDOMINAL INFLAMATION AT INFUSION SITE.
Preferred term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 262
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	271
Duration of AE	10 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: AE Leading to Discontinuation of Study Drug

Event Description	DYSKINESIA
Preferred term	ジスキネジア
AE Onset Date / Rx Day	[redacted]20[redacted] / 297
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	305
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #7: Event of Interest - Infusion Site Related Infections

Event Description	ABSCESS NEAR OLD INFUSION SITE.
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 344 (14 days after last treatment)
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	350 (20 DAYS AFTER LAST TREATMENT)
Duration of AE	7 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はデンマークの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，右膝の反応性関節炎を発現した。

Event 4 の臨床経過：

関連する病歴は，関節リウマチであった。他の併用療法は，投与 263 日目実施の腹部超音波検査，投与 270 日目実施の右肩の超音波検査，投与 262 日目実施の膝の超音波ガイド下穿刺，及び投与 265 日目実施の右膝蓋骨の X 線検査であった。

投与 262 日目，被験者は右膝の反応性関節炎を発現した。

入院前，被験者は右膝に疼痛及び腫脹があった。投与 262 日目，被験者は高熱，疼痛，CRP 高値のため入院した。被験者は右膝に歩行時の痛み，腫脹及び発赤があり，左腹部の皮下に 10 × 5 cm の注入部位炎症（非重篤）があった。入院中，膝の感染症が疑われた。被験者は抗生物質 tazocin の静脈内投与を開始した。メトトレキサートは感染症の治療中は中止された。投与 262 日目，滑液の培養では感染の徴候はなかった。また，被験者は右肩の滑液包炎（非重篤）があり，kenalog 注射の治療を受けた。投与 273 日目，被験者はほぼ正常な感染率で退院した。

被験者に tazocin 及びプレドニゾロンが投与された。

Causality for ABBV-951 (Open Label)

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1) Reactive arthritis (10037994) (Arthritis reactive (10003267)) [v.24.0] [10037994]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of REACTIVE ARTHRITIS IN RIGHT KNEE

- Investigator: P. I. Suspect this AE is caused and due to inflammation (AE [redacted]).

- AbbVie: More likely related to incidental infection and reported inflammation in a subject with history of rheumatoid arthritis.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] COVID-19 SPUTUM TEST:** Negative

[redacted] **20[redacted] CRP:** 187.6 MG/L (normal 0 to 8)

[redacted] **20[redacted] CULTURE:** (Synovial fluid): Negative

[redacted] **20[redacted] NEUTROPHILS ABS:** 14.4 X10**9/L (normal 2 to 7)

[redacted] **20[redacted] PLATELET COUNT:** 411 X10**9/L (normal 165 to 400)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.3 X10**9/L (normal 3.50 to 10.0)

[redacted] **20[redacted] XRAY RIGHT PATELLA:** osteoarthritis

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位膿瘍	X	X		X
注入部位紅斑				X
注入部位浮腫				X
注入部位疼痛				X
注入部位丘疹				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
POSTMENOPAUSAL	NOT REPORTED
INSOMNIA	20[redacted]
EDEMA OF LEGS	20[redacted]
CONSTIPATION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	6 CIGARETTE	15	19[redacted]

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.43	0	0	60	0.15	[redacted]/1
ABBV-951	0.39	0	0	60	0.15	[redacted]/2
ABBV-951	0.41	0	0	60	0.15	[redacted]/8
ABBV-951	0.43	0	0	60	0.19	[redacted]/15
ABBV-951	0.5	0	0	60	0.19	[redacted]/22
ABBV-951	0.5	0	0	60	0.19	[redacted]/29

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	807.64		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1687.01		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		51.22	SC / ONCE	[redacted] / 13	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		51.22	SC / ONCE	[redacted] / 14	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1696.57		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15

ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
ROPINIROLE	6.000 mg	QD	Y-M: 20[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	2,5+573 mg	QD	Y-M: 20[redacted] / -350
ENTACAPONE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -279
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	0,5 ENVOLUPE OTHER: ENVOLUPE	QD	Y-M: 20[redacted] / -223
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted] / -202
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted] / -84
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted] / -57
MELATONIN	2 mg	QD	Y-M: 20[redacted] / -39
POTASSIUM CHLORIDE	750 mg	QD	Y-M: 20[redacted] / -39

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BENDROFLUMETHIAZIDE;POTASSIUM CHLORIDE	2,5+573 mg	QD	Y-M: 20[redacted] / -350	ONGOING
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	0,5 ENVOLUPE OTHER: ENVOLUPE	QD	Y-M: 20[redacted] / -223	ONGOING
MELATONIN	2 mg	QD	Y-M: 20[redacted] / -39	ONGOING
POTASSIUM CHLORIDE	750 mg	QD	Y-M: 20[redacted] / -39	ONGOING
CYANOCOBALAMIN; FOLIC ACID;PYRIDOXINE	0,5 MG VIT. B1; 0,8 MG FOLIC ACID; 3 MG VIT. B6 mg	QD	Y-M: 20[redacted] / 8	ONGOING
BENZYLPENICILLIN	1,2 g	TID	Y-M: 20[redacted] / 43	Y-M: 20[redacted] / 44

CLINDAMYCIN	300 mg	TID	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 45
PHENOXYMETHYLPENICILLIN	1000 mg	TID	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 45

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	STINGING SENSATION AT INFUSION SITE
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 1
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	1
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 28
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	16 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 28

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	16 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAPULES AT INFUSION SITE
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 28
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	43
Duration of AE	16 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	SUBCUTANEOUS ABSCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 43
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 43): NPTST047-BLOOD CULTURE: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 43): BLOOD CULTURE: NEGATIVE-NO; WOUND GRAFTING: POSITIVE-GROWTH OF STAPHYLOCOCCUS AUREUS

AE Stopped Rx Day	70 (27 DAYS AFTER LAST TREATMENT)
Duration of AE	28 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はデンマークの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に注入部位の皮下膿瘍を発現した。

Event 6 の臨床経過：

関連する病歴は，元喫煙者（1 日 6 本を 15 年間），パーキンソン病，両下肢の浮腫，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 43 日目，被験者は注入部位の皮下膿瘍を発現した。投与 70 日目，注入部位の皮下膿瘍は消失した。

投与 28 日目，被験者は注入部位の紅斑，浮腫，及び丘疹（いずれも非重篤）を発現した。

投与 43 日目，被験者は入院した。左下腹部の注射部位に腫脹及び発赤のある直径 10 cm の皮下膿瘍が認められた。膿の漏出を伴う 3 cm の自然穿孔も認められた。同日，全身麻酔下で腹部膿瘍の切開及びドレナージを行った。術後，被験者に発熱はなかった。投与 45 日目，被験者は退院した。

本事象により治験薬投与は完全に中止された。

被験者にフェノキシメチルペニシリン，ベンジルペニシリン，及びクリンダマイシンが投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

FURIX for EDEMA OF LEGS ([redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET CR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUBCUTANEOUS ABSCESS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] WOUND CULTURE:** Positive for growth of staphylococcus aureus.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
オンオフ現象	X	X		
錯感覚				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
APPENDICITIS	19[redacted]
ARTERIAL HYPERTENSION	19[redacted]
POSTMENOPAUSAL	20[redacted]
GONARTHROSIS LEFT	20[redacted]
HYPERCHOLESTERINEMIA	20[redacted]
HYPOTHROIDISM	20[redacted]
LUMBAR SPONDYLARTHROSIS	20[redacted]
RENAL CYST	20[redacted]
SCIATICA	20[redacted]
CERVICAL SPONDYLARTHROSIS	20[redacted]
RHIZARTHROSIS BILATERAL	20[redacted]
ACTINIC CERATOSIS	20[redacted]
CARPAL TUNNEL SYNDROM LEFT	20[redacted]
CARPAL TUNNEL SYNDROM RIGHT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
APPENDECTOMY	19[redacted]
CARPAL TUNNEL OPERATION RIGHT	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/1
ABBV-951	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/2
ABBV-951	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/8
ABBV-951	0.4	0.46	0.34	60	0.24	[redacted]20[redacted]/17
ABBV-951	0.4	0.46	0.34	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.51	0.54	0.46	60	0.3	[redacted]20[redacted]/29
ABBV-951	0.51	0.54	0.46	60	0.3	[redacted]20[redacted]/46

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	646.11		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	1284.38		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951	1290.69		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1297.7		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	418.33		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1370.61		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	399.38		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	779.64		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	779.81		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9

ABBV-951		97.32	SC / ONCE	[redacted] / 10	
ABBV-951	1357.12		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		97.32	SC / ONCE	[redacted] / 11	
ABBV-951	1293.77		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		64.88	SC / ONCE	[redacted] / 12	
ABBV-951	1339.36		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		32.44	SC / ONCE	[redacted] / 13	
ABBV-951	1306.92		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		32.44	SC / ONCE	[redacted] / 14	
ABBV-951	1319.38		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		129.77	SC / ONCE	[redacted] / 15	
ABBV-951	1425.76		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		64.88	SC / ONCE	[redacted] / 16	
ABBV-951	1340.89		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		81.96	SC / ONCE	[redacted] / 17	
ABBV-951	1639.37		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		81.96	SC / ONCE	[redacted] / 18	
ABBV-951	1567.14		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		81.96	SC / ONCE	[redacted] / 19	
ABBV-951	1516.94		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		40.98	SC / ONCE	[redacted] / 20	
ABBV-951	1546.99		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1579.43		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		102.45	SC / ONCE	[redacted] / 22	
ABBV-951	1690.76		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		51.22	SC / ONCE	[redacted] / 23	
ABBV-951	1689.05		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		51.22	SC / ONCE	[redacted] / 24	
ABBV-951	1721.84		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		51.22	SC / ONCE	[redacted] / 25	
ABBV-951	1593.78		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951		51.22	SC / ONCE	[redacted] / 26	
ABBV-951	1694.86		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		102.45	SC / ONCE	[redacted] / 27	
ABBV-951	1667.20		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		204.9	SC / ONCE	[redacted] / 28	
ABBV-951	1678.13		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28

ABBV-951		51.22	SC / ONCE	[redacted] / 29	
ABBV-951	1890.03		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951		51.22	SC / ONCE	[redacted] / 30	
ABBV-951	2032.26		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		153.67	SC / ONCE	[redacted] / 31	
ABBV-951	2049.51		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951		102.45	SC / ONCE	[redacted] / 32	
ABBV-951	2042.51		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951		51.22	SC / ONCE	[redacted] / 33	
ABBV-951	1965.33		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951		51.22	SC / ONCE	[redacted] / 34	
ABBV-951	1981.72		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951		51.22	SC / ONCE	[redacted] / 35	
ABBV-951	1981.38		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951		51.22	SC / ONCE	[redacted] / 36	
ABBV-951	2072.56		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951		51.22	SC / ONCE	[redacted] / 37	
ABBV-951	2062.83		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951		102.45	SC / ONCE	[redacted] / 38	
ABBV-951	2087.41		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951		51.22	SC / ONCE	[redacted] / 39	
ABBV-951	2114.56		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	2135.05		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951		256.12	SC / ONCE	[redacted] / 41	
ABBV-951	2127.37		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted] / 42	
ABBV-951	2114.05		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		51.22	SC / ONCE	[redacted] / 43	
ABBV-951	2121.73		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		51.22	SC / ONCE	[redacted] / 44	
ABBV-951	2072.56		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951		51.22	SC / ONCE	[redacted] / 45	
ABBV-951	2016.72		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951		102.45	SC / ONCE	[redacted] / 46	
ABBV-951	2088.27		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951		102.45	SC / ONCE	[redacted] / 47	
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 48	
ABBV-951	2072.56		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 49	
ABBV-951	2133.52		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 50	
ABBV-951	2082.29		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	2140.00		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 52	
ABBV-951	2152.47		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LEVOTHYROXINE SODIUM;POTASSIUM IODIDE	75 ug	QD	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]
CANDESARTAN	8 mg	BID	Y-M: 20[redacted]
BIPERIDEN	2.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.050 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	QID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	150.000 mg	QD	Y-M: 20[redacted]-[redacted]
TORASEMIDE	5 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.520 mg	TID	Y-M: 20[redacted]-[redacted]
BIPERIDEN	2.000 mg	BID	Y-M: 20[redacted]-[redacted]
BIPERIDEN	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.520 mg	BID	Y-M: 20[redacted]-[redacted]
BIPERIDEN	0.500 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]

CARBIDOPA;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	300.000 mg	QD	Y-M: 20[redacted]
SAFINAMIDE	50.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted] / -365
CARBIDOPA;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted] / -365
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -267
CARBIDOPA;LEVODOPA	250.000 mg	QID	Y-M: 20[redacted] / -267
CARBIDOPA;LEVODOPA	250.000 mg	QID	Y-M: 20[redacted] / -241
CARBIDOPA;LEVODOPA	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -239
CARBIDOPA;LEVODOPA	560.000 mg	TID	Y-M: 20[redacted] / -223
CARBIDOPA;LEVODOPA	700.000 mg	TID	Y-M: 20[redacted] / -222
CARBIDOPA;LEVODOPA	560.000 mg	TID	Y-M: 20[redacted] / -218
CARBIDOPA;LEVODOPA	420.000 mg	BID	Y-M: 20[redacted] / -215
CARBIDOPA;LEVODOPA	560.000 mg	BID	Y-M: 20[redacted] / -215
NEBIVOLOL	5 mg	QD	Y-M: 20[redacted] / -207
BLINDED THERAPY	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -195
BLINDED THERAPY	420.000 mg	BID	Y-M: 20[redacted] / -195
BLINDED THERAPY	560.000 mg	BID	Y-M: 20[redacted] / -195
CARBIDOPA;LEVODOPA	140.000 mg	BID	Y-M: 20[redacted] / -102
CARBIDOPA;LEVODOPA	280.000 mg	BID	Y-M: 20[redacted] / -102
CARBIDOPA;LEVODOPA	280.000 mg	QID	Y-M: 20[redacted] / -102
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -75
CARBIDOPA;LEVODOPA	250.000 mg	QID	Y-M: 20[redacted] / -75

FLUOROURACIL	1 g	BID	Y-M: 20[redacted] / -39
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE	15 mg	QD	Y-M: 20[redacted] / -5

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LEVOTHYROXINE SODIUM;POTASSIUM IODIDE	75 ug	QD	Y-M: 20[redacted]	ONGOING
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]	ONGOING
CANDESARTAN	8 mg	BID	Y-M: 20[redacted]	Y-M: 20[redacted] / 44
TORASEMIDE	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 44
NEBIVOLOL	5 mg	QD	Y-M: 20[redacted] / -207	ONGOING
FLUOROURACIL	1 g	BID	Y-M: 20[redacted] / -39	ONGOING
CYANOCOBALAMIN; PYRIDOXINE HYDROCHLORIDE;THIAMINE MONONITRATE	15 mg	QD	Y-M: 20[redacted] / -5	Y-M: 20[redacted] / 13
LIDOCAINE HYDROCHLORIDE	1 mL	OTHER: 1X	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
TRIAMCINOLONE ACETONIDE	1 mL	OTHER: 1X	Y-M: 20[redacted] / 10	Y-M: 20[redacted] / 10
ACETYLSALICYLIC ACID	500 mg	QD	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 38
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 44
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 44
CANDESARTAN	8 mg	OTHER: 2-0-1	Y-M: 20[redacted] / 45	ONGOING
TORASEMIDE	10 mg	QD	Y-M: 20[redacted] / 45	ONGOING
LORAZEPAM	0.25 mg	OTHER: 1X EVENING 21.JAN.2021	Y-M: 20[redacted] / 52	Y-M: 20[redacted] / 52

Event #1: Serious Adverse Event

Event Description	SUDDEN OFF STATE RELATED TO PARKINSONS DISEASE
Preferred term	オンオフ現象
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	45
Duration of AE	8 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	WORSENING OF PARKINSONS SYMPTOMES
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Event of Interest - Polyneuropathy

Event Description	PINS AND NEEDLES LIKE PARAESTHESIA UBIQUOUS
Preferred term	錯感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	45
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #3: Event of Interest - Polyneuropathy

Event Description	PINS AND NEEDLES LIKE PARAESTHESIA HANDS AND FEET
Preferred term	錯感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 46
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	77 (25 DAYS AFTER LAST TREATMENT)
Duration of AE	32 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: AE Leading to Discontinuation of Study Drug

Event Description	SEVERE OFF-STATE
Preferred term	オンオフ現象
AE Onset Date / Rx Day	[redacted]20[redacted] / 52
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	52
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #5: Serious Adverse Event

Event Description	WORSENING OF MOTORFLUCTUATION
Preferred term	オンオフ現象
AE Onset Date / Rx Day	[redacted]20[redacted] / 53 (1 day after last treatment)
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	77 (25 DAYS AFTER LAST TREATMENT)
Duration of AE	25 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	DISCONTINUATION OF SUBCUTANEOUS LEVODOPA INFUSION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病に関連する突然のオフ状態を発現した。

Event 1 の臨床経過：

投与 38 日目，被験者はパーキンソン病に関連する突然のオフ状態を発現した。投与 45 日目，パーキンソン病に関連する突然のオフ状態は消失した。

投与 38 日目，被験者は重度の振戦，運動緩慢及び浮動性めまいを伴う重度のオフ状態を発現した。ファーストレスキュー薬が投与されたにもかかわらず，症状は増強した。マドパーによる治療も行われた。治療後 30 分以内に症状の緩和がみられなかったため，被験者は最寄りの病院に搬送され，入院した。投与 45 日目，被験者は退院した。

被験者にマドパーLT が投与された。

The patient's past medications include:

BIPERIDEN for PARKINSON'S DISEASE ([redacted])

ISICOM for PARKINSON'S DISEASE ([redacted])

LEVOCOMP for PARKINSON'S DISEASE ([redacted])

MADOPAR DISPERSIBLE for PARKINSON'S DISEASE ([redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted])

LEVODOPA-CARBIDOPA for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Unpredictable off motor fluctuations (10067209) (On and off phenomenon (10030312)) [v.23.1] [10067209]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUDDEN OFF STATE RELATED TO PARKINSON'S DISEASE

- Investigator: Worsening of Parkinson's symptoms

- AbbVie: More likely related to underlying Parkinson's disease in an advanced age subject.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] COVID 19 TEST:** nasopharyngeal swab, tested negative

[redacted] **20[redacted] CT ANGIO:** no fresh ischemia, no intercranial bleeding

[redacted] **20[redacted] CT CRANIAL:** no fresh ischemia, no intercranial bleeding

[redacted] **20[redacted] MRI CRANIAL:** no Fresh ischemia

[redacted] **20[redacted] NLG/EMG:** no note for PNP, sensomotoric KTS both sides

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，運動症状の日内変動の悪化を発現した。

Event 5 の臨床経過：

関連する病歴は，甲状腺機能低下症，パーキンソン病，非喫煙者及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 53 日目，被験者は運動症状の日内変動の悪化を発現した。投与 77 日目，運動症状の日内変動の悪化は消失した。

本事象発現前，投与 52 日目，被験者は非重篤で重度のオフ状態を発現した。

投与 53 日目，被験者は運動症状の日内変動の悪化及びオフ状態に関連するしびれにより入院した。これは治験薬投与の中止後の経口薬の調整が原因で発生した。被験者は精神病理学的に軽度のうつ病であり，左側の運動緩慢，硬直，及び左側の断続的な振戦を発現した。投与 77 日目，被験者は退院した。

The patient's past medications include:

BIPERIDEN for PARKINSON'S DISEASE ([redacted])

ISICOM for PARKINSON'S DISEASE ([redacted], Started [redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted], Started [redacted], Started [redacted])

LEVOCOMP for PARKINSON'S DISEASE ([redacted])

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE for PARKINSON'S DISEASE ([redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted], Started [redacted])

IPX203 CD/LD for PARKINSON'S DISEASE ([redacted])

LEVODOPA/CARBIDOPA for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Motor fluctuations (10067208) (On and off phenomenon (10030312)) [v.23.1] [10067208]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF MOTORFLUCTUATION

- Investigator: Discontinuation of subcutaneous levodopa infusion.

- AbbVie: More likely related to concurrent non-serious event of severe off-state with discontinuation of subcutaneous infusion of study drug the day before in an advanced aged patient with a history of Parkinson's disease

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Paraesthesia: Onset is chronic, more than 4 weeks. Subject experienced pins and needles like paraesthesia. Sensmoto: Sensory, Axondemy: Axonal, Pattern of involvement: Polyneuropathy: abnormal, suspected small-fiber-polyneuropathia, distal, symmetric dysaethesia on fingers and toes, Symmetric: abnormal, distal symmetric affecting fingers and toes. EMG performed on [redacted] 20[redacted] showed no signs of PNP, proof of CTS on right wrist.
Paraesthesia: Onset is subacute >1 week <4 weeks. Subject experienced pins and needles like paraesthesia. Sensmoto: Sensory, Axondemy: Axonal, Pattern of involvement: Polyneuropathy: abnormal, distal symmetric dysaesthesia on fingers and toes, suspected small-fiber PNP, Symmetric: abnormal, distal symmetric affecting fingers and toes. No diagnostic tests performed.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
虚血性大腸炎	X			
注入部位膿瘍	X			X
腸出血	X			
肺炎	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
PARKINSON DISEASE	20[redacted]
HIGH BLOOD PRESSURE	20[redacted]
HYPERLIPIDAEMIA	20[redacted]
VARICES	20[redacted]
BRONCHITIS	20[redacted]
URINARY INCONTINENCE	20[redacted]
SLEEP DISORDER	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
VARICEAL OPERATION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			

PIPES NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.19	0	0	0	0	[redacted]/1
ABBV-951	0.19	0	0	60	0.11	[redacted]/2
ABBV-951	0.19	0	0	60	0.11	[redacted]/8
ABBV-951	0.21	0	0	60	0.15	[redacted]/15
ABBV-951	0.24	0	0	60	0.19	[redacted]/28
ABBV-951	0.24	0	0	60	0.15	[redacted]/36
ABBV-951	0.24	0	0	60	0.15	[redacted]/42
ABBV-951	0.26	0	0	60	0.15	[redacted]/91
ABBV-951	0.26	0	0	60	0.15	[redacted]/191
ABBV-951	0.26	0	0	60	0.15	[redacted]/274

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	308.20		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	778.62		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	765.64		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	775.37		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	772.13		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	752.66		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	765.64		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	772.13		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	768.88		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	752.66		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	772.13		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		56.34	SC / ONCE	[redacted] / 12	
ABBV-951	775.37		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		56.34	SC / ONCE	[redacted] / 13	
ABBV-951	755.91		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13

ABBV-951		37.56	SC / ONCE	[redacted] / 14	
ABBV-951	778.62		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		128.06	SC / ONCE	[redacted] / 15	
ABBV-951	805.25		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		76.83	SC / ONCE	[redacted] / 16	
ABBV-951	853.40		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		76.83	SC / ONCE	[redacted] / 17	
ABBV-951	839.06		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		128.06	SC / ONCE	[redacted] / 18	
ABBV-951	853.40		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		102.45	SC / ONCE	[redacted] / 19	
ABBV-951	853.40		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		179.28	SC / ONCE	[redacted] / 20	
ABBV-951	835.47		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		153.67	SC / ONCE	[redacted] / 21	
ABBV-951	853.40		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		204.9	SC / ONCE	[redacted] / 22	
ABBV-951	828.30		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		153.67	SC / ONCE	[redacted] / 23	
ABBV-951	856.99		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		153.67	SC / ONCE	[redacted] / 24	
ABBV-951	849.82		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		153.67	SC / ONCE	[redacted] / 25	
ABBV-951	835.47		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951		179.28	SC / ONCE	[redacted] / 26	
ABBV-951	856.99		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		153.67	SC / ONCE	[redacted] / 27	
ABBV-951	824.72		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		97.32	SC / ONCE	[redacted] / 28	
ABBV-951	904.63		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	971.22		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951		97.32	SC / ONCE	[redacted] / 30	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		97.32	SC / ONCE	[redacted] / 31	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951		97.32	SC / ONCE	[redacted] / 32	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32

ABBV-951		97.32	SC / ONCE	[redacted] / 33	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	963.03		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	971.22		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	971.22		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951		51.22	SC / ONCE	[redacted] / 47	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951		76.83	SC / ONCE	[redacted] / 48	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		102.45	SC / ONCE	[redacted] / 49	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951		102.45	SC / ONCE	[redacted] / 50	
ABBV-951	954.83		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		102.45	SC / ONCE	[redacted] / 51	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951		153.67	SC / ONCE	[redacted] / 52	
ABBV-951	954.83		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		128.06	SC / ONCE	[redacted] / 53	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951		102.45	SC / ONCE	[redacted] / 54	
ABBV-951	971.22		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		128.06	SC / ONCE	[redacted] / 55	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		153.67	SC / ONCE	[redacted] / 56	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951		102.45	SC / ONCE	[redacted] / 57	
ABBV-951	946.63		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57

ABBV-951		128.06	SC / ONCE	[redacted] / 58	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951		153.67	SC / ONCE	[redacted] / 59	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951		102.45	SC / ONCE	[redacted] / 60	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951		179.28	SC / ONCE	[redacted] / 61	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951		179.28	SC / ONCE	[redacted] / 62	
ABBV-951	954.83		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951		153.67	SC / ONCE	[redacted] / 63	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951		179.28	SC / ONCE	[redacted] / 64	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951		128.06	SC / ONCE	[redacted] / 65	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951		128.06	SC / ONCE	[redacted] / 66	
ABBV-951	954.83		SC / CONTINUOUS	[redacted] / 66	[redacted] / 66
ABBV-951		128.06	SC / ONCE	[redacted] / 67	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 67	[redacted] / 67
ABBV-951		153.67	SC / ONCE	[redacted] / 68	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 68	[redacted] / 68
ABBV-951		102.45	SC / ONCE	[redacted] / 69	
ABBV-951	938.44		SC / CONTINUOUS	[redacted] / 69	[redacted] / 69
ABBV-951		153.67	SC / ONCE	[redacted] / 70	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951		153.67	SC / ONCE	[redacted] / 71	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951		153.67	SC / ONCE	[redacted] / 72	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951		153.67	SC / ONCE	[redacted] / 73	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951		128.06	SC / ONCE	[redacted] / 74	
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951		153.67	SC / ONCE	[redacted] / 75	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951		153.67	SC / ONCE	[redacted] / 76	

ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951		153.67	SC / ONCE	[redacted] / 77	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951		128.06	SC / ONCE	[redacted] / 78	
ABBV-951	946.63		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951		179.28	SC / ONCE	[redacted] / 79	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951		153.67	SC / ONCE	[redacted] / 80	
ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951		179.28	SC / ONCE	[redacted] / 81	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951		153.67	SC / ONCE	[redacted] / 82	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951		179.28	SC / ONCE	[redacted] / 83	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951		128.06	SC / ONCE	[redacted] / 84	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951		179.28	SC / ONCE	[redacted] / 85	
ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951		153.67	SC / ONCE	[redacted] / 86	
ABBV-951	975.32		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951		153.67	SC / ONCE	[redacted] / 87	
ABBV-951	954.83		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		153.67	SC / ONCE	[redacted] / 88	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		153.67	SC / ONCE	[redacted] / 89	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
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ABBV-951	1056.60		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
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ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 324	
ABBV-951	1029.96		SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 325	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 326	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 327	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 328	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 329	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 330	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 331	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 332	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 333	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 334	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 335	

ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 336	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 337	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 338	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 339	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 340	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 341	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 342	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 343	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 344	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 345	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 346	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 347	
ABBV-951	1056.60		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 348	
ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 349	
ABBV-951	1025.52		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 350	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 351	
ABBV-951	1061.04		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 352	
ABBV-951	1025.52		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 353	
ABBV-951	1052.16		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353

ABBV-951		153.67	SC / ONCE	[redacted] / 354
ABBV-951	1016.64		SC / CONTINUOUS	[redacted] / 354 [redacted] / 354
ABBV-951		153.67	SC / ONCE	[redacted] / 355
ABBV-951	1061.04		SC / CONTINUOUS	[redacted] / 355 [redacted] / 355
ABBV-951		153.67	SC / ONCE	[redacted] / 356
ABBV-951	1056.60		SC / CONTINUOUS	[redacted] / 356 [redacted] / 356
ABBV-951		153.67	SC / ONCE	[redacted] / 357
ABBV-951	1021.08		SC / CONTINUOUS	[redacted] / 357 [redacted] / 357
ABBV-951		153.67	SC / ONCE	[redacted] / 358
ABBV-951	1052.16		SC / CONTINUOUS	[redacted] / 358 [redacted] / 358

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
TORASEMIDE	10 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted]
ROPINIROLE	4.000 mg	BID	Y-M: 20[redacted]
VITAMIN B12 NOS	1000 ug	OTHER: 2X / WEEK	Y-M: 20[redacted] / -35

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
TORASEMIDE	10 mg	QD	Y-M: 20[redacted]	NOT REPORTED
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted]	NOT REPORTED
VITAMIN B12 NOS	1000 ug	OTHER: 2X / WEEK	Y-M: 20[redacted] / -35	ONGOING
CEFAZOLIN	2 g	TID	Y-M: 20[redacted] / 36	Y-M: 20[redacted] / 41
METAMIZOLE SODIUM	500 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / 37	NOT REPORTED
POLIHEXANIDE	10 mL	BID	Y-M: 20[redacted] / 37	NOT REPORTED
METHIONINE	500 mg	TID	Y-M: 20[redacted] / 132	NOT REPORTED
CEFOTAXIME SODIUM	2 g	TID	Y-M: 20[redacted] / 236	Y-M: 20[redacted] / 241

Event #1: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	SUBCUTANEOUS ABSCESS ABDOMINAL AN INFUSION SITE

Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 33
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 36): CREATININE: 49 [59 - 104] UMOL/L; HEMATOCRIT: 0.39 [0.42 - 0.5] FRACTION OF 1; HEMOGLOBIN: 129 [140 - 174] G/L; LEUKOCYTES: 8.7 [4.4 - 11.3] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 13.6 [22.3 - 49.9] %; MONOCYTES: 0.7 [0 - 0.5] 10^9/L; MONOCYTES/LEUKOCYTES: 8.4 [0.7 - 7.5] %; NPTST059-C-REAKTIVES PROTEIN: 28.7 [0 - 5] MG/L; NPTST113-ERYTHROCYTES: 4.2 [4.5 - 5.9] 10^12/L; [redacted]20[redacted] (RX DAY 38): NPTST059-C-REAKTIVES PROTEIN: 15.7 [0 - 5] MG/L; [redacted]20[redacted] (RX DAY 41): NPTST059-C-REAKTIVES PROTEIN: 4 [0 - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 36): WOUND BACTERIA: POSITIVE-STAPHYLOCOCCUS HAEMOLYTICUS

AE Stopped Rx Day	42
Duration of AE	10 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	ISCHEMIC COLITIS WITH
Preferred term	虚血性大腸炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 129
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 130): BILIRUBIN: 27 [5 - 21] UMOL/L; CREATININE: 57 [62 - 115] UMOL/L; GLUCOSE: 6.7 [4.1 - 5.9] MMOL/L; NPTST058-C-REACTIVES PROTEIN: 15.59 [0 - 10] MG/L; NPTST074-CHLORID: 110 [98 - 107] MMOL/L; NPTST113-ERYTHROCYTES: 4.36 [4.5 - 5.9] 10^12/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	133
Duration of AE	5 DAYS
Severity	MODERATE

Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	ISCHAEMIC COLITIS AS A RESULT OF AN OCCLUSIVE EMBOLISM
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Serious Adverse Event

Event Description	INTESTINAL BLEEDING
Preferred term	腸出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 129
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 130): BILIRUBIN: 27 [5 - 21] UMOL/L; CREATININE: 57 [62 - 115] UMOL/L; GLUCOSE: 6.7 [4.1 - 5.9] MMOL/L; NPTST058-C-REACTIVES PROTEIN: 15.59 [0 - 10] MG/L; NPTST074-CHLORID: 110 [98 - 107] MMOL/L; NPTST113-ERYTHROCYTES: 4.36 [4.5 - 5.9] 10^12/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	133
Duration of AE	5 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	ISCHAEMIC COLITIS AS A RESULT OF AN OCCLUSIVE EMBOLISM
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event

Event Description	PNEUMONIA

Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 236
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 236): BILIRUBIN: 25 [5 - 21] UMOL/L; NPTST059-C-REAKTIVES PROTEIN: 65.97 [0 - 10] MG/L; [redacted]20[redacted] (RX DAY 238): NPTST059-C-REAKTIVES PROTEIN: 71.53 [0 - 10] MG/L	
Microbiology	
[redacted]20[redacted] (RX DAY 236): URINE ERYTHROCYTES: POSITIVE-200 Z/UL; URINE LEUKOCYTES: POSITIVE-70 Z/UL	
AE Stopped Rx Day	240
Duration of AE	5 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	BACTERIAL INFECTION OF THE LUNGS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，腹部注入部位の皮下膿瘍を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，高血圧，高脂血症，非喫煙者，及び非飲酒者であった。

投与 32 日目，被験者は腹部注入部位の皮下膿瘍を発現した。投与 42 日目，腹部注入部位の皮下膿瘍は消失した。

投与 32 日目，被験者は治験薬を投与した部位に局所的な疼痛及び炎症を発現した。症状が進行し，投与 36 日目にこれらの症状によって被験者は入院した。右腹部領域に赤みを帯び，硬さがあり，温かい腫瘤を伴う皮下膿瘍が確認された。投与 38 日目，被験者の膿瘍に対し外科的治療が行われ，抗生物質が投与された。投与 42 日目，被験者の症状は改善し，退院して治療を継続した。

被験者に NOVAMINSULFON，セファゾリン，及び PRONTOSAN LIQUID が投与された。

The patient's past medications include:

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE (MADOPAR HBS) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE STANDARD (MADOPAR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.0] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SUBCUTANEOUS ABSCESS ABDOMINAL AN INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI: 35.15 kg/m2**

[redacted] **20[redacted] CREATININE:** 49 umol (normal 59 to 104)

[redacted] **20[redacted] CRP:** 28.7 MG/L (normal 0.0 to 5.0)

[redacted] **20[redacted] CRP:** 4.0 MG/L (normal 0.0 to 5.0)

[redacted] **20[redacted] SMEAR:** Intraoperative smear: Positive for Staphylococcus Haemolyticus

[redacted] **20[redacted] WBC:** 8.7 G/L (normal 4.4 to 9.2)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，腸出血を伴った虚血性大腸炎を発現した。

Event 2 及び 3 の臨床経過：

関連する病歴は，パーキンソン病，高血圧，高脂血症，静脈瘤，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 129 日目，被験者は腸出血を伴った虚血性大腸炎を発現した。投与 133 日目腸出血を伴った虚血性大腸炎は消失した。

投与 129 日目，被験者は下着に出血を認めた。投与 130 日目，被験者は入院した。直腸の指診にて出血が認められたが，下痢，痔核，嘔吐，又は発熱は認められなかった。バイタルサインは正常であった。入院時診断は下部胃腸出血であった。被験者の臨床経過は，それ以降，出血，及び下痢はなく，むしろ便秘気味で，悪心，嘔吐，発熱，腹部痛，呼吸困難のいずれもなく，血液動態も問題なかった。診断のため，結腸内視鏡検査が実施され，S 字結腸に 10 cm を超える循環虚血領域及び横行結腸中央部にポリープ及び憩室を伴う虚血性大腸炎の可能性が明らかになり，生検が実施された。発現時以降，出血は認められず，考えられる虚血性大腸炎の発生源が不明であったため，特別な治療は必要とされなかった。投与 133 日目，被験者は退院した。

被験者に L-メチオニンが投与された。

The patient's past medications include:

MADOPAR HBS for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CORONA VACCINE BIONTHEC PFIZER for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Intestinal bleeding (10071824) (Intestinal haemorrhage (10059175)) [v.24.1] [10071824]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Ischemic colitis (10023037) (Colitis ischaemic (10009895)) [v.24.1] [10023037]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ISCHEMIC COLITIS WITH INTESTINAL BLEEDING

- **Investigator:** Ischemic colitis as a result of an occlusive embolism

- **AbbVie:** More likely related to reported possible ischemic colitis and history of hyperlipidemia in an elderly patient with underlying Parkinson's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BILIRUBIN:** 1.56 mg/dL (normal 0.3 to 1.2)

[redacted] **20[redacted] CHLORIDE:** 110 MMOL/L (normal 98 to 107)

[redacted] **20[redacted] COLON BIOPSY:** Histologically ischaemic colitis confirmed. Tubular adenoma of the colon mucosa in transversum with only discrete intraepithelial neoplasia

[redacted] **20[redacted] COLONOSCOPY:** Possible ischaemic colitis, polyp in the middle of colon transversum, some diverticuli. Ischaemic colitis histologically confirmed, no further treatment necessary. Another unrelated finding is a tubullary adenoma of the colon mucosa in transversum with discrete intraepithelial neoplasia. Polyp was removed during coloscopy.

[redacted] **20[redacted] CREATININE:** 0.65 mg/dL (normal 0.7 to 1.3)

[redacted] **20[redacted] CRP:** 15.59 MG/L (normal 0 to 10)

[redacted] **20[redacted] ERYTHROCYTES:** 4.36 X10**12/L (normal 4.5 to 5.9)

[redacted] **20[redacted] GLUCOSE:** 121 mg/dL (normal 74 to 106)
Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，肺炎を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，高血圧，高脂血症，尿失禁，睡眠障害，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 236 日目，被験者は肺炎を発現した。投与 240 日目，肺炎は消失した。

投与 236 日目，被験者は発熱，健康状態の低下，及び咳嗽のため入院した。被験者は腹痛及び呼吸困難を否定した。入院時に恥骨上尿道カテーテルを留置した。臨床検査及び診断検査を完了した。被験者の尿道カテーテルは交換され，抗生物質が投与された。投与 240 日目，被験者は退院した。

被験者にセフォタキシムが投与された。

The patient's past medications include:

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE STANDARD for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CORONA VACCINE BIONTHEC PFIZER for VACCINE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Pneumonia (10035664) (Pneumonia (10035664)) [v.24.1] [10035664]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PNEUMONIA

- **Investigator:** Bacterial infection of the lungs

- **AbbVie:** More likely an incidental infection in an elderly patient with Parkinson Disease. Elderly patients are at increased risk for developing community acquired pneumonia.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BILIRUBIN:** 1.44 mg/dL (normal 0.3 to 1.2)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 64.97 MG/L (normal 0 to 10)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 71.53 MG/L (normal 0 to 10)

20[redacted] CHEST X-RAY: Pneumonia typical changes of the right lung

[redacted] **20[redacted] URINE ERYTHROCYTES:** Positive, 200

[redacted] **20[redacted] URINE LEUKOCYTES:** Positive, 70

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
四肢膿瘍	X			
注入部位紅斑				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
HALLUX VALGUS BOTH SIDES	19[redacted]
KNEE MALPOSITION RIGHT SIDE	19[redacted]
ARTERIAL HYPOTENSION	20[redacted]
MAMMA CARCINOMA LEFT SIDE	20[redacted]
KNEE ARTHROSIS RIGHT SIDE	20[redacted]
CHRONIC SINUSITIS MAXILLARIS RIGHT SIDE	20[redacted]
KNEE ARTHROSIS LEFT SIDE	20[redacted]
PARKINSON'S DISEASE	20[redacted]
DEPRESSIVE SYNDROME	20[redacted]
CHRONICAL SLEEP THROUGH DISORDER	20[redacted]
HYPOTHYREOSIS	20[redacted]
KARPALTUNNEL SYNDROME BOTH SIDES	20[redacted]
MAMMA CARCINOMA RIGHT SIDE	20[redacted]
CONSTIPATION	20[redacted]
PAIN IN BOTH WRIST JOINTS	20[redacted]
LUMBALGIA	20[redacted]
HYPERSALIVATION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
UTERUS ECTOMY	19[redacted]
HALLUX VALGUS CORRECTION BOTH SIDES	19[redacted]
KNEE- MALPUSITION - OPERATION RIGHT SIDE	19[redacted]
KNEE- MALPUSITION - OPERATION RIGHT SIDE	19[redacted]
METAL REMOVING AFTER KNEE- MALPUSITION - OPERATION RIGHT SIDE	20[redacted]
KNEE TOTAL ENDOPROTHESIS RIGHT SIDE	20[redacted]
KNEE- ARTHROSCOPY LEFT SIDE	20[redacted]
KNEE TOTAL ENDOPROTHESIS LEFT SIDE	20[redacted]
MAMMA REMOVAL RIGHT SIDE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.57	0.68	0.46	60	0.24	[redacted]/1
ABBV-951	0.57	0.52	0.46	60	0.24	[redacted]/2
ABBV-951	0.57	0.54	0.52	60	0.24	[redacted]/8
ABBV-951	0.57	0.54	0.52	60	0.24	[redacted]/15
ABBV-951	0.57	0.54	0.5	60	0.3	[redacted]/21
ABBV-951	0.57	0.54	0.5	60	0.3	[redacted]/29
ABBV-951	0.57	0.54	0.5	60	0.3	[redacted]/43
ABBV-951	0.57	0.54	0.58	60	0.3	[redacted]/64
ABBV-951	0.57	0.58	0.54	60	0.3	[redacted]/78
ABBV-951	0.57	0.58	0.54	60	0.3	[redacted]/98
ABBV-951	0.57	0.6	0.54	60	0.3	[redacted]/106
ABBV-951	0.58	0.62	0.54	60	0.24	[redacted]/133
ABBV-951	0.62	0.65	0.58	60	0.24	[redacted]/147

ABBV-951	0.65	0.68	0.62	60	0.24	[redacted]/162
ABBV-951	0.68	0.71	0.65	60	0.24	[redacted]/183
ABBV-951	0.75	0.77	0.7	60	0.24	[redacted]/246
ABBV-951	0.77	0.8	0.73	60	0.3	[redacted]/274
ABBV-951	0.79	0.82	0.73	60	0.24	[redacted]/288

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1090.06		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2253.04		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		40.98	SC / ONCE	[redacted] / 3	
ABBV-951	2130.96		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		40.98	SC / ONCE	[redacted] / 4	
ABBV-951	2155.71		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		81.96	SC / ONCE	[redacted] / 5	
ABBV-951	2239.38		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		122.94	SC / ONCE	[redacted] / 6	
ABBV-951	2250.82		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		81.96	SC / ONCE	[redacted] / 7	
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2214.45		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		122.94	SC / ONCE	[redacted] / 13	
ABBV-951	2240.06		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		163.92	SC / ONCE	[redacted] / 14	
ABBV-951	2249.28		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		122.94	SC / ONCE	[redacted] / 19	
ABBV-951	2183.20		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		81.96	SC / ONCE	[redacted] / 20	

ABBV-951	2177.23		SC / CONTINUOUS	[redacted]20 / 20	[redacted]20 / 20
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 21	[redacted]20 / 21
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 22	[redacted]20 / 22
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 23	[redacted]20 / 23
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 24	[redacted]20 / 24
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 25	[redacted]20 / 25
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20 / 26	[redacted]20 / 26
ABBV-951		256.12	SC / ONCE	[redacted]20 / 27	
ABBV-951	2166.47		SC / CONTINUOUS	[redacted]20 / 27	[redacted]20 / 27
ABBV-951		153.67	SC / ONCE	[redacted]20 / 28	
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20 / 28	[redacted]20 / 28
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 29	[redacted]20 / 29
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 30	[redacted]20 / 30
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 31	[redacted]20 / 31
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 32	[redacted]20 / 32
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 33	[redacted]20 / 33
ABBV-951		102.45	SC / ONCE	[redacted]20 / 34	
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20 / 34	[redacted]20 / 34
ABBV-951		51.22	SC / ONCE	[redacted]20 / 35	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20 / 35	[redacted]20 / 35
ABBV-951	2049		SC / CONTINUOUS	[redacted]20 / 36	[redacted]20 / 36
ABBV-951	2049		SC / CONTINUOUS	[redacted]20 / 37	[redacted]20 / 37
ABBV-951	2049		SC / CONTINUOUS	[redacted]20 / 38	[redacted]20 / 38
ABBV-951	2049		SC / CONTINUOUS	[redacted]20 / 39	[redacted]20 / 39
ABBV-951	2049		SC / CONTINUOUS	[redacted]20 / 40	[redacted]20 / 40
ABBV-951		51.22	SC / ONCE	[redacted]20 / 41	
ABBV-951	2019.63		SC / CONTINUOUS	[redacted]20 / 41	[redacted]20 / 41
ABBV-951		204.9	SC / ONCE	[redacted]20 / 42	
ABBV-951	2245.70		SC / CONTINUOUS	[redacted]20 / 42	[redacted]20 / 42
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 43	[redacted]20 / 43
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 44	[redacted]20 / 44
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 45	[redacted]20 / 45
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 46	[redacted]20 / 46
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 47	[redacted]20 / 47
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 48	[redacted]20 / 48
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 49	[redacted]20 / 49
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20 / 50	[redacted]20 / 50

ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 65	[redacted] / 65
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 66	[redacted] / 66
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 67	[redacted] / 67
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 68	[redacted] / 68
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 69	[redacted] / 69
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951	2335.86	SC / CONTINUOUS	[redacted] / 87	[redacted] / 87

ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	2335.86		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2329.20		SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		256.12	SC / ONCE	[redacted] / 96	
ABBV-951	2271.65		SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		153.67	SC / ONCE	[redacted] / 97	
ABBV-951	2285.14		SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
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ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 106	[redacted] / 106
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 108	[redacted] / 108
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ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 110	[redacted] / 110
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 111	[redacted] / 111
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ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 113	[redacted] / 113
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 114	[redacted] / 114
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 115	[redacted] / 115
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ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 117	[redacted] / 117
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 118	[redacted] / 118
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 119	[redacted] / 119
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ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 121	[redacted] / 121
ABBV-951	2212.92		SC / CONTINUOUS	[redacted] / 122	[redacted] / 122

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ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	2212.92	SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159

ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
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ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2868.6	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted]
LEVOTHYROXINE SODIUM	50 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	11 TIMES PER DAY	Y-M: 20[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRIMIDONE	125.000 mg	BID	Y-M: 20[redacted]-[redacted]
SELENIUM	300 ug	QD	Y-M: 20[redacted]-[redacted] / -252
LETROZOLE	2.5 mg	QD	Y-M: 20[redacted]-[redacted] / -188
CARBIDOPA;LEVODOPA	175.000 mg	QD	Y-M: 20[redacted]-[redacted] / -83
CARBIDOPA;LEVODOPA	300.000 mg	QD	Y-M: 20[redacted]-[redacted] / -83
CARBIDOPA;LEVODOPA	700.000 mg	QID	Y-M: 20[redacted]-[redacted] / -83
EXEMESTANE	25 mg	QD	Y-M: 20[redacted]-[redacted] / -68
CLOZAPINE	6.25 mg	TID	Y-M: 20[redacted]-[redacted] / -44

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LEVOTHYROXINE SODIUM	50 mg	QD	Y-M: 20[redacted]	ONGOING
SELENIUM	300 ug	QD	Y-M: 20[redacted] / -252	ONGOING
EXEMESTANE	25 mg	QD	Y-M: 20[redacted] / -68	ONGOING
CLOZAPINE	6.25 mg	TID	Y-M: 20[redacted] / -44	ONGOING
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875/125 mg	TID	Y-M: 20[redacted] / 228	Y-M: 20[redacted] / 232
AMPICILLIN SODIUM;SULBACTAM SODIUM	3 g	QD	Y-M: 20[redacted] / 228	Y-M: 20[redacted] / 232
POTASSIUM	40 mmol	BID	Y-M: 20[redacted] / 228	Y-M: 20[redacted] / 245
IBUPROFEN	600 mg	TID	Y-M: 20[redacted] / 228	Y-M: 20[redacted] / 251
PANTOPRAZOLE SODIUM SESQUIHYDRATE	20 mg	QD	Y-M: 20[redacted] / 228	Y-M: 20[redacted] / 251
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875/125 mg	BID	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 246

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYHTEMA ABDOMEN (INFUSION SITE)
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 12
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	ABSCESS RIGHT FOREARM
Preferred term	四肢膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 228
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	234
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	DIRTY SPLINTER WAS ACQURED DURING GARDENING. A SEVERE WOUND INFECTION OCCURRED, SURGERY WAS NECESSARY TO REMOVE THE DIRTY WOODEN PARTICLES.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に右前腕の膿瘍を発現した。

Event 2 の臨床経過：

関連する病歴はパーキンソン病であった。

投与 228 日目，被験者は右前腕の膿瘍を発現した。投与 234 日目，右前腕の膿瘍は消失した。

日時は不明であるが，被験者はガーデニング中に汚れた破片で怪我をした。その破片によって重度の創傷感染を発現した。投与 228 日目，被験者は親指の腫脹及び疼痛が増強し，緊急治療室に来院した。同日，被験者は右前腕の膿瘍のため入院した。投与 229 日目，膿瘍を除去し，投与 232 日目，被験者は退院した。

被験者にアモキシシリン／クラブラン酸，unacid，イブプロフェン，pantozol，及びカリウムが投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA EXTENDED RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Abscess limb (10050473) (Abscess limb (10050473)) [v.24.1] [10050473]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ABSCESS RIGHT FOREARM

- Investigator: Dirty splinter was acquired during gardening. A severe wound infection occurred and surgery was necessary to remove the dirty wooden particles.

- AbbVie: More likely a complication of reported contaminated splinter injury in an elderly patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 5[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
パーキンソン病	X			
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
NICOTIN ABUSUS	19[redacted]
ANKLE JOINT ARTHROSIS LEFT SIDE	19[redacted]
ANKLE JOINT FRACTURE LEFT SIDE	19[redacted]
PSORIASIS	19[redacted]
PRESBYOPY BOTH SIDES	20[redacted]
UTERUS MYOMA	20[redacted]
VULVA CARCINOMA	20[redacted]
LUMBALGIA	20[redacted]
LUMBAR VERTEBRA PAIN SYNDROME	20[redacted]
UNEQUAL LEG LENGTH	20[redacted]
SEPTUM INFARCTION	20[redacted]
STRUMA NODOSA RIGHT SIDE	20[redacted]
THYROID ADENOMA	20[redacted]
GONALGIA RIGHT SIDE	20[redacted]
MENISCUSGANGLIOM RIGHT KNEE	20[redacted]
CONSTIPATION	20[redacted]
SHOULDER LUXATION	20[redacted]
LOSS OF WEIGHT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED

PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
HYSTERECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	41	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.2	0.24	0.16	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.19	0.22	0.17	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.22	0.23	0.21	60	0.11	[redacted]20[redacted]/3
ABBV-951	0.22	0.23	0.21	60	0.11	[redacted]20[redacted]/9
ABBV-951	0.23	0.24	0.22	60	0.15	[redacted]20[redacted]/11
ABBV-951	0.24	0.26	0.23	60	0.11	[redacted]20[redacted]/15
ABBV-951	0.24	0.26	0.23	60	0.11	[redacted]20[redacted]/22

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	399.55		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6

ABBV-951	835.82		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	899.85		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	918.63		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	925.46		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	966.44		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	10 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -133
PRAMIPEXOLE	0.175 mg	10 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -133
APOMORPHINE	10.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -105

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]	ONGOING
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]-[redacted] / 18	ONGOING

Event #1: Serious Adverse Event

Event Description	WORSENING OF PD SYMPTOMS
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 44 (25 days after last treatment)
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	49 (30 DAYS AFTER LAST TREATMENT)
Duration of AE	6 DAYS

Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	ADJUSTMENT OF PD MEDICATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はドイツの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病の症状の悪化を発現した。

Event 1 の臨床経過：

関連する病歴は，乾癬，パーキンソン病，体重減少，レボドパ誘発性ジスキネジア，喫煙者（1 日 10 本を 41 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。投与 44 日目，被験者はパーキンソン病の症状が悪化した。投与 49 日目，パーキンソン病の症状の悪化は消失した。

投与の約 1 ヵ月後，すくみ足及び不安定な歩行が再発した。投与 44 日目，被験者は入院し，診断検査が実施された。投与 49 日目，被験者は退院した。

治験責任医師によると，投与 19 日目に被験者は自分でポンプ注入をすることが怖くなったため，ポンプ注入を中止した。数回のトレーニング及びパーキンソン病症状の悪化の後，被験者はポンプ注入の「毎日のトレーニング」を受けるために入院した。

The patient's past medications include:

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.24034006]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF PARKINSON’S DISEASE SYMPTOMS

- Investigator: Adjustment of PD medication.

- AbbVie: More likely related to preexisting Parkinson disease in an elderly subject, possibly exacerbated by earlier infusion pump discontinuation due to fear of self application.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位膿瘍				X
注入部位紅斑		X		X
注入部位皮膚剥脱				X
注入部位硬結		X		X
注入部位感染				X
注入部位結節		X		X
注入部位反応				X
注射部位浮腫				X
パーキンソン病	X			
体重減少				X
** Disc. due to adverse event				X
** Disc. due to lack of efficacy				X
** Disc. due to other: lack of effect and and infusion site reactions				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
HYDROCELE	19[redacted]
FALLING	19[redacted]
DIABETIS MELLITIS	20[redacted]
BURSITIS HIP	20[redacted]
INCREASED CHOLESTEROL	20[redacted]
LUXATION SHOULDER	20[redacted]
SEBORRHEIC ECZEMA WHOLE BODY	20[redacted]
BASALCCELCARCINOMA	20[redacted]
HALLUCINATIONS	20[redacted]

OLD HEART ATTACK	20[redacted]
CONSTIPATION	20[redacted]
DRY SKIN UPPERRIGHT OF BELLY	20[redacted]
VIT B12 DEFFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.33	0.4	0.27	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.33	0.4	0.27	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.4	0.48	0.33	60	0.15	[redacted]20[redacted]/9
ABBV-951	0.37	0.48	0.33	60	0.11	[redacted]20[redacted]/11
ABBV-951	0.38	0.48	0.33	60	0.24	[redacted]20[redacted]/16
ABBV-951	0.42	0.48	0.33	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.42	0.48	0.33	60	0.3	[redacted]20[redacted]/30
ABBV-951	0.47	0.48	0.33	60	0.3	[redacted]20[redacted]/38
ABBV-951	0.55	0.66	0.48	60	0.3	[redacted]20[redacted]/44

ABBV-951	0.55	0.66	0.33	60	0.3	[redacted]/51

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	591.64		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		18.78	SC / ONCE	[redacted] / 2	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		131.47	SC / ONCE	[redacted] / 3	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		93.91	SC / ONCE	[redacted] / 4	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		75.13	SC / ONCE	[redacted] / 5	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		150.26	SC / ONCE	[redacted] / 6	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		206.60	SC / ONCE	[redacted] / 7	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		131.47	SC / ONCE	[redacted] / 8	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		76.83	SC / ONCE	[redacted] / 9	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		25.61	SC / ONCE	[redacted] / 10	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		56.34	SC / ONCE	[redacted] / 11	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		93.91	SC / ONCE	[redacted] / 12	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		37.56	SC / ONCE	[redacted] / 13	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		56.34	SC / ONCE	[redacted] / 14	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		56.34	SC / ONCE	[redacted] / 15	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		40.98	SC / ONCE	[redacted] / 17	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17

ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37

ABBV-951		153.67	SC / ONCE	[redacted] / 38	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951		51.22	SC / ONCE	[redacted] / 39	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951		102.45	SC / ONCE	[redacted] / 40	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951		102.45	SC / ONCE	[redacted] / 41	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted] / 42	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		102.45	SC / ONCE	[redacted] / 43	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		153.67	SC / ONCE	[redacted] / 44	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951		51.22	SC / ONCE	[redacted] / 45	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951		51.22	SC / ONCE	[redacted] / 46	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951		51.22	SC / ONCE	[redacted] / 47	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951		51.22	SC / ONCE	[redacted] / 50	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		51.22	SC / ONCE	[redacted] / 51	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951		51.22	SC / ONCE	[redacted] / 52	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		102.45	SC / ONCE	[redacted] / 53	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		51.22	SC / ONCE	[redacted] / 55	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		51.22	SC / ONCE	[redacted] / 56	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58

ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 62	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 64	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
METFORMIN	850 mg	TID	Y-M: 20[redacted]
APOMORPHINE	1.000 mg	16 TIMES PER DAY	Y-M: 20[redacted]
CLOZAPINE	37 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted] / -265
MACROGOL	10 g	PRN	Y-M: 20[redacted] / -104
SIMVASTATIN	40 mg	QD	Y-M: 20[redacted] / -45
TRIAMCINOLONE ACETONIDE	1 mg	QD	Y-M: 20[redacted] / -45
BETAMETHASONE	1 mg	QD	Y-M: 20[redacted] / -42
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -42
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted] / -42
CYANOCOBALAMIN	DOSE VIT B12 INJ IS UNKNOWN OTHER: UNKNOWN	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -26
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT PARAFFIN	20 mg	BID	Y-M: 20[redacted] / -15

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
METFORMIN	850 mg	TID	Y-M: 20[redacted]	ONGOING
CLOZAPINE	37 mg	QD	Y-M: 20[redacted]	ONGOING
MACROGOL	10 g	PRN	Y-M: 20[redacted] / -104	ONGOING
TRIAMCINOLONE	1 mg	QD	Y-M: 20[redacted] / -45	ONGOING

ACETONIDE				
SIMVASTATIN	40 mg	QD	Y-M: 20[redacted] / -45	Y-M: 20[redacted] / 1
BETAMETHASONE	1 mg	QD	Y-M: 20[redacted] / -42	ONGOING
CYANOCOBALAMIN	DOSE VIT B12 INJ IS UNKNOWN OTHER: UNKNOWN	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -26	Y-M: 20[redacted] / 45
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT PARAFFIN	20 mg	BID	Y-M: 20[redacted] / -15	ONGOING
NITROFURANTOIN	100 mg	BID	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 10
HYDROCORTISONE	1 OTHER: APPLICATION	BID	Y-M: 20[redacted] / 22	ONGOING
FLUCLOXACILLIN SODIUM	500 mg	QID	Y-M: 20[redacted] / 22	Y-M: 20[redacted] / 42
CARBASALATE CALCIUM	100 mg	QD	Y-M: 20[redacted] / 31	ONGOING
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 65	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD EDEMA AROUND THE INJECTION SITE.
Preferred term	注射部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	46 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ASSESMENT, SLIGHT GLAZED APPEARANCE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	32 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Infusion Site Related Infections

Event Description	SKIN INFECTION AT INFUSION SITE.
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 19
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	29 DAYS
Severity	MODERATE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	ABCESS LEFT ON BELLY, AT INFUSION SITE.
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	26 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION ON RIGHT SIDE OF THE BELLY, AT INFUSION SITE
Preferred term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	47
Duration of AE	26 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	STRONG REACTION SPREADING BEYOND THE INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 30
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	47
Duration of AE	18 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	LEFT AND RIGHT OF THE BELLY; REDNESS OF THE SKIN 5/D AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 51
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	FLAKING 5/D AT INFUSION SITE
Preferred term	注入部位皮膚剥脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 51
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 51
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	UNRESTRICTED ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 61

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #11: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SCLEROSIS AT THE INFUSION SITE.
Preferred term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 61
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #12: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODE AT INFUSION SITE.
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 61
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #13: Serious Adverse Event

Event Description	WORSENING PARKINSONS DISEASE
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 65 (1 day after last treatment)
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	67 (3 DAYS AFTER LAST TREATMENT)

Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	CHANGE IN CON MEDS.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #14: Serious Adverse Event

Event Description	WORSENING PARKINSONS DISEASE
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 73 (9 days after last treatment)
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	74 (10 DAYS AFTER LAST TREATMENT)
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	CHANGE IN CON MEDS.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオランダの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，投与 65 日目及び投与 73 日目にパーキンソン病の悪化を発現した。

Event 13 及び 14 の臨床経過：

関連する病歴は，パーキンソン病，糖尿病，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 64 日目，効果不十分及び注入部位反応のため，被験者の希望によって治験薬の投与が中止された。

投与 65 日目，被験者はパーキンソン病の悪化を発現した。投与 67 日目，パーキンソン病の悪化は消失した。投与 73 日目，被験者はパーキンソン病の悪化を発現した。投与 74 日目，パーキンソン病の悪化は消失した。

投与 65 日目，被験者はパーキンソン病治療のためのデュオドーパ液剤の用量調整のため入院した。2 日目の投与 67 日目，最適用量に達し，被験者は退院した。入院中，異常は認められなかった。

投与 73 日目，被験者はパーキンソン病治療のための PEG J プローブを留置するために入院した。合併症もなく PEG J チューブが留置され，被験者は投与 74 日目に退院した。

被験者に CD/LD が投与された。

The patient's past medications include:

APOMORPHINE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SELEGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.23.1] [10034006]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.23.1] [10034006]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING PARKINSON'S DISEASE

- Investigator: Change in con meds.

- AbbVie: More likely related to a history of Parkinson's disease. At the time of the event patient had stopped study drug for 1 day and was admitted to transition to Duodopa.

Event of WORSENING PARKINSON'S DISEASE

- Investigator: Change in con meds.

- AbbVie: More likely related to a history of Parkinson's disease. At the time of the event patient had stopped study drug for 1 day and was admitted to place PEG J tube.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] BODY WEIGHT: 7[redacted] KG

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 7[redacted]. [redacted] kg. Weight at time of event 7[redacted] kg. Weight loss occurred over a period of 1 month. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss coincided with worsening PD symptoms. Subject experienced temporal events of dyskinesia worsening since treatment began and infection.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
過換気	X	X		
低カリウム血症	X	X		
注入部位浮腫				X
パーキンソン病	X			
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	WHITE

Medical History	Onset Year
POLLINOSIS	19[redacted]
CARPAL TUNNEL SYNDROME RIGHT.	20[redacted]
HYPERTENSION	20[redacted]
CONSTIPATION	20[redacted]
VIT B12 DECREASED	20[redacted]
PAIN RIGHT ARM	20[redacted]
PAIN RIGHT LEG	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
OPERATION KNEE	19[redacted]
CARPAL TUNNEL SYNDROME OPERATION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.73	0.8	0.53	60	0.11	[redacted]/1
ABBV-951	0.67	0.8	0.53	60	0.15	[redacted]/2
ABBV-951	0.67	0.8	0.53	60	0.11	[redacted]/9

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		25.61	SC / ONCE	[redacted] / 2	
ABBV-951	1338.50		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		25.61	SC / ONCE	[redacted] / 3	
ABBV-951	2551.17		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2734.21		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2734.21		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2699.89		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		25.61	SC / ONCE	[redacted] / 7	
ABBV-951	2722.77		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
TOLCAPONE	200.000 mg	BID	Y-M: 20[redacted] / -209
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	QD	Y-M: 20[redacted] / -132

CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -132
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	QD	Y-M: 20[redacted] / -132
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / -41
VALSARTAN	100 mg	OTHER: ONCE A DAY	Y-M: 20[redacted] / -19

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / -41	ONGOING
VALSARTAN	100 mg	OTHER: ONCE A DAY	Y-M: 20[redacted] / -19	Y-M: 20[redacted] / 6
POTASSIUM CHLORIDE	40 mmol	OTHER: 10 MMOL/HOUR	Y-M: 20[redacted] / 5	Y-M: 20[redacted] / 6
LOSARTAN	100 mg	OTHER: ONCE A DAY	Y-M: 20[redacted] / 6	ONGOING
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 11	ONGOING
OXAZEPAM	10 mg	PRN	Y-M: 20[redacted] / 14	ONGOING
FENTANYL CITRATE	100 ug	OTHER: ONCE	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 14
PARACETAMOL	UNKNOWN OTHER: UNKNOWN	OTHER: ONCE	Y-M: 20[redacted] / 14	Y-M: 20[redacted] / 14
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	25 mL	QD	Y-M: 20[redacted] / 36	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT INFUSION SITE.
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	HYPERVENTILATION
Preferred term	過換気
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	4[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 5): POTASSIUM: 2.8 [3.5 - 5.1] MMOL/L; [redacted]20[redacted] (RX DAY 6): NPTST213-PCO2: 5 [4.7 - 6.4] KPA; POTASSIUM: 3.5 [3.5 - 5.1] MMOL/L

Microbiology	

NOT REPORTED

AE Stopped Rx Day	45 (37 DAYS AFTER LAST TREATMENT)
Duration of AE	41 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	WORSENING PD
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	HYPOKALAMIA
Preferred term	低カリウム血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 5
Age at AE Onset	4[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 5): POTASSIUM: 2.8 [3.5 - 5.1] MMOL/L; [redacted]20[redacted] (RX DAY 6): NPTST213-PCO2: 5 [4.7 - 6.4] KPA; POTASSIUM: 3.5 [3.5 - 5.1] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	6
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	HYPERVENTILATION
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event

Event Description	PARKINSON DISEASE.
Preferred term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 23 (15 days after last treatment)
Age at AE Onset	4[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	DUE TO INITIATION OF A NEW DRUGTHERAPY, THE SUBJECT

	WAS ADMITTED.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオランダの 4[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，過換気及び低カリウム血症を発現した。

Event 2 及び 3 の臨床経過：

関連する病歴は，花粉症，パーキンソン病，高血圧，ビタミンB12減少，非喫煙者，及び非飲酒者であった。

投与 5 日目，被験者は過換気及び低カリウム血症を発現した。投与 6 日目低カリウム血症は消失した。投与 45 日目，過換気は消失した。

被験者はパーキンソン病治療のため，投与初日から治療ポンプを使用していた。翌日の来院時に被験者に問題はなかった。投与 3 日目から，被験者はパーキンソン病の悪化を訴えた。被験者は，ポンプが適切に作動していないか，投与されている薬剤量が少なすぎると信じていた。被験者はかなりのエネルギーを要したが，それでもスーパーマーケットに出かけた。被験者は衰弱し，非常に疲れたため椅子を出してもらうよう頼んだ。被験者は，自身の薬剤量が少なすぎることに気がついた。被験者はパーキンソン病の症状が増大したため，張り詰め，ストレスを感じ，不安を感じた。

被験者は胸部痛，息切れ，左右の手足にチクチクする感覚を認めた。救急車が呼ばれ，被験者は救急診療部に移送された。血液検査が実施された。カリウム濃度は 2.8 mmol/L であり，カリウムが静脈内投与された。投与 5 日目，被験者は過換気を長時間訴え，治療後も改善しなかったため，入院した。入院中，呼吸訓練が実施された。投与 6 日目，被験者は退院した。

治験薬投与は中止された。

治験薬の注入部位における皮内の浮腫は非重篤となった。

被験者にロサルタン，塩化カリウム，PERFALAN，フェンタニル，及びオキサゼパムが投与された。

Causality for ABBV-951 (Open Label)

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1) Hyperventilation (10020910) (Hyperventilation (10020910)) [v.23.1] [10020910]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

2) Hypokalemia (10021018) (Hypokalaemia (10021015)) [v.23.1] [10021018]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HYPERVENTILATION

- Investigator: Worsening PD

- AbbVie: More likely related to a physiologic reaction to psychological stressors in a patient with Parkinson's disease.

Event of HYPOKALEMIA

- Investigator: Hyperventilation.

- AbbVie: More likely related to concurrent event of Hyperventilation in a patient with Parkinson's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **BLOOD PRESSURE:** 194/103 MMHG

[redacted] 20[redacted] **CO2:** 17 no units

[redacted] 20[redacted] **CO2:** 5 no unit (normal 4.7 to 6.4)

[redacted] 20[redacted] **ECG:** Sinus rhythm, intermediate heart axis, peak T waves, normal conduction times, no ST-depression or ST-elevations.

[redacted] 20[redacted] **PCO2:** 2.9 KPA (normal 4.7 to 6.4)

[redacted] 20[redacted] **PH:** 7.63 no unit (normal 7.35 to 7.45)

[redacted] 20[redacted] **POTASSIUM:** 2.0 MMOL/L (normal 3.5 to 5.1)

[redacted] 20[redacted] **POTASSIUM:** 2.8 MMOL/L (normal 3.5 to 5.1)

[redacted] 20[redacted] **POTASSIUM:** 3.5 MMOL/L (normal 3.5 to 5.1)
Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオランダの 4[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 23 日目，被験者はパーキンソン病を発現した。

投与 23 日目，被験者は新たな薬剤治療を開始するため入院した。薬剤を正確な用量に調整した同日に，被験者は退院し帰宅した。

The patient's past medications include:

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease (10061536) (Parkinson's disease (10061536)) [v.23.1] [10061536]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PARKINSON'S DISEASE

- Investigator: Due to initiation of a new drug therapy, the subject was admitted.

- AbbVie: More likely related to a history of Parkinson's disease. At the time of event patient had been off study drug for over 6 days and the patient was hospitalized for the titration of a different Parkinson's disease treatment.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想				X
幻聴				X
混合性幻覚				X
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位硬結				X
注入部位結節				X
注入部位浮腫				X
注入部位反応				X
妄想症				X
精神病性障害	X			X
精神病症状				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ALLERGY FOR WASP STING. HAD ONCE AN ANAPHYLACTIC SHOCK AFTER A WASP STING	NOT REPORTED
EMOTION REGULATION DISORDER	NOT REPORTED
OBSESSIVE THOUGHTS	NOT REPORTED
PARANOID THOUGHTS	NOT REPORTED
HYPERCHOLESTEROLEMIA	20[redacted]
ANGINA PECTORIS	20[redacted]
TRANSIENT ISCHEMIC ATTACK	20[redacted]
IMPINGEMENT SYNDROME	20[redacted]
DEPRESSION AND ANXIETY DISORDER	20[redacted]
OBSTIPATION	20[redacted]
PERSISTENT PAIN AFTER HALLUX VALGUS OSTEOTOMY LEFT SIDE	20[redacted]
DELAYED GASTRIC EMPTYING	20[redacted]

NEGATIVE SELF-IMAGE	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
URINARY TRACT INFECTION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RIGHT SHOULDER SURGERY	20[redacted]
LEFT SHOULDER SURGERY	20[redacted]
CHEVRON OSTEOTOMY HALLUX VALGUS LEFT SIDE	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.73	0	0.59	60	0.19	[redacted]20[redacted]/1
ABBV-951	0.77	0	0.62	60	0.19	[redacted]20[redacted]/2
ABBV-951	0.6	0.62	0.5	60	0.19	[redacted]20[redacted]/6
ABBV-951	0.62	0.65	0.5	60	0.19	[redacted]20[redacted]/13
ABBV-951	0.62	0.65	0.5	60	0.19	[redacted]20[redacted]/21
ABBV-951	0.63	0.65	0.53	60	0.19	[redacted]20[redacted]/28
ABBV-951	0.6	0.62	0.53	60	0.19	[redacted]20[redacted]/42
ABBV-951	0.55	0.58	0.5	60	0.15	[redacted]20[redacted]/48

ABBV-951	0.45	0.48	0.4	60	0.15	[redacted]/62
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/70
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/76
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/91
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/105
ABBV-951	0.37	0.39	0.31	60	0.15	[redacted]/146
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/182
ABBV-951	0.35	0.37	0.3	60	0.15	[redacted]/233
ABBV-951	0.33	0.35	0.3	60	0.15	[redacted]/273
ABBV-951	0.31	0.33	0.28	60	0.15	[redacted]/329
ABBV-951	0.31	0.33	0.28	60	0.15	[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		32.44	SC / ONCE	[redacted] / 1	
ABBV-951	1343.97		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2792.95		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2691.02		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2523.85		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		32.44	SC / ONCE	[redacted] / 5	
ABBV-951	2413.72		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2054.12		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		64.88	SC / ONCE	[redacted] / 11	
ABBV-951	2253.55		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		64.88	SC / ONCE	[redacted] / 12	
ABBV-951	2296.92		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		32.44	SC / ONCE	[redacted] / 13	
ABBV-951	2392.20		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17

ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	2483.04		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	2297.09		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	2359.76		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2540.76		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2540.76		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2540.76		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
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ABBV-951	1434.3	SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	1434.3	SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
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ABBV-951	1352.34	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1352.34	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
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ABBV-951	1352.34	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
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ABBV-951	1249.20	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	1238.62	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]-[redacted]
ISOSORBIDE MONONITRATE	30 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]

TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	2.000 mg	QD	Y-M: 20[redacted]
TRAMADOL	50 mg	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	QID	Y-M: 20[redacted] / -352
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -201
ENTACAPONE	200.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -201
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -109
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -79
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	300.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -79
NITROFURANTOIN	100 mg	BID	Y-M: 20[redacted] / -31

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]	ONGOING
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]	ONGOING
ISOSORBIDE MONONITRATE	30 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 187
TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]	ONGOING
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]	ONGOING
MACROGOL;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 166
TRAMADOL	50 mg	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 63
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	ONGOING
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 1
NITROFURANTOIN	100 mg	BID	Y-M: 20[redacted] / -31	Y-M: 20[redacted] / -26
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 48	Y-M: 20[redacted] / 54

FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 51
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 51	Y-M: 20[redacted] / 61
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 54	Y-M: 20[redacted] / 63
CLOZAPINE	6.25 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 62
CLOZAPINE	12.5 mg	QD	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 66
PYRIDOXINE	50 mg	QD	Y-M: 20[redacted] / 63	ONGOING
OXYCODONE HYDROCHLORIDE	5 mg	PRN	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 121
CLOZAPINE	18.75 mg	QD	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 69
LORAZEPAM	2 mg	PRN	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 86
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 69	Y-M: 20[redacted] / 77
CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 77	Y-M: 20[redacted] / 84
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 84	Y-M: 20[redacted] / 100
CLOZAPINE	18.75 mg	QD	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 114
HYDROCORTISONE ACETATE	10 OTHER: MG/G	QD	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 133
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 114	Y-M: 20[redacted] / 167
FLUTICASONE	0.5 OTHER: MG/G	QD	Y-M: 20[redacted] / 133	ONGOING
CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 167	Y-M: 20[redacted] / 175
CLOZAPINE	37.5 mg	QD	Y-M: 20[redacted] / 175	Y-M: 20[redacted] / 196
ISOSORBIDE MONONITRATE	60 mg	QD	Y-M: 20[redacted] / 187	ONGOING
CLOZAPINE	43.75 mg	QD	Y-M: 20[redacted] / 196	Y-M: 20[redacted] / 205
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 205	Y-M: 20[redacted] / 212
GLYCERYL TRINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 212	ONGOING
METFORMIN	500 mg	QD	Y-M: 20[redacted] / 212	ONGOING
CLOZAPINE	56.25 mg	QD	Y-M: 20[redacted] / 212	Y-M: 20[redacted] / 219
CLOZAPINE	62.5 mg	QD	Y-M: 20[redacted] / 219	Y-M: 20[redacted] / 226
CLOZAPINE	68.75 mg	QD	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 233
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 240
CLOZAPINE	37.5 mg	QD	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 246
CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 247	Y-M: 20[redacted] / 253
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 254	Y-M: 20[redacted] / 358
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 329	ONGOING
CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 359	Y-M: 20[redacted] / 360
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 361	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	3
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MIMIMAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 12
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	4 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	9 SUBCUTANEUOUS NODULI AT INFUSION SITE AT RIGHT UPPER QUADRANT OF ABDOMEN
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	258
Duration of AE	245 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	5 SUBCUTANEUOUS NODULI AT INFUSION SITE AT RIGHT LOWER QUADRANT OF ABDOMEN
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	258
Duration of AE	245 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	8 SUBCUTANEUOUS NODULI AT INFUSION SITE AT LEFT UPPER QUADRANT OF ABDOMEN
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	258
Duration of AE	245 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	4 SUBCUTANEUOUS NODULI AT INFUSION SITE AT LEFT LOWER QUADRANT OF ABDOMEN
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	258
Duration of AE	245 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE. LOCATION ON ABDOMEN NOT KNOWN ANYMORE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 21
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	23

Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL AND AUDITORY HALLUCINATIONS
Preferred term	混合性幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 33
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	86
Duration of AE	54 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害

AE Onset Date / Rx Day	[redacted]20[redacted] / 33
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	62
Duration of AE	30 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 46
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 51): HEMATOCRIT: 0.32 [0.35 - 0.46] FRACTION OF 1; HEMOGLOBIN: 108 [118 - 156] G/L; LEUKOCYTES: 9.1 [3.7 - 10.9] 10^9/L; LYMPHOCYTES: 0.96 [1 - 3.6] 10^9/L; NPTST054-C REACTIVE PROTEINE: 79 [0 - 10] MG/L; NEUTROPHILS: 7.29 [1.63 - 7.17] 10^9/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	62
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 48
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	51
Duration of AE	4 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 63
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 64): ALANINE AMINOTRANSFERASE: 5 [0 - 34] U/L; CREATININE: 48 [44 - 80] UMOL/L; GLUCOSE: 5.5 [4 - 6.4] MMOL/L; HEMOGLOBIN: 118 [118 - 156] G/L; LEUKOCYTES: 6 [3.7 - 10.9] 10^9/L; NPTST304-TSH: 1.91 [0.35 - 3.5] MU/L; POTASSIUM: 4.4 [3.5 - 5] MMOL/L; SODIUM: 143 [135 - 145] MMOL/L

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	86
Duration of AE	24 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #13: Event of Interest - Hallucinations/Psychosis

Event Description	ACOUSTIC HALLUCINATIONS
Preferred term	幻聴
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Event of Interest - Hallucinations/Psychosis

Event Description	PARANOID THOUGHTS
Preferred term	妄想症
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	121
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE AT RIGHT UPPER QUADRANT OF ABDOMEN
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 128
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	134
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE AT LEFT LOWER QUADRANT OF ABDOMEN
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 128
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	134
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #17: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE AT LEFT UPPER QUADRANT OF ABDOMEN
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 144
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	158
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #18: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS "HARDNESS" OF 4 CM AT INFUSION SITE AT LEFT UPPER QUADRANT
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 144
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	258
Duration of AE	115 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #19: Event of Interest - Hallucinations/Psychosis

Event Description	PARANOID THOUGHTS
Preferred term	妄想症
AE Onset Date / Rx Day	[redacted]20[redacted] / 159
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #20: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 181
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	184
Duration of AE	4 DAYS
Severity	MILD

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #21: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING DELUSIONS
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 205
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	232
Duration of AE	28 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #22: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA AT INFUSION SITE AT RIGHT UPPER QUADRANTR
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 262

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	272
Duration of AE	11 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #23: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF PSCYHOTIC SYMPTOMS
Preferred term	精神病症状
AE Onset Date / Rx Day	[redacted]20[redacted] / 322
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #24: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE AT RIGHT UPPER QUADRANT
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 343
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #25: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEUOUS HARDENING AT INFUSION SITE AT RIGHT UPPER QUADRANT
Preferred term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 343
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING

Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオランダの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位蜂巣炎を発現した。

Event 10 の臨床経過：

関連する病歴は，高コレステロール血症，パーキンソン病，起立性低血圧，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 46 日目，被験者は注入部位蜂巣炎を発現した。投与 62 日目，注入部位蜂巣炎は消失した。

投与 46 日目，被験者は皮膚の紅斑及び皮下の肥厚を伴う異常を認めた。被験者は内科医にかかり，抗生物質（フルクロキサシリン）の投与を開始した。被験者は 37.7℃の発熱のため緊急治療室に来院した。境界が極めて明瞭で腫脹した 5 × 3 cm の紅斑が被験者の右上腹部に認められた。その他の部位でも、2 × 3 cm の紅斑及び腫脹が認められた。臨床検査が実施された。抗生物質による治療がクリンダマイシンに変更された。

被験者にクリンダマイシン及びフルクロキサシリンが投与された。

The patient's past medications include:

SINEMET CR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET IR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.22.1] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Causal relationship

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY TEMPERATURE:** 37.7 Degrees C

[redacted] **20[redacted] CRP:** 79 MG/L (normal 0 to 10)

[redacted] **20[redacted] HEMATOCRIT:** 0.32 L/L (normal 0.35 to 0.46)

[redacted] **20[redacted] HEMOGLOBIN:** 6.7 MMOL/L (normal 7.3 to 9.7)

[redacted] **20[redacted] LEUCOCYTES:** 9.1 X10**9/L

[redacted] **20 LYMPHOCYTES ABS:** 0.96 X10**9/L (normal 1.00 to 3.6)

[redacted] **20[redacted] NEUTROPHILS ABS:** 7.29 X10**9/L (normal 1.63 to 7.7)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 9.1 X10**9/L (normal 3.7 to 10.9)
Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオランダの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病性障害を発現した。

Event 12 の臨床経過：

関連する病歴は，パーキンソン病，うつ病及び不安障害，自己イメージの否定，強迫観念，情動調節障害，偏執的思考，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 63 日目，被験者は精神病性障害を発現した。投与 86 日目，精神病性障害は消失した。

被験者には，過去にうつ病エピソード及び 20[redacted] 年に心的外傷の病歴があった。投与から約 1 ヵ月目の終わりから，被験者は妄想を発現しており，クエチアピン及びクロザピンを開始し，ポンプの注入速度を低下させたにもかかわらず，徐々に悪化した。

本事象の発現前の投与 33 日目から投与 63 日目まで，被験者は非重篤な精神病性障害を発現した。

投与 63 日目，被験者は精神病性障害のため入院した。入院中，クロザピンを 25 mg に増量し，その後投与 77 日目に 31.25 mg に増量した。被験者は妄想症，カプグラ妄想，誇大妄想，及び幻聴を発現した。入院最終日に被験者の精神病性障害が完全寛解に達したときに，クロザピンの投与量を再度 25 mg に減量した。投与 86 日目，被験者は完全寛解であり，退院した。

被験者にクロザピン，ロラゼパム，及びクエチアピンが投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA (SINEMET CR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA (SINEMET IR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR DISPERSIBLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR HBS for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Psychosis (10037234) (Psychotic disorder (10061920)) [v.23.0] [10037234]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOSIS

- Investigator: Not Applicable

- AbbVie: More likely related to a history of Parkinson's disease, depression disorder, anxiety disorder, negative self-image and emotion regulation disorder, obsessive thoughts and paranoid thoughts and advanced age

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** <5 U/L

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
錯乱状態		X		
転倒				X
幻覚		X		X
注入部位蜂巣炎	X			X
注入部位結節				X
** Disc. due to adverse event				X
** Disc. due to lack of efficacy				X
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
CHRONIC PHARYNGEAL DRYNESS,	NOT REPORTED
MENOPAUSE	19[redacted]
DIABETES MELLITUS II	20[redacted]
DEPRESSIVE SYMTPMS RELATED TO PARKINSON'S DISEASE	20[redacted]
HIP FRACTURE	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
SLEEP REM DISORDER RELATED TO PAKINSON'S DISEASE	20[redacted]
CARPAL TUNNEL SYNDROME	20[redacted]
URINE INCONTINENCE	20[redacted]
MILD OBSTRUCTIVE SLEEP APNEA HYPOPNEA SYNDROME	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

ONSET OF MOTOR FLUCTUATION 20[redacted]

Prior Procedures	Procedure Year
ROTATOR CUFF REPAIR	20[redacted]
RIGHT HIP REPLACEMENT	20[redacted]
LUMBAR SPINAL ARTHRODESIS	20[redacted]
REPLACEMENT HIP PROTHESIS	20[redacted]
BILATERAL CATARACT SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.53	0.64	0.42	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.47	0.56	0.37	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.6	0.72	0.45	60	0.15	[redacted]20[redacted]/9
ABBV-951	0.75	0.9	0.6	60	0.19	[redacted]20[redacted]/10
ABBV-951	0.9	0.93	0.87	60	0.24	[redacted]20[redacted]/16
ABBV-951	0.8	0.96	0.64	60	0.24	[redacted]20[redacted]/23
ABBV-951	0.86	0.89	0.83	60	0.3	[redacted]20[redacted]/26
ABBV-951	0.83	0.86	0.8	60	0.3	[redacted]20[redacted]/28
ABBV-951	0.86	0.89	0.83	60	0.3	[redacted]20[redacted]/39
ABBV-951	0.83	0.86	0.8	60	0.3	[redacted]20[redacted]/77
ABBV-951	0.83	0.86	0.8	60	0.3	[redacted]20[redacted]/94
ABBV-951	0.83	0.86	0.8	75	0.3	[redacted]20[redacted]/120
ABBV-951	0.83	0.86	0.8	60	0.3	[redacted]20[redacted]/184
ABBV-951	0.7	0.75	0.58	90	0.3	[redacted]20[redacted]/234
ABBV-951	0.63	0.7	0.58	90	0.3	[redacted]20[redacted]/248

ABBV-951	0.6	0.63	0.58	90	0.3	[redacted]/276
ABBV-951	0.53	0.58	0.42	60	0.3	[redacted]/310

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		18.78	SC / ONCE	[redacted] / 8	
ABBV-951	1482.11		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		102.45	SC / ONCE	[redacted] / 9	
ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2294.88		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		32.44	SC / ONCE	[redacted] / 14	
ABBV-951	3072.81		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		64.88	SC / ONCE	[redacted] / 15	
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	3688.2		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	3605.72		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	3401.34		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34

ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70

ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 92	
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 93	
ABBV-951	3401.34		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]
METFORMIN	850 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	2.100 mg	QD	Y-M: 20[redacted]
SIMVASTATIN	10 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA	200.000 mg	TID	Y-M: 20[redacted]

MONOHYDRATE;ENTACAPONE;LEVODOPA			
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
CLONAZEPAM	2 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
GLICLAZIDE	60 MG mg	BID	Y-M: 20[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	4.500 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted] / -267
VORTIOXETINE	10 mg	QD	Y-M: 20[redacted] / -167
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -131
ROSUVASTATIN CALCIUM	10 mg	QD	Y-M: 20[redacted] / -68
APOMORPHINE HYDROCHLORIDE	3.000 mg	QD	Y-M: 20[redacted] / -33

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]	ONGOING
METFORMIN	850 mg	QD	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	2 mg	QD	Y-M: 20[redacted]	ONGOING
GLICLAZIDE	60 MG mg	BID	Y-M: 20[redacted]	ONGOING
VORTIOXETINE	10 mg	QD	Y-M: 20[redacted] / -167	ONGOING
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -131	ONGOING
ROSUVASTATIN CALCIUM	10 mg	QD	Y-M: 20[redacted] / -68	ONGOING
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1 g	TID	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 23
AMOXICILLIN;CLAVULANIC ACID	875/125 mg	TID	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 32
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 24	ONGOING
HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;T	1 OTHER: TABLET	QD	Y-M: 20[redacted] / 24	ONGOING

HIAMINE HYDROCHLORIDE				
TOCOPHERYL ACETATE	400 mg	QD	Y-M: 20[redacted] / 65	ONGOING
METOCLOPRAMIDE	10 mg	OTHER: SINGLE DOSE	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 86
SULPIRIDE	100 OTHER: MG/ML	OTHER: SINGLE DOSE	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 86
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 94
BETAHISTINE HYDROCHLORIDE	16 mg	TID	Y-M: 20[redacted] / 88	Y-M: 20[redacted] / 89
ALENDRONATE SODIUM;COLECALCIFEROL	70 MG/756000 UI mg	OTHER: 1 PILL EVERY 7 DAYS	Y-M: 20[redacted] / 108	ONGOING
CALCIUM CARBONATE;COLECALCIFEROL	1000 /880 OTHER: MG/UI	QD	Y-M: 20[redacted] / 108	ONGOING
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 157	Y-M: 20[redacted] / 160
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted] / 255	Y-M: 20[redacted] / 283
OLANZAPINE	5 mg	QD	Y-M: 20[redacted] / 283	Y-M: 20[redacted] / 301
OLANZAPINE	7.5 mg	QD	Y-M: 20[redacted] / 301	Y-M: 20[redacted] / 306
OLANZAPINE	10 mg	QD	Y-M: 20[redacted] / 306	ONGOING

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	CASUAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 12
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	12
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 19
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): NPTST262-PROTEIN C REACTIVE: 105 [NOT REPORTED - 5] MG/L; [redacted]20[redacted] (RX DAY 24): NPTST055-C- REACTIVE PROTEIN: 97 [NOT REPORTED - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 23): BLOOD BLOOD CULTURE: NEGATIVE

AE Stopped Rx Day	120
Duration of AE	102 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUTINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	23
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS NODULES.AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 120
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 180
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	300
Duration of AE	121 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #6: AE Leading to Discontinuation of Study Drug

Event Description	SEVERE　CONFUSIONAL STATE
Preferred term	錯乱状態
AE Onset Date / Rx Day	[redacted]20[redacted] / 300
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	312 (3 DAYS AFTER LAST TREATMENT)
Duration of AE	13 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位蜂巣炎を発現した。

Event 2 の臨床経過：

関連する病歴は，糖尿病，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 18 日目，被験者は注入部位蜂巣炎を発現した。投与 120 日目，注入部位蜂巣炎は消失した。

投与 23 日目，被験者は腹部の注入部位において増強する疼痛を伴う皮下の結節及び紅斑のため入院した。注入部位を評価したところ，注入部位を超えて拡大する強い反応が認められた。該当部位は赤らみ，紅斑が広がっていた。挿入部位を変更した。被験者は治療を受け，血液培養が実施された。投与 24 日目，被験者は退院した。抗生物質の治療によって被験者の症状は改善し，紅斑は消失した。しかし，皮下の結節は残存しており，若干の痛みを伴った。退院後，膿瘍を除去するために腹部超音波が実施された。

被験者に AUGMENTINE が投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.22.1] [10065455]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** Not an abscess. Found to be subcutaneous tissue changes related to cellulitis process.

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] C REACTIVE PROTEIN:** 105 MG/L (normal <5)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
気管支拡張症	X			
悪液質				X
挫傷				X
食欲減退				X
転倒				X
頭部損傷				X
注入部位結節				X
体重減少				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
ASTHMA	19[redacted]
BRONCHIECTASIS	20[redacted]
STERNAL FRACTURE	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
OPHTHALMOPLEGIC MIGRAINE	20[redacted]
HERPES ZOSTER	20[redacted]
ACHILLES TENDINITIS APPEARING AFTER TAKING QUINOLONES	20[redacted]
CHRONIC BRONCHIAL INFECTION BY PSEUDOMONE	20[redacted]
CHRONIC CONSTIPATION	20[redacted]
WEIGHT LOSS	20[redacted]
KYPHOSIS	20[redacted]
POSITIVE FECAL OCCULT BLOOD TEST WITH NORMAL COLONOSCOPY	20[redacted]
POLYMYALGIA RHEUMATICA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE	20[redacted]

PARKINSON'S DISEASE DIAGNOSIS 20[redacted]

Prior Procedures	Procedure Year
SURGERY	20[redacted]
HERNIOPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.23	0.28	0.18	60	0.11	[redacted]20[redacted]/1
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/2
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/7
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/14
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/21
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/26
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/42
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/91
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/181
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/217
ABBV-951	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/280
ABBV-951	0.25	0	0	60	0.15	[redacted]20[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1145.39		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1024.5		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6

ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	307.35	SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	721.41	SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	298.81	SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	670.19	SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	396.99	SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	704.34	SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 64	[redacted] / 64
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 65	[redacted] / 65

ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102

ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248

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ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 250	[redacted] / 250
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 251	[redacted] / 251
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 252	[redacted] / 252
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 253	[redacted] / 253
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 254	[redacted] / 254
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 255	[redacted] / 255
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 275	[redacted] / 275
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ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 277	[redacted] / 277
ABBV-951	414.06	SC / CONTINUOUS	[redacted] / 278	[redacted] / 278
ABBV-951	695.80	SC / CONTINUOUS	[redacted] / 279	[redacted] / 279
ABBV-951	286.00	SC / CONTINUOUS	[redacted] / 280	[redacted] / 280
ABBV-951	665.92	SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	1024.5	SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	439.68	SC / CONTINUOUS	[redacted] / 365	[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PRAMIPEXOLE	0.260 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	2.100 mg	QD	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
PRAMIPEXOLE	2.100 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	BID	Y-M: 20[redacted]
FLUTICASONE	184/22 ug	QD	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted] / -350
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted] / -349
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted] / -349
COLISTIMETHATE SODIUM	1 MIU	BID	Y-M: 20[redacted] / -267
CALCIUM CARBONATE;COLECALCIFEROL	1500/400 IU	QD	Y-M: 20[redacted] / -118
PREDNISONE	5 mg	QD	Y-M: 20[redacted] / -118
RISEDRONATE SODIUM	75 mg	OTHER: 4 PILLS MONTHLY	Y-M: 20[redacted] / -118
CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	0.5/250/250 mg	QD	Y-M: 20[redacted] / -110
CYANOCOBALAMIN	1000 ug	OTHER: MONTHLY	Y-M: 20[redacted] / -15
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -15

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
FLUTICASONE	184/22 ug	QD	Y-M: 20[redacted]	ONGOING
COLISTIMETHATE SODIUM	1 MIU	BID	Y-M: 20[redacted] / -267	Y-M: 20[redacted] / 217
CALCIUM CARBONATE;COLECALCIFEROL	1500/400 IU	QD	Y-M: 20[redacted] / -118	Y-M: 20[redacted] / 365
PREDNISONE	5 mg	QD	Y-M: 20[redacted] / -118	Y-M: 20[redacted] / 365
RISEDRONATE SODIUM	75 mg	OTHER: 4 PILLS MONTHLY	Y-M: 20[redacted] / -118	Y-M: 20[redacted] / 365
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / 15
CYANOCOBALAMIN	1000 ug	OTHER: MONTHLY	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / 138
INFLUENZA VACCINE		OTHER: ONCE	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 21
ITRACONAZOLE	100 mg	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 31
AZITHROMYCIN	250 mg	OTHER: EVERY 48H	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 217
MUPIROCIN	2%	BID	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 42
BETAMETHASONE VALERATE;FUSIDIC ACID	1 OTHER: MG/G	BID	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 52
PYRIDOXINE HYDROCHLORIDE	300 mg	OTHER: EVERY 48H	Y-M: 20[redacted] / 55	ONGOING
BRIVUDINE	125 mg	QD	Y-M: 20[redacted] / 149	Y-M: 20[redacted] / 156
CIPROFLOXACIN	50 mg	BID	Y-M: 20[redacted] / 158	Y-M: 20[redacted] / 178
CYANOCOBALAMIN; PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	0.5/250/250 mg	BID	Y-M: 20[redacted] / 217	ONGOING
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 217	ONGOING
BEMIPARIN SODIUM	3500 IU	QD	Y-M: 20[redacted] / 218	Y-M: 20[redacted] / 232
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 218	Y-M: 20[redacted] / 232
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	2/250 OTHER: G/MG	TID	Y-M: 20[redacted] / 218	Y-M: 20[redacted] / 232
ALPRAZOLAM	1 mg	QD	Y-M: 20[redacted] / 221	Y-M: 20[redacted] / 232
ITRACONAZOLE	100 mg	QD	Y-M: 20[redacted] / 229	Y-M: 20[redacted] / 232
COLISTIMETHATE SODIUM	2 MIU	BID	Y-M: 20[redacted] / 233	ONGOING

IPRATROPIUM BROMIDE	20 ug	BID	Y-M: 20[redacted]-[redacted] / 233	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ONE INFLAMMATORY NODULE IN ABDOMEN (LEFT PERIUMBILICAL SITE) WHERE INFUSION WAS ADMINISTERED
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 21
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	91
Duration of AE	71 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Falls And Associated Injuries

Event Description	BRUISED WOUND ON THE FOREHEAD
Preferred term	挫傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	24
Duration of AE	2 DAYS

Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	23
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Falls And Associated Injuries

Event Description	HEAD TRAUMA
Preferred term	頭部損傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 23

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	24
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ONE MORE INFLAMMATORY NODULE IN ABDOMEN IN RIGHT PERIUMBILICAL SITE (WHERE INFUSION WAS ADMINISTERED)
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 26
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	42
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ONE INFLAMMATORY NODULE IN ABDOMEN (SUPRAUMBILICAL SITE) WHERE INFUSION WAS ADMINISTERED
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 37
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	91
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SEVERAL NODULES IN ABDOMEN (PERIUMBILICAL SITE) WHERE INFUSION WAS ADMINISTERED
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 91
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Weight Loss

Event Description	CONSTITUTIONAL SYNDROME
Preferred term	悪液質
AE Onset Date / Rx Day	[redacted]20[redacted] / 203
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	234
Duration of AE	32 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Weight Loss

Event Description	ANOREXIA

Preferred term	食欲減退
AE Onset Date / Rx Day	[redacted]20[redacted] / 203
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	234
Duration of AE	32 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 203
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	234
Duration of AE	32 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Serious Adverse Event

Event Description	BRONCHIECTASIS WORSENING
Preferred term	気管支拡張症
AE Onset Date / Rx Day	[redacted]20[redacted] / 217
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 217): LEUKOCYTES: 16.1 [3.5 - 10.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 12.5 [20 - 44] %; NPTST053-C REACTIVE PROTEIN: 46.5 [0 - 5] MG/L; NPTST164-LACTATO DESHIDROGENASA: 334 [0 - 248] U/L; NPTST213-PCO2: 31.2 [35 - 48] MMHG; NPTST220-PCR COVID-19: NEGATIVE [NOT REPORTED - NOT REPORTED] POSITIVE/NEGATIVE; NPTST247-PO2: 77.4 [83 - 108] MMHG; NEUTROPHILS: 13.15 [1.5 - 7.7] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 217): BLOOD BLOOD CULTURE: NEGATIVE-NO FINDINGS; OTHER NASOPHARYNGEAL PCR COVID 19: NEGATIVE; URINE URINE CULTURE: NEGATIVE-NO FINDINGS; [redacted]20[redacted] (RX DAY 223): SPUTUM MICROBIOLOGICAL CULTURE: POSITIVE-ESCHERICHIA COLI >1000000 UFC/ML AND ASPERGILLUS FUMIGATUS

AE Stopped Rx Day	232
Duration of AE	16 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	SECONDARY INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，気管支拡張症の悪化を発現した。

Event 11 の臨床経過：

関連する病歴は，喘息，気管支拡張症，パーキンソン病，帯状疱疹，シュードモナスによる慢性気管支炎，体重減少，脊柱後弯症，リウマチ性多発筋痛，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 217 日目，被験者は気管支拡張症の悪化を発現した。投与 232 日目，気管支拡張症の悪化は消失した。

投与 217 日目，被験者は入院した。被験者は安静時以外に最小から中程度の努力呼吸を要する進行性の呼吸困難及び発熱を発現した。その他の症状は，無力症，筋肉痛，食欲不振，体重減少，下痢，悪心，嘔吐，咳嗽，及び気管支重複感染であった。投与 232 日目，被験者は退院した。治験責任医師は，両側性気管支拡張症はおそらく重複感染であったと述べた。被験者はグラム陰性の大腸菌感染が認められた。

被験者に BEMIPARINA SODICA，アルプラゾラム，イトラコナゾール，PIPERACILINA SODICA/TAZOBACTAM SODICO，及びオメプラゾールが投与された。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted])

SINEMET IR for PARKINSONS DISEASE ([redacted])

SINEMET CR for PARKINSONS DISEASE ([redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted])

SAFINAMIDE for PARKINSONS DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Bronchiectasis (10006445) (Bronchiectasis (10006445)) [v.23.0] [10006445]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of BRONCHIECTASIS WORSENING

- Investigator: Secondary infection

- AbbVie: More likely related to a incidental infection in an advanced aged patient with a history of asthma, bronchiectasis, chronic bronchial infection by pseudomonas, kyphosis, Parkinson's disease and polymyalgia rheumatica requiring concomitant chronic medication prednisone.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMEN X-RAY:** NO FINDINGS

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] CHEST CT:** SUPERINFECTED BRONCHIECTASIS

[redacted] **20[redacted] CHEST X-RAY:** PARENCHYMAL OPACITIES OF RETROCARDIAC LOCATION AND LEFT BASAL LUNG THAT COULD BE RELATED TO INCIPIENT INFECTIOUS PROCESS

[redacted] **20[redacted] LACTATO DESHIDROGENASA:** 334 U/L (normal 0 to 248)

[redacted] **20[redacted] LYMPHOCYTES:** 12.50% (normal 20 to 44)

[redacted] **20[redacted] NEUTROPHILS ABS:** 13.15 X10**3/MCL (normal 1.50 to 7.70)

[redacted] **20[redacted] PCO2:** 31.2 mmHg (normal 35.0 to 48.0)

[redacted] **20[redacted] PCR COVID-19:** Negative

[redacted] **20[redacted] PO2:** 77.4 mmHg (normal 83.0 to 108.0)

[redacted] **20[redacted] SPUTUM CULTURE:** Positive. ESCHERICHIA COLI >1000000 UFC/ML AND ASPERGILLUS FUMIGATUS

[redacted] **20[redacted] URINE CULTURE:** Negative

[redacted] **20[redacted] WEIGHT SCREENING:** 6[redacted].[redacted] KG

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.14 X10**3/MCL (normal 3.50 to 10.50)

[redacted] **20[redacted] WHOLE BODY PET SCAN:** Bilateral bronchiectasis probably superinfected

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 6[redacted].[redacted] kg. Weight at time of event 5[redacted] kg. Weight loss occurred over a period of 1 month. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced constitutional syndrome and temporal episodes of loss of appetite, chronic diarrhea, infection, bronchial superinfection, vomiting, anorexia and asthenia.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
構語障害	X			
注入部位紅斑				X
注入部位浮腫				X
錯感覚	X			X
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
DISKINESIA	NOT REPORTED
DYSARTHRIA	NOT REPORTED
LEFT FOOT ZAMBO	19[redacted]
POLLEN ALLERGY	19[redacted]
ALLERGY TO ANIMAL EPITHELIUM	20[redacted]
INSOMNIA	20[redacted]
MENOPAUSE	20[redacted]
RIGHT ARM FUNCTIONAL DISABILITY	20[redacted]
RIGHT HUMERUS FRACTURE	20[redacted]
VITAMIN B12 DEFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
LEFT FOOT ZAMBO SURGERY	19[redacted]
RIGHT HUMERUS FRACTURE SURGERY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	15 CIGARETTE	15	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.5	0	0	720	0.19	[redacted]20[redacted]/1
ABBV-951	0.5	0	0	720	0.19	[redacted]20[redacted]/2
ABBV-951	0.45	0	0	720	0.19	[redacted]20[redacted]/3
ABBV-951	0.45	0	0	720	0.19	[redacted]20[redacted]/9
ABBV-951	0.45	0.41	0.37	720	0.19	[redacted]20[redacted]/16
ABBV-951	0.45	0.41	0.37	720	0.19	[redacted]20[redacted]/23
ABBV-951	0.41	0	0	720	0.19	[redacted]20[redacted]/30

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1075.72		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	1828.73		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14

ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1680.18		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
MELATONIN	1.98 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]-[redacted]
TRIHEXYPHENIDYL	2.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.700 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]-[redacted]
CYANOCOBALAMIN	1000 ug	OTHER: MONTHLY	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -263
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted] / -231
APOMORPHINE	3.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -140
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted]-[redacted] / -31
CYANOCOBALAMIN	1000 ug	OTHER: EVERY WEEK	Y-M: 20[redacted]-[redacted] / -24

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
MELATONIN	1.98 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted]-[redacted] / -31	Y-M: 20[redacted]-[redacted] / -25
CYANOCOBALAMIN	1000 ug	OTHER: EVERY WEEK	Y-M: 20[redacted]-[redacted] / -24	ONGOING
LORAZEPAM	1 mg	QD	Y-M: 20[redacted]-[redacted] / 2	Y-M: 20[redacted]-[redacted] / 4

Event #1: Serious Adverse Event

Event Description	SEVERE DYSARTRIA
Preferred term	構語障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	4
Duration of AE	3 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event, Event of Interest - Polyneuropathy

Event Description	RIGHT ARM PARESTESIAS
Preferred term	錯感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	4
Duration of AE	3 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE RIGHT ABDOMINAL ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 16
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SECOND RIGHT ABDOMINAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE LEFT ABDOMINAL EDEMA
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，重度の構語障害及び右腕の錯感覚を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，運動機能変動の発現，パーキンソン病，不眠症，閉経，右腕の機能障害，右上腕骨骨折，右上腕骨骨折の外科手術，ビタミン B12 欠乏症，レボドパ誘発性ジスキネジア，元喫煙者（1 日 15 本を 15 年間），及び飲酒者（1 日 2 杯未満）であった。

投与初日の翌日，被験者は重度の構語障害及び右腕の錯感覚を発現した。投与 4 日目，重度の構語障害及び右腕の錯感覚は消失した。

本事象発現前（日時不明）に，被験者は重症度が低かったが，組入れ前に上記の事象を発現していた。投与初日の翌日，被験者は構語障害，右手の錯感覚，及び全身性ジスキネジアのため入院した。虚血性脳卒中は除外された。注入速度を 0.5 mL/時間から 0.35 mL/時間に低下させた。ジスキネジア及び構語障害は 2 日目に消失した。その後，注入速度を 0.45 mL/時間に調整した。被験者の症状は完全に改善し，投与 4 日目に退院した。

The patient's past medications include:

TRIHEXYPHENIDYL for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for UNKNOWN INDICATION ([redacted] 20[redacted] - [redacted] 20[redacted])

RASAGILINE for UNKNOWN INDICATION ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Paresthesia upper limb (10054539) (Paraesthesia (10033775)) [v.23.0] [10054539]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Dysarthria (10013887) (Dysarthria (10013887)) [v.23.0] [10013887]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SEVERE DYSARTRIA, RIGHT ARM PARESTESIAS

- Investigator: Not applicable

- AbbVie: More likely related to pre-existing conditions in a subject with history of dysarthria, Parkinson's disease, right humerus fracture and right humerus fracture surgery.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CRANIAL CT SCAN:** Normal

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
ドーパミン調節障害症候群	X			
注入部位膿瘍	X			X
注入部位紅斑				X
注入部位血腫				X
注入部位結節				X
注入部位反応				X
傾眠				X
体重減少				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
HEPATITIS A	19[redacted]
OCCASIONAL HEADACHES	19[redacted]
DRY EYE	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
POST-MENOPAUSAL	20[redacted]
PTERIGION	20[redacted]
DEGENERATIVE DISCOPATHY	20[redacted]
LUMBALGIA	20[redacted]
LEFT LEG GASTROCTECNIUS FIBRILLARY RUPTURE	20[redacted]
ALLERGY TO SAFINAMIDE	20[redacted]
INTOLERANCE TO HIGH DOSE OF APOMORPHINE	20[redacted]
LOW LEVELS OF VITAMIN B12 IN BLOOD ANALYSES	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]

PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
ENDOMETRIAL ABLATION	20[redacted]
DEEP BRAIN STIMULATION (BILATERAL SUBTHALAMUS)	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	15 CIGARETTE	5	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.37	0	0	60	0.3	[redacted]20[redacted]/1
ABBV-951	0.3	0	0	60	0.3	[redacted]20[redacted]/2
ABBV-951	0.33	0	0	60	0.3	[redacted]20[redacted]/8
ABBV-951	0.33	0	0	60	0.3	[redacted]20[redacted]/15
ABBV-951	0.3	0	0	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.33	0	0	60	0.3	[redacted]20[redacted]/29
ABBV-951	0.33	0	0	60	0.3	[redacted]20[redacted]/43
ABBV-951	0.33	0	0	60	0.3	[redacted]20[redacted]/92
ABBV-951	0.25	0	0	60	0.3	[redacted]20[redacted]/156
ABBV-951	0.27	0	0	60	0.3	[redacted]20[redacted]/176
ABBV-951	0.27	0	0	60	0.3	[redacted]20[redacted]/184
ABBV-951	0.3	0	0	60	0.3	[redacted]20[redacted]/281
ABBV-951	0.33	0	0	60	0.11	[redacted]20[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	694.95		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 2	
ABBV-951	1345.51		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 3	
ABBV-951	1203.78		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 4	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 5	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 6	
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 7	
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 8	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 9	
ABBV-951	1298.04		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 10	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 11	
ABBV-951	1222.74		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 12	
ABBV-951	1290.35		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1205.83		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 14	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 17	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 18	

ABBV-951	1307.26		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1267.81		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 22	
ABBV-951	1200.71		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	1162.80		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		358.57	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	1193.54		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 27	
ABBV-951	1024.5		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1173.05		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1257.57		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 33	
ABBV-951	1250.91		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 36	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36

ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	1301.62		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1312.89		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1267.81		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	1284.72		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 47	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 48	
ABBV-951	1205.83		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 49	
ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 50	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 52	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 53	
ABBV-951	1267.81		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 54	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 55	

ABBV-951	1273.45		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 56	
ABBV-951	1250.91		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 57	
ABBV-951	1064.96		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 58	
ABBV-951	1222.74		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 59	
ABBV-951	1205.83		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 60	
ABBV-951	1217.10		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	1307.26		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 62	
ABBV-951	1307.26		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 64	
ABBV-951	1284.72		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 65	
ABBV-951	1284.72		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 66	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 67	
ABBV-951	1205.83		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 68	
ABBV-951	1267.81		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 69	
ABBV-951	1273.45		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 70	
ABBV-951	957.90		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 71	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 72	
ABBV-951	1188.93		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 73	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73

ABBV-951		204.9	SC / ONCE	[redacted] / 74	
ABBV-951	1234.01		SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951		256.12	SC / ONCE	[redacted] / 75	
ABBV-951	1324.16		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951		102.45	SC / ONCE	[redacted] / 76	
ABBV-951	1228.37		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951		51.22	SC / ONCE	[redacted] / 77	
ABBV-951	1211.47		SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951		153.67	SC / ONCE	[redacted] / 78	
ABBV-951	1295.99		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951		102.45	SC / ONCE	[redacted] / 79	
ABBV-951	1335.43		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	1239.64		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951		51.22	SC / ONCE	[redacted] / 81	
ABBV-951	1239.64		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951		153.67	SC / ONCE	[redacted] / 82	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	1307.26		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951		153.67	SC / ONCE	[redacted] / 84	
ABBV-951	1318.53		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
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ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	1142.31		SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	1126.95		SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 296	
ABBV-951	1126.95		SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	476.39		SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	660.80		SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	1132.07		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 301	
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 308	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308

ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 309	
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 312	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 315	
ABBV-951	1126.95		SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1178.17		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342

ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1126.95	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	1229.4	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	NOT REPORTED	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]-[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
APOMORPHINE	3.000 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	100.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	16.000 mg	QD	Y-M: 20[redacted]-[redacted]
ALPRAZOLAM	0.25 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]-[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]

CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -290
DOMPERIDONE	10 mg	QD	Y-M: 20[redacted] / -276
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / -154
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted] / -45
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted] / -45
CYANOCOBALAMIN	1000 ug	OTHER: WEEKLY	Y-M: 20[redacted] / -21
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted] / -2

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ALPRAZOLAM	0.25 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 335
DOMPERIDONE	10 mg	QD	Y-M: 20[redacted] / -276	Y-M: 20[redacted] / 1
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / -154	Y-M: 20[redacted] / 345
CYANOCOBALAMIN	1000 ug	OTHER: WEEKLY	Y-M: 20[redacted] / -21	Y-M: 20[redacted] / 19
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 2	Y-M: 20[redacted] / 27
GRANISETRON	1 mg	BID	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 32
OMEPRAZOLE	MG ug	QD	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 43
CYANOCOBALAMIN	1000 ug	OTHER: MONTHLY	Y-M: 20[redacted] / 30	Y-M: 20[redacted] / 43
BETAMETHASONE DIPROPIONATE;GENTAMICIN SULFATE	0.5 +1 OTHER: MG/G	BID	Y-M: 20[redacted] / 156	Y-M: 20[redacted] / 289
MUPIROCIN	2%	QD	Y-M: 20[redacted] / 156	Y-M: 20[redacted] / 289
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1 g	TID	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 259
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 263
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 259	Y-M: 20[redacted] / 263
CLINDAMYCIN	300 mg	BID	Y-M: 20[redacted] / 259	Y-M: 20[redacted] / 263
ALPRAZOLAM	0,25 mg	OTHER: SIX TIMES PER DAY	Y-M: 20[redacted] / 336	Y-M: 20[redacted] / 346
CLORAZEPATE DIPOTASSIUM	5 mg	QD	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 344
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 348
GRANISETRON	1 g	QD	Y-M: 20[redacted] / 345	Y-M: 20[redacted] / 348
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 345	Y-M: 20[redacted] / 348
SERTRALINE	200 mg	QD	Y-M: 20[redacted] / 346	ONGOING
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted] / 346	Y-M: 20[redacted] / 347
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / 346	Y-M: 20[redacted] / 364

CLONAZEPAM	0,25 mg	BID	Y-M: 20[redacted]-[redacted] / 347	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	92
Duration of AE	85 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT GLAZED APPEREANCE AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	92
Duration of AE	85 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 141
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	225 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	GLUTEUS NODULES AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 156
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	365
Duration of AE	210 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RIGHT GLAZING APPEARANCE AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 156
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	176
Duration of AE	21 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 176
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	190 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MARKED GLAZING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 176
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	190 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	RIGHT GLUTEAL ABSCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 258
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 258): LEUKOCYTES: 32 [4 - 10] 10^9/L; NPTST216-PCR (PROTEIN C REACTIVE): 8.17 [0 - 0.5] MG/DL; NPTST218-PCR CORONAVIRUS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 259): URINE MICROBIOLOGICAL EXAMINATION: NEGATIVE-NO INFECTION PRESENCE; OTHER NASOPHARYNGEAL SMEAR PCR SARS-COV2: NEGATIVE-NO RELEVANT FINDINGS

AE Stopped Rx Day	269
Duration of AE	12 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RIGHT ABDOMEN HEMATOMA AT INFUSION SITE
Preferred term	注入部位血腫

AE Onset Date / Rx Day	[redacted]20[redacted] / 281
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	365
Duration of AE	85 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Serious Adverse Event

Event Description	DOPAMINERGIC DYSREGULATION
Preferred term	ドーパミン調節障害症候群
AE Onset Date / Rx Day	[redacted]20[redacted] / 336
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 346): PROTEIN: 61 [64 - 83] G/L	
Microbiology	
[redacted]20[redacted] (RX DAY 344): OTHER NASOPHARYNGEAL SAMPLE PCR SARS-COV-2: NEGATIVE	
AE Stopped Rx Day	346
Duration of AE	11 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

Other cause of event	PARKINSON'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #11: Event of Interest - Weight Loss

Event Description	WEIHGT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 336
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	355
Duration of AE	20 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest - Somnolence

Event Description	DROWSINESS
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 347
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	348
Duration of AE	2 DAYS

Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest - Somnolence

Event Description	DROWSINESS
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 348
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，右臀部の注入部位に膿瘍を発現した。

Event 8 の臨床経過：

関連する病歴は，うつ病，パーキンソン病，変性椎間板症，腰痛，血液検査によるビタミン B12 低値，元喫煙者（1 日 15 本を 5 年間），及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 258 日目，被験者は右臀部の注入部位膿瘍を発現した。投与 269 日目，右臀部の注入部位膿瘍は消失した。

投与 258 日目，発熱（39.3°C）及び右大殿筋の疼痛のため被験者は来院した。検査の結果，患部は硬く，紅斑を呈し，疼痛及び腫脹を伴っているようにみられた。該当部位は治験薬の皮下穿刺部位と一致していた。投与 259 日目，被験者は排膿及びデブリードマンのため緊急外科手術を受けた。術後合併症は認められず，同日被験者は退院した。

被験者にシプロフロキサシン，クリンダマイシン，AUGMENTINE，及びパラセタモールが投与された。

The patient's past medications include:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

STALEVO for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ZONISAMIDE for PARKINSON'S DISEASE (20[redacted] - 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA SUSTAINED RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], Started [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.23.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of RIGHT GLUTEAL ABSCESS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL CT:** Trabeculation of right gluteal fat with fluid sheet and air bubble suggestive of abscess.

[redacted] **20[redacted] BODY TEMPERATURE:** 39.3 Degrees C

[redacted] 20[redacted] **BODY WEIGHT:** 5[redacted] KG

[redacted] 20[redacted] **COVID-19 VIRUS TEST:** PCR-Negative

[redacted] 20[redacted] **MICROBIOLOGICAL EXAMINATION (URINE):** No infection present

[redacted] 20[redacted] **PCR (PROTEIN C REACTIVE):** 8.14 mg/dL (normal 0 to 0.5)

[redacted] 20[redacted] **PCR SARS-COV2:** Negative

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 32.04 X10**3/MCL (normal 4 to 10)
Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，ドーパミン調節障害を発現した。

Event 10 の臨床経過：

関連する病歴は，不安，うつ病，閉経，パーキンソン病，血液検査によるビタミン B12 低値，元喫煙者（1 日 15 本を 5 年間），及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 336 日目，被験者はドーパミン調節障害を発現した。投与 346 日目，ドーパミン調節障害は消失した。

投与 344 日目，被験者はアカシジア，不安，及び重度のジスキネジアを呈する運動障害の診察で来院した。被験者の血液動態は安定し，発熱もなかったが，前回の来院から体重は減少していた。被験者は家族に関する問題による重度の不安のため，自身でレボドパを服用したことを認めた。被験者はドーパミン治療の調整及び精神状態の検査のため，同日入院した。本被験者は不安及びレボドパの要求に良好な臨床的進展がみられた。投与 348 日目，被験者は安定し退院した。

被験者に TRANXILIUM，SINEMET IR，オメプラゾール，パラセタモール，クロナゼパム，及びグラニセトロンが投与された。

The patient's past medications include:

BACTROBAN for GLUTEUS NODULE ([redacted] 20[redacted] - [redacted] 20[redacted])

DIPROGENTA for NODULE GLUTEUS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Dopamine dysregulation syndrome (10067468) (Dopamine dysregulation syndrome (10067468)) [v.23.1] [10067468]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of DOPAMINERGIC DYSREGULATION

- Investigator: Not related.

- AbbVie: More likely related history of anxiety, depression and reported family problems

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] PCR SARS-COV-2:** Negative

[redacted] **20[redacted] PROTEIN:** 60.6 G/L (normal 60 to 83)

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 4[redacted].[redacted] kg. Weight at time of event 4[redacted] kg. Weight loss occurred over a period of 1 month. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced worsening dyskinesia and no other prevalent circumstances or reasons provided for weight loss.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
悪液質	X		X	X
全身性強直性間代性発作	X			
注入部位紅斑				X
注入部位浮腫				X
注入部位丘疹				X
尿路感染	X	X		
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
POST MENOPAUSAL CONDITION.	20[redacted]
DYSLIPIDEMIA	20[redacted]
ANXIETY	20[redacted]
UROLITHIASIS	20[redacted]
HEMATURIA	20[redacted]
DEPRESSION	20[redacted]
SLEEP DISORDER	20[redacted]
BEHAVIOURAL DISORDER	20[redacted]
URINARY TRACT INFECTION	20[redacted]
BILATERAL RENAL CORTICAL CYSTS.	20[redacted]
CHOLELITHIASIS	20[redacted]
PNEUMONIA	20[redacted]
PAIN	20[redacted]
URINARY TRACT INFECTION.	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.5	0.6	0.4	5	0.3	[redacted]20[redacted]/1
ABBV-951	0.5	0.55	0.45	5	0.3	[redacted]20[redacted]/3
ABBV-951	0.55	0.6	0.5	5	0.3	[redacted]20[redacted]/8
ABBV-951	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/15
ABBV-951	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/22
ABBV-951	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/29
ABBV-951	0.58	0.65	0.55	5	0.3	[redacted]20[redacted]/45
ABBV-951	0.58	0.61	0.55	60	0.3	[redacted]20[redacted]/92
ABBV-951	0.62	0.63	0.61	60	0.24	[redacted]20[redacted]/135
ABBV-951	0.58	0.61	0.55	60	0.15	[redacted]20[redacted]/183
ABBV-951	0.58	0.61	0.55	60	0.19	[redacted]20[redacted]/235

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1455.64		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58

ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	2403.30		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93

ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 106	[redacted] / 106
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 108	[redacted] / 108
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 109	[redacted] / 109
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 110	[redacted] / 110
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 111	[redacted] / 111
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 112	[redacted] / 112
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 113	[redacted] / 113
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 114	[redacted] / 114
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 115	[redacted] / 115
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 116	[redacted] / 116
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 117	[redacted] / 117
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 118	[redacted] / 118
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 119	[redacted] / 119
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 120	[redacted] / 120
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 121	[redacted] / 121
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 122	[redacted] / 122
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 123	[redacted] / 123
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 124	[redacted] / 124
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 125	[redacted] / 125
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 126	[redacted] / 126
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 127	[redacted] / 127
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 128	[redacted] / 128
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 129	[redacted] / 129
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 130	[redacted] / 130

ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 131	[redacted] / 131
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 132	[redacted] / 132
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 133	[redacted] / 133
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 134	[redacted] / 134
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 135	[redacted] / 135
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 136	[redacted] / 136
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 137	[redacted] / 137
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 138	[redacted] / 138
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 139	[redacted] / 139
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 140	[redacted] / 140
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 141	[redacted] / 141
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 142	[redacted] / 142
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 143	[redacted] / 143
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 144	[redacted] / 144
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 145	[redacted] / 145
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 146	[redacted] / 146
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 147	[redacted] / 147
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 148	[redacted] / 148
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 149	[redacted] / 149
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 150	[redacted] / 150
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 151	[redacted] / 151
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 152	[redacted] / 152
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 153	[redacted] / 153
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 154	[redacted] / 154
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 155	[redacted] / 155
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 156	[redacted] / 156
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 157	[redacted] / 157
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 158	[redacted] / 158
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 159	[redacted] / 159
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 160	[redacted] / 160
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 161	[redacted] / 161
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 162	[redacted] / 162
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 163	[redacted] / 163
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 164	[redacted] / 164
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 165	[redacted] / 165
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 166	[redacted] / 166
ABBV-951	2663.7	SC / CONTINUOUS	[redacted] / 167	[redacted] / 167

ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2663.7	SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	2629.55	SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	1721.16	SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ALPRAZOLAM	0.25 mg	OTHER: IF THE PATIENTS NEEDS FOR ANXIETY, IT DEPENDS ON THE DAY (MANY DAYS, 2/DAY; SOMETIMES, 3/DAY)	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	187.500 mg	QID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	BID	Y-M: 20[redacted]-[redacted]
ATORVASTATIN	20 mg	QD	Y-M: 20[redacted]-[redacted]
ROPINIROLE	4.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted]
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted]-[redacted]
BROMAZEPAM	1.5 mg	OTHER: 1-0-2 (1.5 MG AT MORNING, 3 MG AT NIGHT).	Y-M: 20[redacted]-[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
VORTIOXETINE HYDROBROMIDE	20 mg	QD	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted]-[redacted] / -360
QUETIAPINE	25 mg	QD	Y-M: 20[redacted]-[redacted] / -209

QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / -209
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted] / -167
IBUPROFEN	600 mg	OTHER: IF THE PATIEN NEEDS FOR PAIN, IT DEPENDS ON THE DAY; FRENQUENTLY, 1-2/DAY.	Y-M: 20[redacted] / -97
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -53
HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	TWO PILLS PER DAY; SEE UNITS. OTHER: 1 CP. = 500 MICROGRAMSOF HYDROXOCOBALAM INHYDROCHLORIDE, 250 MG	BID	Y-M: 20[redacted] / -53
FOSFOMYCIN	1 g	QD	Y-M: 20[redacted] / -25

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ALPRAZOLAM	0.25 mg	OTHER: IF THE PATIENTS NEEDS FOR ANXIETY, IT DEPENDS ON THE DAY (MANY DAYS, 2/DAY; SOMETIMES, 3/DAY)	Y-M: 20[redacted]	Y-M: 20[redacted] / 215
ATORVASTATIN	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 274
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 191
BROMAZEPAM	1.5 mg	OTHER: 1-0-2 (1.5 MG AT MORNING, 3 MG AT NIGHT).	Y-M: 20[redacted]	Y-M: 20[redacted] / 215
VORTIOXETINE HYDROBROMIDE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 215
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / -209	Y-M: 20[redacted] / 149
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / -209	Y-M: 20[redacted] / 149
IBUPROFEN	600 mg	OTHER: IF THE PATIEN NEEDS FOR PAIN, IT DEPENDS ON THE DAY; FRENQUENTLY, 1-2/DAY.	Y-M: 20[redacted] / -97	Y-M: 20[redacted] / 274
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -53	Y-M: 20[redacted] / -7

HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	TWO PILLS PER DAY; SEE UNITS. OTHER: 1 CP. = 500 MICROGRAMSOF HYDROXOCOBALAMINHYDROCHLORIDE, 250 MG	BID	Y-M: 20[redacted] / -53	Y-M: 20[redacted] / -7
FOSFOMYCIN	1 g	QD	Y-M: 20[redacted] / -25	Y-M: 20[redacted] / -24
CEFDITOREN	200 mg	BID	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 12
MUPIROCIN	20 OTHER: MG/G	PRN	Y-M: 20[redacted] / 38	Y-M: 20[redacted] / 71
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 MG AMOXICILLIN AND 125 MG CLAVULANIC ACID mg	TID	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 51
PREDNISONE	30 MG AND PROGRESSIVELY DECREASING DOSE mg	QD	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 52
PREDNISONE	30 mg	QD	Y-M: 20[redacted] / 139	Y-M: 20[redacted] / 144
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 MG AMOXICILLIN / 125 MG CLAVULANIC ACID mg	TID	Y-M: 20[redacted] / 139	Y-M: 20[redacted] / 150
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 149	Y-M: 20[redacted] / 215
QUETIAPINE	75 mg	QD	Y-M: 20[redacted] / 149	Y-M: 20[redacted] / 215
TRAZODONE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 207	Y-M: 20[redacted] / 308
CEFIXIME	200 mg	BID	Y-M: 20[redacted] / 213	Y-M: 20[redacted] / 221
QUETIAPINE	200 mg	QD	Y-M: 20[redacted] / 215	Y-M: 20[redacted] / 283
VORTIOXETINE HYDROBROMIDE	10 mg	QD	Y-M: 20[redacted] / 215	Y-M: 20[redacted] / 297
ALPRAZOLAM	0.5 mg	TID	Y-M: 20[redacted] / 215	Y-M: 20[redacted] / 312
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 / 125 (AMOXICILLIN / CLAVULANIC) mg	TID	Y-M: 20[redacted] / 246	Y-M: 20[redacted] / 257
PREDNISONE	30 mg	QD	Y-M: 20[redacted] / 246	Y-M: 20[redacted] / 257
METFORMIN	850 mg	QD	Y-M: 20[redacted] / 250	Y-M: 20[redacted] / 274
ERTAPENEM	1 g	QD	Y-M: 20[redacted] / 268	Y-M: 20[redacted] / 275
LORMETAZEPAM	2 mg	QD	Y-M: 20[redacted] / 268	Y-M: 20[redacted] / 283
PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 274	Y-M: 20[redacted] / 274

PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	4 g	TID	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 275
CEFEPIME	2 g	TID	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 284
OLANZAPINE	5 mg	QD	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 284
LACOSAMIDE	100 mg	BID	Y-M: 20[redacted] / 276	Y-M: 20[redacted] / 281
TRAZODONE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted] / 277	Y-M: 20[redacted] / 285
LACOSAMIDE	200 mg	BID	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 286
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 283	Y-M: 20[redacted] / 284
ONDANSETRON HYDROCHLORIDE	4 mg	OTHER: BID IF IT IS NECESSARY ONLY	Y-M: 20[redacted] / 283	Y-M: 20[redacted] / 290
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 283	Y-M: 20[redacted] / 300
QUETIAPINE	100 mg	QD	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 285
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted] / 285	Y-M: 20[redacted] / 285
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 285	Y-M: 20[redacted] / 286
TRAZODONE HYDROCHLORIDE	25 mg	QD	Y-M: 20[redacted] / 285	Y-M: 20[redacted] / 286
LORMETAZEPAM	1 mg	QD	Y-M: 20[redacted] / 285	Y-M: 20[redacted] / 300
AMOXICILLIN;CLAVULANIC ACID	2 g	TID	Y-M: 20[redacted] / 286	Y-M: 20[redacted] / 299
LACOSAMIDE	150 mg	BID	Y-M: 20[redacted] / 286	Y-M: 20[redacted] / 301
ONDANSETRON HYDROCHLORIDE	4 mg	OTHER: TID IF IT IS NECESSARY ONLY	Y-M: 20[redacted] / 290	Y-M: 20[redacted] / 299
POTASSIUM	2.2 g	QD	Y-M: 20[redacted] / 291	Y-M: 20[redacted] / 295
MIRTAZAPINE	15 mg	QD	Y-M: 20[redacted] / 297	Y-M: 20[redacted] / 299
DOMPERIDONE	10 mg	BID	Y-M: 20[redacted] / 297	Y-M: 20[redacted] / 317
METHYLPREDNISOLONE	20 mg	TID	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 299
LEVETIRACETAM	250 mg	BID	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 300
AMOXICILLIN;CLAVULANIC ACID	500 mg	TID	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 310
SERTRALINE	50 mg	QD	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 310
ONDANSETRON HYDROCHLORIDE	4 mg	OTHER: ONLY IF IT IS NECESSARY FOR PRESENTING SYMPTOMS	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 317
METHYLPREDNISOLONE	10 mg	TID	Y-M: 20[redacted] / 300	Y-M: 20[redacted] / 302
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 300	Y-M: 20[redacted] / 310

LACOSAMIDE	100 mg	BID	Y-M: 20[redacted] / 301	Y-M: 20[redacted] / 301
HYDROCORTISONE	100 mg	TID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 302
HYDROCORTISONE	50 mg	TID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 306
LACOSAMIDE	150 mg	BID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 306
MIDAZOLAM	3 mg	BID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 306
MIDAZOLAM	3 mg	OTHER: IF IT WAS NECESSARY	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 312
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 317
EZETIMIBE	10 mg	QD	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 310
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 317
PREDNISONE	15 mg	QD	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 317
LACOSAMIDE	100 mg	BID	Y-M: 20[redacted] / 307	Y-M: 20[redacted] / 312
AMITRIPTYLINE	10 mg	BID	Y-M: 20[redacted] / 310	Y-M: 20[redacted] / 313
LACOSAMIDE	50 mg	BID	Y-M: 20[redacted] / 312	Y-M: 20[redacted] / 313
MIDAZOLAM	4 mg	OTHER: IF IT WAS NECESSARY	Y-M: 20[redacted] / 312	Y-M: 20[redacted] / 313
ALPRAZOLAM	0.25 mg	QID	Y-M: 20[redacted] / 312	Y-M: 20[redacted] / 315
LEVETIRACETAM	500 mg	BID	Y-M: 20[redacted] / 312	Y-M: 20[redacted] / 315
AMITRIPTYLINE	10 mg	QD	Y-M: 20[redacted] / 313	Y-M: 20[redacted] / 315
MIDAZOLAM	2.5 mg	OTHER: IF IT WAS NECESSARY	Y-M: 20[redacted] / 313	Y-M: 20[redacted] / 315
LACOSAMIDE	50 mg	QD	Y-M: 20[redacted] / 313	Y-M: 20[redacted] / 317
DIAZEPAM	2.5 mg	TID	Y-M: 20[redacted] / 315	Y-M: 20[redacted] / 315
AMITRIPTYLINE	20 mg	QD	Y-M: 20[redacted] / 315	Y-M: 20[redacted] / 316
MIDAZOLAM	7.5 mg	OTHER: IF IT WAS NECESSARY	Y-M: 20[redacted] / 315	Y-M: 20[redacted] / 316
DIAZEPAM	5 mg	TID	Y-M: 20[redacted] / 315	Y-M: 20[redacted] / 317
LEVETIRACETAM	750 mg	BID	Y-M: 20[redacted] / 315	Y-M: 20[redacted] / 317
LACOSAMIDE	25 mg	QD	Y-M: 20[redacted] / 317	Y-M: 20[redacted] / 317
MIDAZOLAM	5 mg	OTHER: IF IT WAS NECESSARY	Y-M: 20[redacted] / 317	Y-M: 20[redacted] / 317
MIDAZOLAM	60 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 317	Y-M: 20[redacted] / 318
MORPHINE	30 mg	TID	Y-M: 20[redacted] / 317	Y-M: 20[redacted] / 318
MIDAZOLAM	75 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 318	Y-M: 20[redacted] / 319
MORPHINE	60 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 318	Y-M: 20[redacted] / 319

HYOSCINE BUTYLBROMIDE	20 mg	TID	Y-M: 20[redacted] / 319	Y-M: 20[redacted] / 320
MIDAZOLAM	100 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 319	Y-M: 20[redacted] / 320
MORPHINE	80 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 319	Y-M: 20[redacted] / 320
MIDAZOLAM	180 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 321
HYOSCINE BUTYLBROMIDE	60 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 321	Y-M: 20[redacted] / 322
MIDAZOLAM	200 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 321	Y-M: 20[redacted] / 322
MORPHINE	180 mg	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 321	Y-M: 20[redacted] / 322
PROPOFOL	50 mL	OTHER: 24 HOURS INFUSION	Y-M: 20[redacted] / 321	Y-M: 20[redacted] / 322

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	8
Duration of AE	6 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	29
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 29
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	37
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	44
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT THE INFUSION SITE.
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	44
Duration of AE	7 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAPULES AT THE INFUSION SITE.
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	44
Duration of AE	7 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 45
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	58
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAPULAS AT THE INFUSION SITE.
Preferred term	注入部位丘疹
AE Onset Date / Rx Day	[redacted]20[redacted] / 45
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	58
Duration of AE	14 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT THE INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	99
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL ERYTHEMA AT INFUSION SITE.
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 139
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	155
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL EDEMA AT INFUSION SITE.
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 139
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	155
Duration of AE	17 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMINAL EDEMA AT INFUSION SITE.
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 244
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	268
Duration of AE	25 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	URINARY TRACT INFECTION
Preferred term	尿路感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 260
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 267): NPTST171-LEUCOCYTES: 262 [0 - 32] CEL/MICROL; NPTST173-LEUKOCYTES: 15.2 [4 - 11] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 267): URINE URINE CULTURE: POSITIVE-MORGANELLA MORGANII; [redacted]20[redacted] (RX DAY 278): URINE URINE CULTURE: NEGATIVE; [redacted]20[redacted] (RX DAY 288): URINE URINE CULTURE: NEGATIVE

AE Stopped Rx Day	288 (14 DAYS AFTER LAST TREATMENT)
Duration of AE	29 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	THIS IS A URINARY TRACT INFECTION. THE URINE SEDIMENT IS PATHOLOGICAL, THE URINE CULTURE IS PENDING.
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #15: Serious Adverse Event

Event Description	GENERALIZED TONIC-CLONIC SEIZURE
Preferred term	全身性強直性間代性発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 275 (1 day after last treatment)

Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 274): ALANINE AMINOTRANSFERASE: 70 [7 - 36] U/L; NPTST247-PO2: 67.7 [80 - 100] MMHG; NEUTROPHILS/LEUKOCYTES: 81.5 [40 - 74] %; [redacted]20[redacted] (RX DAY 283): NPTST123-FOLIC ACID: 2.4 [5.3 - 24] NG/ML; NPTST126-GAMMA-GLUTAMYL TRANSFERASE: 51 [5 - 36] IU/L; NEUTROPHILS/LEUKOCYTES: 79.1 [40 - 74] %; [redacted]20[redacted] (RX DAY 290): GLUCOSE: 8.2 [3.9 - 6.1] MMOL/L; NEUTROPHILS/LEUKOCYTES: 83.6 [40 - 74] %; [redacted]20[redacted] (RX DAY 299): NPTST097-CRP: 2.37 [0 - 5] MG/DL; NPTST134-GSV: 78 [1 - 20] MM; NEUTROPHILS/LEUKOCYTES: 78.6 [40 - 74] %; [redacted]20[redacted] (RX DAY 302): CHOLESTEROL: 6.75 [0 - 5.74] MMOL/L; NPTST206-O2 SATURATION (%): 90.6 [95 - 99] %; NPTST247-PO2: 57.5 [80 - 100] MMHG; NEUTROPHILS/LEUKOCYTES: 84.8 [40 - 74] %; [redacted]20[redacted] (RX DAY 303): CREATININE: 27 [49 - 90] UMOL/L; [redacted]20[redacted] (RX DAY 313): NPTST127-GASOMETRY: 57.7 [80 - 100] %; [redacted]20[redacted] (RX DAY 317): LEUKOCYTES: 11.9 [4 - 11.5] 10^9/L; NPTST134-GSV: 46 [1 - 20] MM; NEUTROPHILS/LEUKOCYTES: 87.5 [40 - 74] %

Microbiology

NOT REPORTED

AE Stopped Rx Day	315 (41 DAYS AFTER LAST TREATMENT)
Duration of AE	41 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	THE PATIENT PRESENTED HOSPITALIZATION WITH RESPIRATORY INFECTION, GENERAL IMPAIRMENT AND CAQUEXIA.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #16: Serious Adverse Event, Death, Event of Interest - Weight Loss

Event Description	CAQUEXIA.
Preferred term	悪液質
AE Onset Date / Rx Day	[redacted]20[redacted] / 311 (37 days after last treatment)
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 267): NPTST171-LEUCOCYTES: 262 [0 - 32] CEL/MICROL; NPTST173-LEUKOCYTES: 15.2 [4 - 11] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 267): URINE URINE CULTURE: POSITIVE-MORGANELLA MORGANII; [redacted]20[redacted] (RX DAY 278): URINE URINE CULTURE: NEGATIVE; [redacted]20[redacted] (RX DAY 288): URINE URINE CULTURE: NEGATIVE

AE Stopped Rx Day	322 (48 DAYS AFTER LAST TREATMENT)
Duration of AE	12 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	IT HAS BEEN IN THE CONTEXT OF URINARY INFECTION, 2 RESPIRATORY INFECTIONS AND PROLONGED BEDDING.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING, RESULTS IN DEATH

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，死亡に至った悪液質，全身性強直性間代性発作，及び尿路感染を発現した。

Event 14，15，及び 16 の臨床経過：

関連する病歴は，閉経，脂質異常症，尿路結石症，血尿，うつ病，睡眠障害，尿路感染，両側性腎皮質嚢胞，尿路感染，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。

本期間を通してABBV-951の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与260日目，被験者は尿路感染を発現した。投与275日目，被験者は全身性強直性間代性発作を発現した。投与288日目，尿路感染は消失した。投与311日目，被験者は悪液質を発現した。投与315日目，全身性強直性間代性発作は消失した。投与322日目，被験者は死亡した。死因は悪液質と報告された。剖検は実施されなかった。

本事象の発現以前に，被験者は投与3日目及び投与213日目に尿路感染（非重篤）を発現していた。被験者の娘の報告によると，入院前に被験者はvery charged urineの状態で，発熱はなく肉眼的に尿の色は濃かった。尿沈殿物は病的であった。ホームホスピタルサービスにより，入院及び抗生物質による治療を開始するよう評価された（エルタペネム静脈内投与 / 24時間）。

投与268日目，被験者は約1週間の全身症状の悪化及び暗色尿のため入院した。入院当日，被験者は多剤耐性の Morganella morganii による尿路感染を併発し，抗生物質を投与された。投与275日目及び投与276日目，被験者は全身性強直性間代性発作を発現し，ラコサミド100 mg静脈内投与 / 12時間を開始した。発作後，被験者は傾眠及び錯乱を認めた。治験責任医師によると症状は好ましくなく，被験者は全身性発作及び吸引による呼吸器感染（非重篤）を発現した。投与278日目，尿培養は陰性であった。投与281日目，被験者は新たな危機的状態になり，ラコサミドの用量を200 mg静脈内投与 / 12時間に増量した。投与286日目，被験者は吸引による呼吸器感染（非重篤）を発現し，ピペラシリン / タゾバクタムが投与された。投与300日目，被験者は抗てんかん薬の減量によって強直性間代性発作を再度発現した。治験責任医師によると，顕著な体重減少が認められたが，被験者がベッドに寝たきりであったため体重は記録されなかった。被験者は食事が困難で，認知機能が低下し，嚥下障害が認められた。治験責任医師によると，被験者の介護者（夫）が癌と診断されたことが被験者の介護に影響した。投与310日目，呼吸器感染は消失し，抗生物質による治療を終了した。投与311日目，被験者は悪液質と診断された。投与315日目，被験者は全身状態の悪化を伴う新たなてんかん発作の危機的状態を呈した。投与316日目，被験者の家族は緩和療法のみの治療を選択した。その後，被験者に対して鎮痛ケアのみが行われた。投与322日目，被験者は全身状態の悪化，悪液質，及び緩和的管理という状況で死亡した。

全身性強直性間代性発作に関連した被験者のリスク因子には，尿路感染を発現した高齢女性であることが含まれた。

別のリスク因子として尿路感染に伴う糖尿病（非重篤）が挙げられた。

投与361日目に受領した情報：AER [redacted] の症例はこのAER[redacted]の症例と統合すべきと判断された。AER [redacted] は論理的に削除される予定である。

被験者にレベチラセタム，ラコサミド，カリウム NM，モルヒネ，エゼチミブ，ジアゼパム，トラゾドン塩酸塩，BUSCAPINA，アミトリプチリン，アルプラゾラム，セフェピム，及びエルタペネムが投与された。

The patient's past medications include:

ROPINIROLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

FOSFOMICINA for URINARY TRACT INFECTION ([redacted] 20[redacted] - [redacted] 20[redacted])

CEFDITOREN for URINARY TRACT INFECTION ([redacted] 20[redacted] - [redacted] 20[redacted])

CEFIXIMA for URINARY INFECTION ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Cachexia (10006895) (Cachexia (10006895)) [v.23.1] [10006895]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Generalized tonic-clonic seizure (10062448) (Generalised tonic-clonic seizure (10018100)) [v.23.1] [10062448]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

3) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.1] [10046571]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CAQUEXIA

- Investigator: It has been in the context of urinary infection, 2 respiratory infections and prolonged bedding.

- AbbVie: More likely related to reported dysphagia and recent events of infections in an advanced aged patient with a history of pneumonia, urinary tract infection, depression and Parkinson's disease.

Event of GENERALIZED TONIC-CLONIC SEIZURE

- Investigator: The patient presented hospitalization with respiratory infection, general impairment and caquexia.

- AbbVie: More likely related to reported urinary tract infection and respiratory infection in a patient with Parkinson disease and advanced age with concomitant medications sertraline and seroquel

Event of URINARY TRACT INFECTION

- Investigator: This is a urinary tract infection. The urine sediment is pathological, the urine culture was pending.

- AbbVie: More likely related to history of diabetes, Parkinson’s disease, urolithiasis, urinary tract infection in a 7[redacted] year old female subject.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 7[redacted] KG

[redacted] **20[redacted] CHEST X-RAY:** No radiological signs of acute pleuropulmonary pathology

[redacted] **20[redacted] CHEST X-RAY:** no radiological signs of acute pleuropulmonary pathology

[redacted] **20[redacted] CHEST X-RAY:** No radiological signs of acute pleuropulmonary pathology

[redacted] **20[redacted] CHEST X-RAY:** No radiological signs of acute pleuropulmonary pathology

[redacted] **20[redacted] CHOLESTEROL:** 261 mg/dL (normal 0 to 222)

[redacted] 20[redacted] **CRANIAL CT:** NO RADIOLOGICAL SIGNS OF ACUTE INTRACRANIAL PATHOLOGY.

[redacted] **20[redacted] CRP:** 2.37 mg/dL (normal 0 to 5)

[redacted] **20[redacted] ECG:** Normal.

[redacted] **20[redacted] EEG:** No paroxistic activity.

[redacted] **20[redacted] EEG:** No paroxistic activity.

[redacted] **20[redacted] FOLIC ACID:** 2.4 NG/ML (normal 5.3 to 24)

[redacted] **20[redacted] GAMMA-GLUTAMYL TRANSFERASE:** 51 U/L (normal 7 to 36)

[redacted] **20[redacted] LEUKOCYTES:** 15.2 X10**9/L (normal 4 to 11)

[redacted] **20[redacted] URINE CULTURE:** positive, Morganella morganii

[redacted] **20[redacted] URINE CULTURE:** negative

[redacted] **20[redacted] URINE CULTURE:** negative

[redacted] **20[redacted] URINE LEUCOCYTES:** 262 CEL/MICROL (normal 0 to 32)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 11.930 X10**9/L (normal 4.0 to 11.0)

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Cachexia: Day 1 weight 6[redacted] kg. Weight at time of event is unknown as per report. Subject lost weight in the context of hospitalization but remained bedridden and weights were not obtained. Weight loss occurred over a period of 4 months. Subject was hospitalized for urinary tract infection and respiratory infection and general impairment. The subject's caregiver/husband became ill and affected the subject's care. The subject experienced temporal and previous episodes of cognitive decline, depression and/or other psychiatric disorders and dysphagia. The subject experienced temporal episodes of malnutrition, loss of appetite and infection.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻視				X
注入部位紅斑				X
精神病性障害	X			X
傾眠				X
体重減少				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
POSTMENOPAUSAL	NOT REPORTED
BIPOLAR DISORDER TYPE I (A CHRONIC CONDITION BUT WITHOUT RELAPSES SINCE 20[redacted]).	20[redacted]
HYPOTHYROIDISM.	20[redacted]
CHOLELITHIASIS.	20[redacted]
COLEDOCOLITHIASIS.	20[redacted]
DEPRESSION	20[redacted]
POLAQUIURIA	20[redacted]
LIPOMATOSIS IN BOTH LOWER ESTREMITIES.	20[redacted]
OBESITY.	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
VARICECTOMY	19[redacted]
LAPAROSCOPIC CHOLECYSTECTOMY.	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.6	0.63	0.57	60	0.3	[redacted]/1
ABBV-951	0.62	0.65	0.59	60	0.3	[redacted]/3
ABBV-951	0.58	0.59	0.57	60	0.3	[redacted]/5
ABBV-951	0.55	0.56	0.54	60	0.3	[redacted]/8
ABBV-951	0.55	0.56	0.54	60	0.3	[redacted]/10
ABBV-951	0.5	0.53	0.47	60	0.3	[redacted]/11
ABBV-951	0.56	0.59	0.53	30	0.3	[redacted]/15
ABBV-951	0.56	0.59	0.53	30	0.3	[redacted]/22
ABBV-951	0.56	0.58	0.54	60	0.3	[redacted]/26
ABBV-951	0.54	0.58	0.5	60	0.3	[redacted]/29
ABBV-951	0.5	0.51	0.49	60	0.3	[redacted]/32
ABBV-951	0.49	0.5	0.48	60	0.3	[redacted]/46
ABBV-951	0.45	0.46	0.44	60	0.3	[redacted]/80
ABBV-951	0.45	0.46	0.44	60	0.3	[redacted]/92
ABBV-951	0.41	0.42	0.4	60	0.3	[redacted]/170
ABBV-951	0.41	0.42	0.4	60	0.3	[redacted]/183
ABBV-951	0.41	0.42	0.4	60	0.3	[redacted]/274
ABBV-951	0.41	0.42	0.4	60	0.19	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2049		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14

ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2186.28		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1947.23		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1987.70		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50

ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87

ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1967.04	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1865.61	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1790.65	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124

ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161

ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	1844.1	SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	1720.30	SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	1582.16	SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198

ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235

ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
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ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309

ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346

ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1680.18	SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	1645.17	SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	1645.17	SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	QID	Y-M: 20[redacted]-[redacted]
FLUOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.700 mg	QID	Y-M: 20[redacted]-[redacted]
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted]-[redacted]
TROSPIUM CHLORIDE	20 mg	BID	Y-M: 20[redacted]-[redacted]
LEVOTHYROXINE SODIUM	50 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	BID	Y-M: 20[redacted]-[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
ENTACAPONE	100.000 mg	QID	Y-M: 20[redacted]-[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted] / -152
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]-[redacted] / -117
HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE	250/250/500 mg	TID	Y-M: 20[redacted]-[redacted] / -117

HYDROCHLORIDE			
ENTACAPONE	100.000 mg	QID	Y-M: 20[redacted] / -92

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
FLUOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 11
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 9
TROSPIUM CHLORIDE	20 mg	BID	Y-M: 20[redacted]	ONGOING
LEVOTHYROXINE SODIUM	50 mg	QD	Y-M: 20[redacted]	ONGOING
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -117	Y-M: 20[redacted] / -4
HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	250/250/500 mg	TID	Y-M: 20[redacted] / -117	Y-M: 20[redacted] / -4
OLANZAPINE	5 mg	QD	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 11
ALPRAZOLAM	0.5 mg	TID	Y-M: 20[redacted] / 11	Y-M: 20[redacted] / 13
OLANZAPINE	7.5 mg	QD	Y-M: 20[redacted] / 11	Y-M: 20[redacted] / 19
TRAZODONE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 11	Y-M: 20[redacted] / 43
OLANZAPINE	10 mg	QD	Y-M: 20[redacted] / 19	Y-M: 20[redacted] / 32
FLUOXETINE	20 mg	QD	Y-M: 20[redacted] / 38	ONGOING
PARACETAMOL	1 g	BID	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 182
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 170
PASSIFLORA INCARNATA	200 mg	QID	Y-M: 20[redacted] / 143	Y-M: 20[redacted] / 193
OLANZAPINE	5 mg	QD	Y-M: 20[redacted] / 170	Y-M: 20[redacted] / 347

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTEMA, BARELY PERCEPTIBLE ON ABDOMEN (INFUSION SITE AREA).
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	5
Duration of AE	3 DAYS
Severity	MILD

Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL HALLUCINATIONS.
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 7
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	16
Duration of AE	10 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS.
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 7
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 8): GLUCOSE: 6.4 [3.9 - 6.1] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	23
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest - Somnolence

Event Description	SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	16
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #5: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 183
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	274
Duration of AE	92 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病性障害を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，双極性障害 I 型（慢性疾患であるが 20[redacted] 年より再発なし），甲状腺機能低下症，うつ病，非喫煙者，及び非飲酒者であった。

投与 7 日目，被験者は精神病性障害を発現した。投与 23 日目，精神病性障害は消失した。

本事象発現前の投与 3 日目に，すくみ足を改善するために治験薬の用量を増量した。被験者の報告によると，治験薬投与開始以降，活動性が増し，何となく気持ちの高ぶりがあり，不眠であった。被験者は朝，過剰なエネルギー及びモチベーションとともに目覚めたが，昼間になると疲労，思考停止，口内乾燥，及び便秘を認めた。投与 5 日目，これらの症状のため治験薬が減量された。

投与 7 日目，被験者の娘は被験者に不信，恐怖，精神運動不穏，及び幻視が認められているのを発見した。投与 8 日目，被験者の娘は被験者の幻覚が増していることを報告し，被験者は緊急治療室に行くよう指示された。同日，被験者は入院した。被験者の徴候及び症状は，興奮，不眠症，口内乾燥，便秘，幻視，及び妄想（ドーパミン作動性薬の副作用）であった。被験者の症状に対し，精神病をコントロールし，運動状態を改善することを目的とした治療を行った。投与 8 日目，被験者に投与していたサフィナミド及びプラミペキソールを中止し，オランザピンを 2.5 mg から 5 mg に増量した。投与 11 日目，被験者は明らかに良くなり，幻視もなく，被験者の症状は軽微な妄想が時折認められるのみで，非常にわずかとなった。更に，被験者の運動状態も改善した。被験者に投与していたフルオキセチンをトラゾドンに変更した。オランザピンの用量は徐々に増量を継続し，投与 19 日目に毎晩 10 mg まで増量した。投与 23 日目，精神科医が被験者を評価し，精神病の症状（又はその他のドーパミン作動性薬の副作用）は認められず，同日，本事象が消失したと結論付けた。

本事象の消失後，投与 24 日目にセルトラリン 25 mg を 2 日間投与し，その後 1 日 50 mg に増量した。退院時の投与 26 日目，被験者はドーパミン作動性薬の二次作用（精神病，疲労，口内乾燥，及び便秘）を認めなかった。

治験責任医師は本事象と ABBV-951 との関連性を関連あるかもしれないと判断したが，ABBV-951 だけでなく，ABBV-951 と併用し，投与を中止した他のドーパミンアゴニスト（MAO-B 阻害薬及びドーパミン拮抗薬）も同様と判断した。

治験責任医師によると，被験者にはうつ病，双極性障害の病歴があった。しかし，これらの病状は良好にコントロールされており，被験者は何年も症状がなかった。被験者は本事象の 20 年以上前に同様の事象を発現していた。

被験者にアルプラゾラム，オランザピン，及びトラゾドンが投与された。

The patient's past medications include:

SELEGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Psychosis (10037234) (Psychotic disorder (10061920)) [v.23.0] [10037234]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to a history of depression and bipolar disorder in an advanced aged patient with concomitant medications of safinamide and pramipexole

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD GLUCOSE:** 116 mg/dL (normal 70 to 110)

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 9[redacted] kg, weight at time of event 8[redacted] kg, weight loss occurred over a period of 6 months, no change in diet or mobility level with pump/infusion therapy, onset of weight loss did not coincide with worsening PD symptoms or eating difficulties, no other prevalent circumstances or reasons provided for weight loss, the subject experienced both temporal and previous episodes of depression and/or other psychiatric disorders.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
ジストニア	X			
幻覚				X
注入部位血管外漏出				X
注入部位浮腫				X
栄養障害				X
多臓器機能不全症候群	X		X	
パーキンソニズム	X	X		
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
HYPERTENSION	NOT REPORTED
HEPATITIS C VIRUS	19[redacted]
OVARIAN CYST	19[redacted]
ANXIETY AND DEPRESSION DISORDER	19[redacted]
KIDNEY CYSTS	19[redacted]
POST MENOPAUSAL	20[redacted]
HIP ARTHROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
SIMPLE ANEXECTOMY	19[redacted]
SIMPLE NEPHRECTOMY	19[redacted]
RIGHT HIP PROTESIS	20[redacted]
RIGHT HIP PROTESIS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.37	0.44	0	60	0.3	[redacted]20[redacted]/1
ABBV-951	0.37	0.44	0	60	0.3	[redacted]20[redacted]/2
ABBV-951	0.37	0.44	0	60	0.3	[redacted]20[redacted]/3
ABBV-951	0.45	0.54	0	60	0.3	[redacted]20[redacted]/9
ABBV-951	0.5	0.6	0	60	0.3	[redacted]20[redacted]/12
ABBV-951	0.38	0.45	0	60	0.3	[redacted]20[redacted]/15
ABBV-951	0.38	0.45	0	60	0.3	[redacted]20[redacted]/22
ABBV-951	0.41	0.49	0	60	0.3	[redacted]20[redacted]/25
ABBV-951	0.52	0.6	0.49	60	0.3	[redacted]20[redacted]/28
ABBV-951	0.52	0.6	0.49	60	0.3	[redacted]20[redacted]/32
ABBV-951	0.6	0.65	0.5	60	0.3	[redacted]20[redacted]/43
ABBV-951	0.6	0.65	0.55	60	0.3	[redacted]20[redacted]/46

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	852.89		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	1503.62		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2

ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 7	
ABBV-951	1663.27		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 9	
ABBV-951	2067.78		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	2212.92		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	2376.84		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1727.99		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	789.88		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	875.94		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	700.75		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	973.27		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1877.56		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1660.37		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	2266.19		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2595.4		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
PRAMIPEXOLE	0.700 mg	TID	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
BISOPROLOL FUMARATE	2.5 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
PAROXETINE	20 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted]
ROPINIROLE	4.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	32.000 mg	QD	Y-M: 20[redacted] / -276
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -194
GLECAPREVIR;PIBRENTASVIR	300/120 mg	QD	Y-M: 20[redacted] / -60

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BISOPROLOL FUMARATE	2.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
PAROXETINE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 66
GLECAPREVIR;PIBRENTASVIR	300/120 mg	QD	Y-M: 20[redacted] / -60	Y-M: 20[redacted] / -1
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 17	Y-M: 20[redacted] / 24
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 34
SERTRALINE	50 mg	QD	Y-M: 20[redacted] / 43	Y-M: 20[redacted] / 56
PHOSPHORIC ACID SODIUM;SODIUM PHOSPHATE DIBASIC	278 + 64 OTHER: MG/ML	PRN	Y-M: 20[redacted] / 46	Y-M: 20[redacted] / 46
LACTULOSE	10 g	TID	Y-M: 20[redacted] / 46	Y-M: 20[redacted] / 56
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / 56	Y-M: 20[redacted] / 57
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 56	Y-M: 20[redacted] / 63
URAPIDIL	16.6 mg	PRN	Y-M: 20[redacted] / 56	Y-M: 20[redacted] / 63
LACOSAMIDE	100 mg	BID	Y-M: 20[redacted] / 57	Y-M: 20[redacted] / 61
ONDANSETRON HYDROCHLORIDE	8 mg	PRN	Y-M: 20[redacted] / 57	Y-M: 20[redacted] / 119

SERTRALINE	50 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 58
ENOXAPARIN	40 mg	QD	Y-M: 20[redacted] / 58	Y-M: 20[redacted] / 62
DIAZEPAM	5 mg	QD	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 59
PHOSPHORIC ACID SODIUM;SODIUM PHOSPHATE DIBASIC	250 mL	QD	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 59
POTASSIUM CHLORIDE	30 mEq	QD	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 59
SODIUM CITRATE ACID;SODIUM LAURYL SULFATE;SORBIC ACID	10 mL	QD	Y-M: 20[redacted] / 59	Y-M: 20[redacted] / 59
DIAZEPAM	5 mg	PRN	Y-M: 20[redacted] / 60	Y-M: 20[redacted] / 61
POTASSIUM CHLORIDE	45 mEq	QD	Y-M: 20[redacted] / 60	Y-M: 20[redacted] / 67
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 60	Y-M: 20[redacted] / 100
LACOSAMIDE	200 mg	BID	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 66
DIAZEPAM	2.5 mg	PRN	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 101
VALPROIC ACID	750 mg	QD	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 63
FACTOR II (PROTHROMBIN);FACTOR IX;FACTOR VII (PROCONVERTIN);FACTOR X (STUART PROWER FACTOR);PROTEIN C (COAGULATION INHIBITOR);PROTEIN S	600 IU	QD	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 64
CLONAZEPAM	1 mg	BID	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 66
VALPROIC ACID	1 OTHER: MG/KG/H	QD	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 67
SODIUM CHLORIDE	250 mL	PRN	Y-M: 20[redacted] / 64	ONGOING
ENOXAPARIN	50 mg	QD	Y-M: 20[redacted] / 64	Y-M: 20[redacted] / 65
DOXAZOSIN	4 mg	QD	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 66
ENOXAPARIN	50 mg	BID	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 108
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 117
THIAMINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 69
LACOSAMIDE	200 mg	BID	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 72
PREDNISONE	50 mg	QD	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 72
ESOMEPRAZOLE	20 mg	QD	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 101
BISOPROLOL	2.5 mg	BID	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 117
MACROGOL	13.8 g	BID	Y-M: 20[redacted] / 67	Y-M: 20[redacted] / 70
DEXKETOPROFEN TROMETAMOL	50 mg	TID	Y-M: 20[redacted] / 68	Y-M: 20[redacted] / 70
POTASSIUM CHLORIDE	30 mEq	QD	Y-M: 20[redacted] / 68	Y-M: 20[redacted] / 71
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 70	Y-M: 20[redacted] / 101

AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1 g	TID	Y-M: 20[redacted] / 71	Y-M: 20[redacted] / 72
MACROGOL	13.8 g	TID	Y-M: 20[redacted] / 71	Y-M: 20[redacted] / 77
METHYLPREDNISOLONE	1000 mg	QD	Y-M: 20[redacted] / 72	Y-M: 20[redacted] / 76
CEFTRIAXONE	2 g	QD	Y-M: 20[redacted] / 72	Y-M: 20[redacted] / 89
FOSFOMYCIN	4 g	TID	Y-M: 20[redacted] / 73	Y-M: 20[redacted] / 78
IMMUNOGLOBULINS NOS	20 g	QD	Y-M: 20[redacted] / 76	Y-M: 20[redacted] / 80
PREDNISONE	50 mg	QD	Y-M: 20[redacted] / 77	Y-M: 20[redacted] / 86
MACROGOL	13.8 g	BID	Y-M: 20[redacted] / 78	Y-M: 20[redacted] / 79
FOSFOMYCIN	1 g	TID	Y-M: 20[redacted] / 78	Y-M: 20[redacted] / 81
METHYLPREDNISOLONE	1000 mg	QD	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 88
PAROXETINE	10 mg	QD	Y-M: 20[redacted] / 86	Y-M: 20[redacted] / 99
INSULIN ASPART	ACCORDING TO GLYCEMIA IU	PRN	Y-M: 20[redacted] / 88	ONGOING
DIAZEPAM	10 mg	QD	Y-M: 20[redacted] / 89	Y-M: 20[redacted] / 89
PREDNISONE	50 mg	QD	Y-M: 20[redacted] / 89	Y-M: 20[redacted] / 99
DIAZEPAM	5 mg	PRN	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 100
INSULIN GLARGINE	12 IU	QD	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 99
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 96
CLORAZEPATE DIPOTASSIUM	10 mg	QD	Y-M: 20[redacted] / 96	Y-M: 20[redacted] / 96
QUETIAPINE	50 mg	BID	Y-M: 20[redacted] / 96	Y-M: 20[redacted] / 101
QUETIAPINE	50 mg	PRN	Y-M: 20[redacted] / 99	Y-M: 20[redacted] / 101
ACENOCOUMAROL	2 mg	QD	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 100
DIAZEPAM	5 mg	TID	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 100
DOMPERIDONE	20 mg	TID	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 101
PREDNISONE	25 mg	QD	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 101
INSULIN GLARGINE	8 IU	QD	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 105
POTASSIUM CHLORIDE	40 mEq	QD	Y-M: 20[redacted] / 100	Y-M: 20[redacted] / 113
DIAZEPAM	2.5 mg	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 101
TIAPRIDE	50 mg	QD	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 101
ERYTHROMYCIN	250 mg	TID	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 105
TIAPRIDE	600 mg	QD	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 108
DEXAMETHASONE	2 mg	TID	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 116
DIAZEPAM	2.5 mg	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 119
DIAZEPAM	5 mg	PRN	Y-M: 20[redacted] / 101	Y-M: 20[redacted] / 119
OMEPRAZOLE SODIUM	40 mg	QD	Y-M: 20[redacted] / 102	ONGOING
CLONAZEPAM	1 mg	PRN	Y-M: 20[redacted] / 102	Y-M: 20[redacted] / 103

INSULIN GLARGINE	6 IU	QD	Y-M: 20[redacted] / 106	ONGOING
BACLOFEN	10 mg	TID	Y-M: 20[redacted] / 110	ONGOING
ENOXAPARIN	50 mg	BID	Y-M: 20[redacted] / 110	ONGOING
CLONAZEPAM	1 mg	TID	Y-M: 20[redacted] / 110	Y-M: 20[redacted] / 117
QUETIAPINE	25 mg	TID	Y-M: 20[redacted] / 113	ONGOING
DEXAMETHASONE	1 mg	TID	Y-M: 20[redacted] / 116	ONGOING
CLONAZEPAM	1 mg	TID	Y-M: 20[redacted] / 117	Y-M: 20[redacted] / 119
HYOSCINE BUTYLBROMIDE	40 mg	QD	Y-M: 20[redacted] / 119	ONGOING
MIDAZOLAM	30 mg	QD	Y-M: 20[redacted] / 119	ONGOING
MORPHINE	3 mg	PRN	Y-M: 20[redacted] / 119	ONGOING
MORPHINE	60 mg	QD	Y-M: 20[redacted] / 119	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SUBCUTANEOUS EXTRAVASATION AROUND THE INFUSION PLACE.
Preferred term	注入部位血管外漏出
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	3
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DEFINITE EDEMA (INFUSION SITE)

Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	9
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event

Event Description	DYSTONIC REACTION
Preferred term	ジストニア
AE Onset Date / Rx Day	[redacted]20[redacted] / 52
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	53
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GENERAL DETERIORATION OF THE SUBJECT (SEE SAE [redacted])
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 56
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	PARKINSONISM
Preferred term	パーキンソニズム
AE Onset Date / Rx Day	[redacted]20[redacted] / 56
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 56): CREATININE: 62 [46 - 92] UMOL/L; GLUCOSE: 5.4 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 133 [120 - 160] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.91 [1.5 - 4.5] 10^9/L; NPTST014-ANION GAP: 12.8 [7 - 16] MMOL/L; NPTST036-BASE EXCESS: 6.4 [-2 - 3] MMOL/L; NPTST039-BASS EXCESS

(STANDAR): 7.7 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST042-BICARBONATE: 32.3 [20 - 30] MMOL/L; NPTST043-BICARBONATE (STANDAR): 28.7 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 14.1 [NOT REPORTED - 5] MG/DL; NPTST065-CARBOXIHEMOGLOBIN: 1.1 [0.5 - 1.5] %; NPTST075-CHLORIDE: 102 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 33.8 [23 - 28] MMOL/L; NPTST157-IONIZED CALCIUM: 4.9 [4.7 - 5.2] MG/DL; NPTST162-LACTATE: 0.9 [0.7 - 2.1] MMOL/L; NPTST188-METAHEMOGLOBIN, WHOLE BLOOD: 0.8 [0 - 1.5] %; NPTST213-PCO2: 50.5 [40 - 50] MMHG; NPTST247-PO2: 21.6 [85 - 100] MMHG; NPTST271-QUICK INDEX: 66 [70 - 100] %; NPTST285-SATURATION 02: 32.7 [NOT REPORTED - NOT REPORTED] %; NPTST307-UREA: 31 [15 - 36] MG/DL; NPTST319-VPM: 12.3 [7.4 - 10.4] FL; PLATELETS: 116 [130 - 450] 10^9/L; POTASSIUM: 3.4 [3.4 - 5] MMOL/L; SODIUM: 147 [136 - 146] MMOL/L; PH: 7.414 [7.35 - 7.5] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 57): ALANINE AMINOTRANSFERASE: 4 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 13 [14 - 36] U/L; LEUKOCYTES: 5.8 [4 - 11] 10^9/L; LYMPHOCYTES: 0.95 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 16.4 [20 - 52] %; NPTST057-C-REACTIVE PROTEIN (CRP): 20.7 [NOT REPORTED - 5] MG/L; NPTST094-CREATIN KINASA: 21 [30 - 135] U/L; NPTST273-RDW: 16.2 [12 - 16] %; NPTST319-VPM: 13 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 73.7 [37 - 72] %; PLATELETS: 111 [130 - 450] 10^9/L; POTASSIUM: 3.3 [3.5 - 5.1] MMOL/L; [redacted]20[redacted] (RX DAY 59): ALANINE AMINOTRANSFERASE: 4 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 11 [14 - 36] U/L; EOSINOPHILS/LEUKOCYTES: 0.7 [1 - 6] %; GLUCOSE: 6.7 [4.1 - 5.9] MMOL/L; LEUKOCYTES: 6.7 [4 - 11] 10^9/L; LYMPHOCYTES: 0.76 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 11.5 [20 - 52] %; MONOCYTES: 0.32 [0.4 - 1.1] 10^9/L; NPTST057-C-REACTIVE PROTEIN (CRP): 25.8 [NOT REPORTED - 5] MG/L; NPTST156-INR: 1.4 [1 - 1.3] RATIO; NPTST271-QUICK INDEX: 54 [70 - 100] %; NPTST273-RDW: 16.2 [12 - 16] %; NPTST319-VPM: 13 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 81.9 [37 - 72] %; PLATELETS: 110 [130 - 450] 10^9/L; POTASSIUM: 3 [3.5 - 5.1] MMOL/L; SODIUM: 146 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 61): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; GLUCOSE: 6.4 [4.1 - 5.9] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 19.3 [NOT REPORTED - 5] MG/L; NPTST118-FERRITIN: 986 [11.1 - 264] NG/ML; NPTST158-IRON: 215 [37 - 170] UG/DL; NPTST167-LDH: 267 [120 - 246] U/L; NPTST299-TRANSFERRIN SATURATION INDEX: 81 [15 - 45] %; [redacted]20[redacted] (RX DAY 62): ALANINE AMINOTRANSFERASE: 5 [8 - 30] U/L; GLUCOSE: 7.2 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 118 [120 - 155] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.82 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 13.6 [20 - 52] %; MONOCYTES: 0.32 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 6.7 [7 - 16] MMOL/L; NPTST031-APTT: 20.7 [22 - 31] SEC; NPTST057-C-REACTIVE PROTEIN (CRP): 9.4 [0 - 5] MG/L; NPTST072-CHCM: 31.2 [33 - 37] G/DL; NPTST075-CHLORIDE: 110 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 29.1 [23 - 28] MMOL/L; NPTST095-CREATIN KINASE: 27 [30 - 135] U/L; NPTST156-INR: 1.4 [1 - 1.3] RATIO; NPTST247-PO2: 69.9 [85 - 100] MMHG; NPTST271-QUICK INDEX: 54 [70 - 100] %; NPTST273-RDW: 18.2 [12 - 16] %; NPTST308-URIC ACID: 1.6 [2.5 - 6.2] MG/DL; NPTST319-VPM: 12.7 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 76.5 [37 - 72] %; PLATELETS: 120 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 63): EOSINOPHILS/LEUKOCYTES: 6.1 [1 - 6] %; HEMOGLOBIN: 116 [120 - 155] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LEUKOCYTES: 5.9 [4 - 11] 10^9/L; LYMPHOCYTES: 1.24 [1.5 - 4.5] 10^9/L; LYMPHOCYTES: 0.83 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 14.1 [20 - 52] %; MONOCYTES: 0.3 [0.4 - 1.1] 10^9/L; MONOCYTES: 0.31 [0.4 - 1.1] 10^9/L; NPTST031-APTT: 21 [22 - 31] SEC; NPTST072-CHCM: 31.8 [33 - 37] G/DL; NPTST072-CHCM: 32.7 [33 - 37] G/DL; NPTST156-INR: 1.3 [1 - 1.3] UNIT NOT REPORTED; NPTST271-QUICK INDEX: 62 [70 - 100] %; NPTST273-RDW: 18.3 [12 - 16] %; NPTST273-RDW: 18.1 [12 - 16] %; NPTST319-VPM: 11.9 [7.4 - 10.4] FL; NPTST319-VPM: 12.1 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 73 [37 - 72] %; PLATELETS: 94 [130 - 450] 10^9/L; PLATELETS: 120 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 64): ERYTHROCYTES: 0 [0 - 5] 10^12/L; GLUCOSE: 3.7 [3.9 - 6.1] MMOL/L; LEUKOCYTES: 0 [0 - 5] 10^9/L; NPTST012-ANFIFISINA ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST102-CV2 ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST124-GAD ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST140-HU ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST201-NMDA RECEPTOR ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST245-PNMA2 ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST280-RI

ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST323-YO ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; PROTEIN: 510 [120 - 600] MG/L; [redacted]20[redacted] (RX DAY 66): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; ALBUMIN: 34 [35 - 50] G/L; CREATININE: 44 [46 - 92] UMOL/L; GLUCOSE: 6.5 [4.1 - 5.9] MMOL/L; LEUKOCYTES: 7.6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.67 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.9 [20 - 52] %; MONOCYTES: 0.29 [0.4 - 1.1] 10^9/L; NPTST015-ANTI-NEUTROPHIL CYTOPLASMIC ANT: C-ANCA: NEGATIV [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST016-ANTI-NEUTROPHIL PERINUCLEAR ANT: P-ANCA: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST017-ANTICOAGULANT LUPIC CONFIRMATIO: 1.19 [NOT REPORTED - NOT REPORTED] RATIO; NPTST018-ANTICOAGULANT LUPIC SCREENING-D: 1.22 [0 - 1.2] RATIO; NPTST019-ANTICOAGULANT LUPICO SCREENING-: 0.89 [0 - 1.2] RATIO; NPTST028-ANTINUCLEAR ANTIBODY, INDIRECT: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST040-BETA-2 GLYCOPROTEIN 1 IGG ANTIB: 3 [0 - 20] U/ML; NPTST041-BETA-2 GLYCOPROTEIN ANTIBODIES: 1 [0 - 20] U/ML; NPTST060-C3C COMPLEMENT, ANTIGEN: 115 [88 - 165] MG/DL; NPTST061-C4 COMPLEMENT, ANTIGEN: 21 [14 - 44] MG/DL; NPTST066-CARDIOLIPIN ANTIBODIES IGM: 2.1 [0 - 20] U/ML; NPTST067-CARDIOLIPIN IGG ANTIBODIES: 15.8 [0 - 20] U/ML; NPTST076-CHROMOGENIC PROTEIN C: 72 [70 - 140] %; NPTST094-CREATIN KINASA: 20 [30 - 135] U/L; NPTST098-CRYOGLOBULINS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST108-DOUBLE-STRANDED DNA ANTIBODIES: 7.3 [NOT REPORTED - 10] IU/ML; NPTST110-ENA RNP ANTIBODIES: 2.3 [NOT REPORTED - 10] U/ML; NPTST111-ENA SM ANTIBODIES: 2.2 [NOT REPORTED - 10] U/ML; NPTST112-ENA SS-A (RO) ANTIBODIES (RO-60: <0.3 [NOT REPORTED - 10] U/ML; NPTST117-EXTRACTABLE NUCLEAR ANTIGEN ANT: 0.4 [NOT REPORTED - 10] U/ML; NPTST128-GEN FACTOR V LEIDEN (MUTATION G: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST139-HOMOCYSTEINE: 41.4 [5 - 12] UMOL/L; NPTST155-INMUNOGLOBULIN G: 1332 [680 - 1530] MG/DL; NPTST175-LUPIC ANTICOAGULANT CONFIRMATIO: 1.1 [0 - 1.2] RATIO; NPTST176-LUPIC ANTICOAGULANT CONFIRMATIO: 1.1 [0 - 1.2] RATIO; NPTST177-LUPIC ANTICOAGULANT CONFIRMATIO: 0.75 [0 - 1.16] RATIO; NPTST203-NT-PROBNP: 905 [0 - 125] PG/ML; NPTST215-PCR: 38.3 [0 - 5] MG/L; NPTST258-PREALBUMIN: 12.7 [17.6 - 36] MG/DL; NPTST263-PROTEIN S ANTIGEN: 127.7 [55 - 123] %; NPTST265-PROTHROMBIN GENE (G20210A MUTAT: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST269-QUANTITATIVE INMUNOGLOBULIN A: 198 [70 - 400] MG/DL; NPTST270-QUANTITATIVE INMUNOGLOBULIN M: 81 [60 - 260] MG/DL; NPTST273-RDW: 16.2 [12 - 16] %; NPTST275-RESISTANCE TO ACTIVATED PROTEIN: 3.28 [2 - 3.5] RATIO; NPTST302-TROPONIN I: 0.01 [0 - 0.12] NG/ML; NPTST308-URIC ACID: 1 [2.5 - 6.2] MG/DL; NPTST319-VPM: 12.9 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 85.5 [37 - 72] %; PLATELETS: 106 [130 - 450] 10^9/L; TRIGLYCERIDES: 1.71 [0 - 1.7] MMOL/L; [redacted]20[redacted] (RX DAY 71): ALBUMIN: 31 [35 - 50] G/L; CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS/LEUKOCYTES: 0.7 [1 - 6] %; GLUCOSE: 5.9 [4.1 - 5.9] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 107 [120 - 155] G/L; LEUKOCYTES: 12.7 [4 - 11] 10^9/L; LYMPHOCYTES: 1.03 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.1 [20 - 52] %; MONOCYTES: 1.14 [0.4 - 1.1] 10^9/L; NPTST029-ANTIROGLOBULIN ANTIBODIES: 10 [10 - 100] IU/ML; NPTST031-APTT: 19.6 [22 - 31] SEC; NPTST057-C-REACTIVE PROTEIN (CRP): 15.6 [0 - 5] MG/L; NPTST072-CHCM: 32.1 [33 - 37] G/DL; NPTST091-CORTISOL: 29.5 [4.5 - 22.7] UG/DL; NPTST118-FERRITIN: 432 [11.1 - 264] NG/ML; NPTST242-PHOSPHATE: 2.2 [2.5 - 4.5] MG/DL; NPTST273-RDW: 16.1 [12 - 16] %; NPTST298-TPO ANTIBODIES: 1.4 [1 - 16] IU/ML; NPTST319-VPM: 10.7 [7.4 - 10.4] FL; NEUTROPHILS: 10.36 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 81.4 [37 - 72] %; SODIUM: 135 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 72): GLUCOSE: 9.8 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 104 [120 - 160] G/L; NPTST006-ACTUALBASE EXCESS: 4.2 [-2 - 3] MMOL/L; NPTST087-CO2 TOTAL: 28.8 [23 - 28.8] MMOL/L; NPTST213-PCO2: 36.5 [40 - 50] MMHG; NPTST247-PO2: 72.3 [85 - 100] MMHG; [redacted]20[redacted] (RX DAY 78): NPTST306-UNSEEN BLOOD: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 79): ALANINE AMINOTRANSFERASE: 41 [8 - 30] U/L; ALBUMIN: 33 [35 - 50] G/L; ASPARTATE AMINOTRANSFERASE: 43 [14 - 36] U/L; CALCIUM: 2.07 [2.1 - 2.55] MMOL/L; CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS: 0.03 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.3 [1 - 6] %; ERYTHROCYTES: 0 [0 - 0] 10^12/L; GLUCOSE: 10

[3.9 - 6.1] MMOL/L; GLUCOSE: 10 [4.1 - 5.9] MMOL/L; GLUCOSE: 7 [4.6 - 6.4] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 109 [120 - 160] G/L; HEMOGLOBIN: 104 [120 - 155] G/L; LEUKOCYTES: 9.6 [4 - 11] 10^9/L; LEUKOCYTES: 0 [0 - 5] 10^9/L; LYMPHOCYTES: 1.03 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 10.7 [20 - 52] %; MONOCYTES: 0.34 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 6.7 [7 - 16] MMOL/L; NPTST031-APTT: 21 [22 - 31] SEC; NPTST044-BICARBONATO: 30.9 [20 - 30] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 5.7 [0 - 5] MG/L; NPTST062-CALCIO IONIZADO: 4.5 [4.7 - 5.2] MG/DL; NPTST072-CHCM: 31.4 [33 - 37] G/DL; NPTST085-CLOURO: 116 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 32.2 [23 - 28] MMOL/L; NPTST103-CV2 ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST116-EXCESO BASES ACTUAL: 6.8 [-2 - 3] MMOL/L; NPTST129-GGT: 229 [12 - 43] U/L; NPTST246-PNMA2 ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST247-PO2: 54.8 [85 - 100] MMHG; NPTST259-PREALBUMINA: 45.3 [17.6 - 36] MG/DL; NPTST273-RDW: 18.5 [12 - 16] %; NPTST307-UREA: 42 [15 - 36] MG/DL; NPTST319-VPM: 11.6 [7.4 - 10.4] FL; NEUTROPHILS: 8.07 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 84.4 [37 - 72] %; PROTEIN: 520 [120 - 600] MG/L; SODIUM: 151 [136 - 146] MMOL/L; SODIUM: 149 [137 - 145] MMOL/L; TRIGLYCERIDES: 3.05 [0 - 1.7] MMOL/L; URATE: 89.23 [148.71 - 368.81] UMOL/L; [redacted]20[redacted] (RX DAY 80): NPTST013-ANFIFISINA ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST020-ANTICUERPOS ANTI-GLICINAR: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST021-ANTICUERPOS CANALES POTASIO: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST024-ANTICUERPOS ONCONEURONALES (HU,: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST141-HU ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST148-IHQ SUPERFICIE NEURONAL: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST202-NMDA RECEPTOR ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST281-RI ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST324-YO ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 87): ALANINE AMINOTRANSFERASE: 68 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 38 [14 - 36] U/L; CHOLESTEROL: 6.78 [0 - 5.17] MMOL/L; CREATININE: 44 [46 - 92] UMOL/L; EOSINOPHILS: 0 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0 [1 - 6] %; ERYTHROCYTES: 3.5 [3.8 - 5.2] 10^12/L; GLUCOSE: 10.2 [4.1 - 5.9] MMOL/L; GLUCOSE: 10.8 [3.9 - 6.1] MMOL/L; HEMATOCRIT: 0.31 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 106 [120 - 155] G/L; HEMOGLOBIN: 109 [120 - 160] G/L; LEUKOCYTES: 7.8 [4 - 11] 10^9/L; LYMPHOCYTES: 0.35 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 4.6 [20 - 52] %; MONOCYTES: 0.22 [0.4 - 1.1] 10^9/L; MONOCYTES/LEUKOCYTES: 2.9 [3 - 13] %; NPTST031-APTT: 19.2 [22 - 31] SEC; NPTST084-CLORURO: 107 [98 - 106] MMOL/L; NPTST116-EXCESO BASES ACTUAL: 3.2 [-2 - 3] MMOL/L; NPTST119-FERRITINA: 674 [11.1 - 264] NG/ML; NPTST129-GGT: 198 [12 - 43] U/L; NPTST163-LACTATO: 3.3 [0.7 - 2.1] MMOL/L; NPTST179-MAGNESIO: 2.4 [1.6 - 2.3] MG/DL; NPTST213-PCO2: 35.1 [40 - 50] MMHG; NPTST247-PO2: 46.3 [85 - 100] MMHG; NPTST259-PREALBUMINA: 44.2 [17.6 - 36] MG/DL; NPTST273-RDW: 21.3 [12 - 16] %; NPTST307-UREA: 75 [15 - 36] MG/DL; NPTST319-VPM: 16.3 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 92.3 [37 - 72] %; PLATELETS: 98 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 96): CREATININE: 44 [46 - 92] UMOL/L; NPTST071-CERULOPLASMINA: 17 [18 - 53] MG/DL; NPTST088-COBRE: 67 [76 - 152] UG/DL; NPTST119-FERRITINA: 419 [11.1 - 264] NG/ML; NPTST129-GGT: 125 [12 - 43] U/L; NPTST179-MAGNESIO: 2.4 [1.6 - 2.3] MG/DL; NPTST259-PREALBUMINA: 39.5 [17.6 - 36] MG/DL; NPTST307-UREA: 72 [15 - 36] MG/DL; SODIUM: 135 [137 - 145] MMOL/L; TRIGLYCERIDES: 1.79 [0 - 1.7] MMOL/L; [redacted]20[redacted] (RX DAY 101): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; CREATININE: 35 [46 - 92] UMOL/L; ERYTHROCYTES: 3.4 [3.8 - 5.2] 10^12/L; HEMATOCRIT: 0.32 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 100 [120 - 160] G/L; HEMOGLOBIN: 103 [120 - 155] G/L; LEUKOCYTES: 5.5 [4 - 11] 10^9/L; LYMPHOCYTES: 0.97 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 17.8 [20 - 52] %; MONOCYTES: 0.36 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 4.8 [7 - 16] MMOL/L; NPTST072-CHCM: 32.3 [33 - 37] G/DL; NPTST084-CLORURO: 110 [98 - 106] MMOL/L; NPTST129-GGT: 79 [12 - 43] U/L; NPTST213-PCO2: 37.7 [40 - 50] MMHG; NPTST247-PO2: 73.8 [85 - 100] MMHG; NPTST273-RDW: 21.7 [12 - 16] %; PLATELETS: 125 [130 - 450] 10^9/L; PROTEIN: 56 [63 - 82] G/L; [redacted]20[redacted] (RX DAY 107): CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS: 0.01 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.2 [1 - 6] %; ERYTHROCYTES: 3.3

[3.8 - 5.2] 10^12/L; GLUCOSE: 8.8 [4.1 - 5.9] MMOL/L; HEMATOCRIT: 0.31 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 98 [120 - 155] G/L; LEUKOCYTES: 4.9 [4 - 11] 10^9/L; LYMPHOCYTES: 0.16 [0.4 - 1.1] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 3.2 [20 - 52] %; MONOCYTES: 0.16 [0.4 - 1.1] 10^9/L; NPTST057-C-REACTIVE PROTEIN (CRP): 93.4 [NOT REPORTED - 5] MG/L; NPTST072-CHCM: 32.1 [33 - 37] G/DL; NPTST149-INDICE DE QUICK: 69 [70 - 100] %; NPTST273-RDW: 20.7 [12 - 16] %; NPTST307-UREA: 10 [15 - 36] MG/DL; NEUTROPHILS/LEUKOCYTES: 92.4 [37 - 72] %; PLATELETS: 88 [130 - 450] 10^9/L; POTASSIUM: 3.4 [3.5 - 5.1] MMOL/L; SODIUM: 136 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 108): EOSINOPHILS: 0.01 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.2 [1 - 6] %; ERYTHROCYTES: 3.2 [3.8 - 5.2] 10^12/L; HEMATOCRIT: 0.3 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 98 [120 - 155] G/L; LEUKOCYTES: 4.1 [4 - 11] 10^9/L; LYMPHOCYTES: 0.35 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.4 [20 - 52] %; MONOCYTES: 0.17 [0.4 - 1.1] 10^9/L; NPTST031-APTT: 21.4 [22 - 31] SEC; NPTST072-CHCM: 32.6 [33 - 37] G/DL; NPTST273-RDW: 20.7 [12 - 16] %; NPTST316-VCM: 94.3 [82 - 94] FL; NEUTROPHILS/LEUKOCYTES: 85.4 [37 - 72] %; PLATELETS: 74 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 116): CREATININE: 27 [46 - 92] UMOL/L; NPTST125-GAD ANTICUERPOS: 7.7 [0 - 17] IU/ML; NPTST145-IA2 (TIROSINA FOSFATASA) ANTICU: 7.2 [0 - 28] IU/ML; NPTST307-UREA: 47 [15 - 36] MG/DL

Microbiology

[redacted]20[redacted] (RX DAY 57): URINE UROCULTIVO: NEGATIVE; [redacted]20[redacted] (RX DAY 64): CEREBROSPINAL FLUID CULTIVO BACTERIOLOGICO: NEGATIVE; CEREBROSPINAL FLUID PCR CITOMEGALOVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR CRYPTOCOCCUS NEOFORMANS/GAT: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR ESCHERICHIA COLI K1 (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR HAEMOPHILLUS INFLUENZAE (FI: NEGATIVE; CEREBROSPINAL FLUID PCR LISTERIA MONOCYTOGENES (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR NEISSERIA MENINGITIDIS (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR PARECHOVIRUS HUMANO (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS AGALACTIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS PNEUMONIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES HUMANO 6 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 1 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 2 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA ZOSTER (FIL: NEGATIVE; [redacted]20[redacted] (RX DAY 65): BLOOD CITOMEGALOVIRUS IGG: POSITIVE-IGG (CURED INFECTION); BLOOD CITOMEGALOVIRUS IGM: NEGATIVE; BLOOD IGG BORRELLIA BURGDORGFERI: NEGATIVE; BLOOD IGM BORRELLIA BURGDORGFERI: NEGATIVE; BLOOD PCR VIRUS HERPES SIMPLEX 1: NEGATIVE; BLOOD PCR VIRUS HERPES SIMPLEX 2: NEGATIVE; BLOOD PCR VIRUS VARICELLA-ZOSTER: NEGATIVE; BLOOD ROSA DE BENGALA (BRUCELLA): NEGATIVE; [redacted]20[redacted] (RX DAY 66): BLOOD AC ANTI-HBS (HEPATITIS B): NEGATIVE; BLOOD AC. HETEROFILOS V. EPSTEIN-BARR: NEGATIVE; BLOOD ANTICUERPOS IGG VHE (HEPATITIS: NEGATIVE; BLOOD ANTICUERPOS IGM VHE (HEPATITIS: NEGATIVE; BLOOD ANTICUERPOS T. PALLIDUM TOTALES: NEGATIVE; BLOOD ANTICUERPOS VHC (HEPATITIS C): POSITIVE-CURED INFECTION; BLOOD ANTICUERPOS VIH 1+2: NEGATIVE; BLOOD CARGA VIRAL VHC: NEGATIVE; BLOOD CITOMEGALOVIRUS IGG: POSITIVE-CURED INFECTION; BLOOD CITOMEGALOVIRUS IGM: NEGATIVE; BLOOD HBSAG (HEPATITIS B): NEGATIVE; BLOOD TOXOPLASMA GONDII IGG: NEGATIVE; BLOOD TOXOPLASMA GONDII IGM: NEGATIVE; BLOOD VCA (V.EPSTEIN-BARR) IGG: POSITIVE-CURED INFECTION; BLOOD VCA (V.EPSTEIN-BARR) IGM: NEGATIVE; BLOOD VHS 1+2 IGG: POSITIVE-CURED INFECTION; BLOOD VHS 1+2 IGM: NEGATIVE; [redacted]20[redacted] (RX DAY 79): CEREBROSPINAL FLUID CARGA VIRAL CMV: NEGATIVE; CEREBROSPINAL FLUID CARGA VIRAL VIRUS BK: NEGATIVE; CEREBROSPINAL FLUID CULTIVO BACTERIOLOGICO: NEGATIVE; CEREBROSPINAL FLUID PCR CITOMEGALOVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR CRYPTOCOCCUS NEOFORMANS/GAT: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR ESCHERICHIA COLI K1 (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR HAEMOPHILLUS INFLUENZAE (FI: NEGATIVE; CEREBROSPINAL FLUID PCR LISTERIA MONOCYTOGENES (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR NEISSERIA MENINGITIDIS

(FIL: NEGATIVE; CEREBROSPINAL FLUID PCR PARECHOVIRUS HUMANO (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS AGALACTIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS PNEUMONIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES HUMANO 6 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 1 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 2 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLEX 1: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLEX 2: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA ZOSTER (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA-ZOSTER: NEGATIVE

AE Stopped Rx Day	119 (63 DAYS AFTER LAST TREATMENT)
Duration of AE	64 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	PROGRESSIVE GENERAL DETERIORATION
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #6: Event of Interest - Weight Loss

Event Description	MALNUTRITION
Preferred term	栄養障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 66 (10 days after last treatment)
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Serious Adverse Event, Death

Event Description	MULTIPLE ORGAN FAILURE
Preferred term	多臓器機能不全症候群
AE Onset Date / Rx Day	[redacted]20[redacted] / 119 (63 days after last treatment)
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 56): CREATININE: 62 [46 - 92] UMOL/L; GLUCOSE: 5.4 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 133 [120 - 160] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.91 [1.5 - 4.5] 10^9/L; NPTST014-ANION GAP: 12.8 [7 - 16] MMOL/L; NPTST036-BASE EXCESS: 6.4 [-2 - 3] MMOL/L; NPTST039-BASS EXCESS (STANDAR): 7.7 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST042-BICARBONATE: 32.3 [20 - 30] MMOL/L; NPTST043-BICARBONATE (STANDAR): 28.7 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 14.1 [NOT REPORTED - 5] MG/DL; NPTST065-CARBOXIHEMOGLOBIN: 1.1 [0.5 - 1.5] %; NPTST075-CHLORIDE: 102 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 33.8 [23 - 28] MMOL/L; NPTST157-IONIZED CALCIUM: 4.9 [4.7 - 5.2] MG/DL; NPTST162-LACTATE: 0.9 [0.7 - 2.1] MMOL/L; NPTST188-METAHEMOGLOBIN, WHOLE BLOOD: 0.8 [0 - 1.5] %; NPTST213-PCO2: 50.5 [40 - 50] MMHG; NPTST247-PO2: 21.6 [85 - 100] MMHG; NPTST271-QUICK INDEX: 66 [70 - 100] %; NPTST285-SATURATION 02: 32.7 [NOT REPORTED - NOT REPORTED] %; NPTST307-UREA: 31 [15 - 36] MG/DL; NPTST319-VPM: 12.3 [7.4 - 10.4] FL; PLATELETS: 116 [130 - 450] 10^9/L; POTASSIUM: 3.4 [3.4 - 5] MMOL/L; SODIUM: 147 [136 - 146] MMOL/L; PH: 7.414 [7.35 - 7.5] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 57): ALANINE AMINOTRANSFERASE: 4 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 13 [14 - 36] U/L; LEUKOCYTES: 5.8 [4 - 11] 10^9/L; LYMPHOCYTES: 0.95 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 16.4 [20 - 52] %; NPTST057-C-REACTIVE PROTEIN (CRP): 20.7 [NOT REPORTED - 5] MG/L; NPTST094-CREATIN KINASA: 21 [30 - 135] U/L; NPTST273-RDW: 16.2 [12 - 16] %; NPTST319-VPM: 13 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 73.7 [37 - 72] %; PLATELETS: 111 [130 - 450] 10^9/L; POTASSIUM: 3.3 [3.5 - 5.1] MMOL/L; [redacted]20[redacted] (RX DAY 59): ALANINE AMINOTRANSFERASE: 4 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 11 [14 - 36] U/L; EOSINOPHILS/LEUKOCYTES: 0.7 [1 - 6] %; GLUCOSE: 6.7 [4.1 - 5.9] MMOL/L; LEUKOCYTES: 6.7 [4 - 11] 10^9/L; LYMPHOCYTES: 0.76 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 11.5 [20 - 52] %; MONOCYTES: 0.32 [0.4 - 1.1] 10^9/L; NPTST057-C-REACTIVE PROTEIN (CRP): 25.8 [NOT REPORTED - 5] MG/L; NPTST156-INR: 1.4 [1 - 1.3] RATIO; NPTST271-QUICK INDEX: 54 [70 - 100] %; NPTST273-RDW: 16.2 [12 - 16] %; NPTST319-VPM: 13 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 81.9 [37 - 72] %; PLATELETS: 110 [130 - 450] 10^9/L; POTASSIUM: 3 [3.5 - 5.1] MMOL/L; SODIUM: 146 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 61): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; GLUCOSE: 6.4 [4.1 - 5.9] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 19.3 [NOT REPORTED - 5] MG/L; NPTST118-FERRITIN: 986 [11.1 - 264] NG/ML; NPTST158-IRON: 215 [37 - 170] UG/DL; NPTST167-LDH: 267 [120 - 246] U/L; NPTST299-TRANSFERRIN SATURATION INDEX: 81 [15 - 45] %; [redacted]20[redacted] (RX DAY 62): ALANINE AMINOTRANSFERASE: 5 [8 - 30] U/L; GLUCOSE: 7.2 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 118 [120 - 155] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.82 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 13.6 [20 - 52] %; MONOCYTES: 0.32 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 6.7 [7 - 16] MMOL/L; NPTST031-APTT: 20.7 [22 - 31] SEC; NPTST057-C-REACTIVE PROTEIN (CRP): 9.4 [0 - 5] MG/L; NPTST072-CHCM: 31.2 [33 - 37] G/DL; NPTST075-CHLORIDE: 110 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 29.1 [23 - 28] MMOL/L; NPTST095-CREATIN KINASE: 27 [30 - 135] U/L; NPTST156-INR: 1.4 [1 - 1.3] RATIO; NPTST247-PO2: 69.9 [85 - 100] MMHG; NPTST271-QUICK INDEX: 54 [70 - 100] %; NPTST273-RDW: 18.2

[12 - 16] %; NPTST308-URIC ACID: 1.6 [2.5 - 6.2] MG/DL; NPTST319-VPM: 12.7 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 76.5 [37 - 72] %; PLATELETS: 120 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 63): EOSINOPHILS/LEUKOCYTES: 6.1 [1 - 6] %; HEMOGLOBIN: 116 [120 - 155] G/L; LEUKOCYTES: 6 [4 - 11] 10^9/L; LEUKOCYTES: 5.9 [4 - 11] 10^9/L; LYMPHOCYTES: 1.24 [1.5 - 4.5] 10^9/L; LYMPHOCYTES: 0.83 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 14.1 [20 - 52] %; MONOCYTES: 0.3 [0.4 - 1.1] 10^9/L; MONOCYTES: 0.31 [0.4 - 1.1] 10^9/L; NPTST031-APTT: 21 [22 - 31] SEC; NPTST072-CHCM: 31.8 [33 - 37] G/DL; NPTST072-CHCM: 32.7 [33 - 37] G/DL; NPTST156-INR: 1.3 [1 - 1.3] UNIT NOT REPORTED; NPTST271-QUICK INDEX: 62 [70 - 100] %; NPTST273-RDW: 18.3 [12 - 16] %; NPTST273-RDW: 18.1 [12 - 16] %; NPTST319-VPM: 11.9 [7.4 - 10.4] FL; NPTST319-VPM: 12.1 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 73 [37 - 72] %; PLATELETS: 94 [130 - 450] 10^9/L; PLATELETS: 120 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 64): ERYTHROCYTES: 0 [0 - 5] 10^12/L; GLUCOSE: 3.7 [3.9 - 6.1] MMOL/L; LEUKOCYTES: 0 [0 - 5] 10^9/L; NPTST012-ANFIFISINA ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST102-CV2 ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST124-GAD ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST140-HU ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST201-NMDA RECEPTOR ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST245-PNMA2 ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST280-RI ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST323-YO ANTIBODIES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; PROTEIN: 510 [120 - 600] MG/L; [redacted]20[redacted] (RX DAY 66): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; ALBUMIN: 34 [35 - 50] G/L; CREATININE: 44 [46 - 92] UMOL/L; GLUCOSE: 6.5 [4.1 - 5.9] MMOL/L; LEUKOCYTES: 7.6 [4 - 11] 10^9/L; LYMPHOCYTES: 0.67 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.9 [20 - 52] %; MONOCYTES: 0.29 [0.4 - 1.1] 10^9/L; NPTST015-ANTI-NEUTROPHIL CYTOPLASMIC ANT: C-ANCA: NEGATIV [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST016-ANTI-NEUTROPHIL PERINUCLEAR ANT: P-ANCA: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST017-ANTICOAGULANT LUPIC CONFIRMATIO: 1.19 [NOT REPORTED - NOT REPORTED] RATIO; NPTST018-ANTICOAGULANT LUPIC SCREENING-D: 1.22 [0 - 1.2] RATIO; NPTST019-ANTICOAGULANT LUPICO SCREENING-: 0.89 [0 - 1.2] RATIO; NPTST028-ANTINUCLEAR ANTIBODY, INDIRECT: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST040-BETA-2 GLYCOPROTEIN 1 IGG ANTIB: 3 [0 - 20] U/ML; NPTST041-BETA-2 GLYCOPROTEIN ANTIBODIES: 1 [0 - 20] U/ML; NPTST060-C3C COMPLEMENT, ANTIGEN: 115 [88 - 165] MG/DL; NPTST061-C4 COMPLEMENT, ANTIGEN: 21 [14 - 44] MG/DL; NPTST066-CARDIOLIPIN ANTIBODIES IGM: 2.1 [0 - 20] U/ML; NPTST067-CARDIOLIPIN IGG ANTIBODIES: 15.8 [0 - 20] U/ML; NPTST076-CHROMOGENIC PROTEIN C: 72 [70 - 140] %; NPTST094-CREATIN KINASA: 20 [30 - 135] U/L; NPTST098-CRYOGLOBULINS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST108-DOUBLE-STRANDED DNA ANTIBODIES: 7.3 [NOT REPORTED - 10] IU/ML; NPTST110-ENA RNP ANTIBODIES: 2.3 [NOT REPORTED - 10] U/ML; NPTST111-ENA SM ANTIBODIES: 2.2 [NOT REPORTED - 10] U/ML; NPTST112-ENA SS-A (RO) ANTIBODIES (RO-60: <0.3 [NOT REPORTED - 10] U/ML; NPTST117-EXTRACTABLE NUCLEAR ANTIGEN ANT: 0.4 [NOT REPORTED - 10] U/ML; NPTST128-GEN FACTOR V LEIDEN (MUTATION G: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST139-HOMOCYSTEINE: 41.4 [5 - 12] UMOL/L; NPTST155-INMUNOGLOBULIN G: 1332 [680 - 1530] MG/DL; NPTST175-LUPIC ANTICOAGULANT CONFIRMATIO: 1.1 [0 - 1.2] RATIO; NPTST176-LUPIC ANTICOAGULANT CONFIRMATIO: 1.1 [0 - 1.2] RATIO; NPTST177-LUPIC ANTICOAGULANT CONFIRMATIO: 0.75 [0 - 1.16] RATIO; NPTST203-NT-PROBNP: 905 [0 - 125] PG/ML; NPTST215-PCR: 38.3 [0 - 5] MG/L; NPTST258-PREALBUMIN: 12.7 [17.6 - 36] MG/DL; NPTST263-PROTEIN S ANTIGEN: 127.7 [55 - 123] %; NPTST265-PROTHROMBIN GENE (G20210A MUTAT: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST269-QUANTITATIVE INMUNOGLOBULIN A: 198 [70 - 400] MG/DL; NPTST270-QUANTITATIVE INMUNOGLOBULIN M: 81 [60 - 260] MG/DL; NPTST273-RDW: 16.2 [12 - 16] %; NPTST275-RESISTANCE TO ACTIVATED PROTEIN: 3.28 [2 - 3.5] RATIO; NPTST302-TROPONIN I: 0.01 [0 - 0.12] NG/ML; NPTST308-URIC ACID: 1 [2.5 - 6.2] MG/DL; NPTST319-VPM: 12.9 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 85.5 [37 - 72] %; PLATELETS: 106 [130 - 450] 10^9/L; TRIGLYCERIDES: 1.71 [0 - 1.7] MMOL/L; [redacted]20[redacted] (RX DAY 71):

ALBUMIN: 31 [35 - 50] G/L; CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS/LEUKOCYTES: 0.7 [1 - 6] %; GLUCOSE: 5.9 [4.1 - 5.9] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 107 [120 - 155] G/L; LEUKOCYTES: 12.7 [4 - 11] 10^9/L; LYMPHOCYTES: 1.03 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.1 [20 - 52] %; MONOCYTES: 1.14 [0.4 - 1.1] 10^9/L; NPTST029-ANTIROGLOBULIN ANTIBODIES: 10 [10 - 100] IU/ML; NPTST031-APTT: 19.6 [22 - 31] SEC; NPTST057-C-REACTIVE PROTEIN (CRP): 15.6 [0 - 5] MG/L; NPTST072-CHCM: 32.1 [33 - 37] G/DL; NPTST091-CORTISOL: 29.5 [4.5 - 22.7] UG/DL; NPTST118-FERRITIN: 432 [11.1 - 264] NG/ML; NPTST242-PHOSPHATE: 2.2 [2.5 - 4.5] MG/DL; NPTST273-RDW: 16.1 [12 - 16] %; NPTST298-TPO ANTIBODIES: 1.4 [1 - 16] IU/ML; NPTST319-VPM: 10.7 [7.4 - 10.4] FL; NEUTROPHILS: 10.36 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 81.4 [37 - 72] %; SODIUM: 135 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 72): GLUCOSE: 9.8 [3.9 - 6.1] MMOL/L; HEMOGLOBIN: 104 [120 - 160] G/L; NPTST006-ACTUALBASE EXCESS: 4.2 [-2 - 3] MMOL/L; NPTST087-CO2 TOTAL: 28.8 [23 - 28.8] MMOL/L; NPTST213-PCO2: 36.5 [40 - 50] MMHG; NPTST247-PO2: 72.3 [85 - 100] MMHG; [redacted]20[redacted] (RX DAY 78): NPTST306-UNSEEN BLOOD: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 79): ALANINE AMINOTRANSFERASE: 41 [8 - 30] U/L; ALBUMIN: 33 [35 - 50] G/L; ASPARTATE AMINOTRANSFERASE: 43 [14 - 36] U/L; CALCIUM: 2.07 [2.1 - 2.55] MMOL/L; CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS: 0.03 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.3 [1 - 6] %; ERYTHROCYTES: 0 [0 - 0] 10^12/L; GLUCOSE: 10 [3.9 - 6.1] MMOL/L; GLUCOSE: 10 [4.1 - 5.9] MMOL/L; GLUCOSE: 7 [4.6 - 6.4] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 109 [120 - 160] G/L; HEMOGLOBIN: 104 [120 - 155] G/L; LEUKOCYTES: 9.6 [4 - 11] 10^9/L; LEUKOCYTES: 0 [0 - 5] 10^9/L; LYMPHOCYTES: 1.03 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 10.7 [20 - 52] %; MONOCYTES: 0.34 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 6.7 [7 - 16] MMOL/L; NPTST031-APTT: 21 [22 - 31] SEC; NPTST044-BICARBONATO: 30.9 [20 - 30] MMOL/L; NPTST057-C-REACTIVE PROTEIN (CRP): 5.7 [0 - 5] MG/L; NPTST062-CALCIO IONIZADO: 4.5 [4.7 - 5.2] MG/DL; NPTST072-CHCM: 31.4 [33 - 37] G/DL; NPTST085-CLOURO: 116 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 32.2 [23 - 28] MMOL/L; NPTST103-CV2 ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST116-EXCESO BASES ACTUAL: 6.8 [-2 - 3] MMOL/L; NPTST129-GGT: 229 [12 - 43] U/L; NPTST246-PNMA2 ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST247-PO2: 54.8 [85 - 100] MMHG; NPTST259-PREALBUMINA: 45.3 [17.6 - 36] MG/DL; NPTST273-RDW: 18.5 [12 - 16] %; NPTST307-UREA: 42 [15 - 36] MG/DL; NPTST319-VPM: 11.6 [7.4 - 10.4] FL; NEUTROPHILS: 8.07 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 84.4 [37 - 72] %; PROTEIN: 520 [120 - 600] MG/L; SODIUM: 151 [136 - 146] MMOL/L; SODIUM: 149 [137 - 145] MMOL/L; TRIGLYCERIDES: 3.05 [0 - 1.7] MMOL/L; URATE: 89.23 [148.71 - 368.81] UMOL/L; [redacted]20[redacted] (RX DAY 80): NPTST013-ANFIFISINA ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST020-ANTICUERPOS ANTI-GLICINAR: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST021-ANTICUERPOS CANALES POTASIO: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST024-ANTICUERPOS ONCONEURONALES (HU,: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST141-HU ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST148-IHQ SUPERFICIE NEURONAL: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST202-NMDA RECEPTOR ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST281-RI ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST324-YO ANTICUERPOS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 87): ALANINE AMINOTRANSFERASE: 68 [8 - 30] U/L; ASPARTATE AMINOTRANSFERASE: 38 [14 - 36] U/L; CHOLESTEROL: 6.78 [0 - 5.17] MMOL/L; CREATININE: 44 [46 - 92] UMOL/L; EOSINOPHILS: 0 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0 [1 - 6] %; ERYTHROCYTES: 3.5 [3.8 - 5.2] 10^12/L; GLUCOSE: 10.2 [4.1 - 5.9] MMOL/L; GLUCOSE: 10.8 [3.9 - 6.1] MMOL/L; HEMATOCRIT: 0.31 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 106 [120 - 155] G/L; HEMOGLOBIN: 109 [120 - 160] G/L; LEUKOCYTES: 7.8 [4 - 11] 10^9/L; LYMPHOCYTES: 0.35 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 4.6 [20 - 52] %; MONOCYTES: 0.22 [0.4 - 1.1] 10^9/L; MONOCYTES/LEUKOCYTES: 2.9 [3 - 13] %; NPTST031-APTT: 19.2 [22 - 31] SEC; NPTST084-CLORURO: 107 [98 - 106] MMOL/L; NPTST116-EXCESO BASES ACTUAL: 3.2 [-2 - 3] MMOL/L; NPTST119-FERRITINA: 674 [11.1 - 264] NG/ML; NPTST129-GGT: 198 [12 - 43] U/L;

NPTST163-LACTATO: 3.3 [0.7 - 2.1] MMOL/L; NPTST179-MAGNESIO: 2.4 [1.6 - 2.3] MG/DL; NPTST213-PCO2: 35.1 [40 - 50] MMHG; NPTST247-PO2: 46.3 [85 - 100] MMHG; NPTST259-PREALBUMINA: 44.2 [17.6 - 36] MG/DL; NPTST273-RDW: 21.3 [12 - 16] %; NPTST307-UREA: 75 [15 - 36] MG/DL; NPTST319-VPM: 16.3 [7.4 - 10.4] FL; NEUTROPHILS/LEUKOCYTES: 92.3 [37 - 72] %; PLATELETS: 98 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 96): CREATININE: 44 [46 - 92] UMOL/L; NPTST071-CERULOPLASMINA: 17 [18 - 53] MG/DL; NPTST088-COBRE: 67 [76 - 152] UG/DL; NPTST119-FERRITINA: 419 [11.1 - 264] NG/ML; NPTST129-GGT: 125 [12 - 43] U/L; NPTST179-MAGNESIO: 2.4 [1.6 - 2.3] MG/DL; NPTST259-PREALBUMINA: 39.5 [17.6 - 36] MG/DL; NPTST307-UREA: 72 [15 - 36] MG/DL; SODIUM: 135 [137 - 145] MMOL/L; TRIGLYCERIDES: 1.79 [0 - 1.7] MMOL/L; [redacted]20[redacted] (RX DAY 101): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; CREATININE: 35 [46 - 92] UMOL/L; ERYTHROCYTES: 3.4 [3.8 - 5.2] 10^12/L; HEMATOCRIT: 0.32 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 100 [120 - 160] G/L; HEMOGLOBIN: 103 [120 - 155] G/L; LEUKOCYTES: 5.5 [4 - 11] 10^9/L; LYMPHOCYTES: 0.97 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 17.8 [20 - 52] %; MONOCYTES: 0.36 [0.4 - 1.1] 10^9/L; NPTST014-ANION GAP: 4.8 [7 - 16] MMOL/L; NPTST072-CHCM: 32.3 [33 - 37] G/DL; NPTST084-CLORURO: 110 [98 - 106] MMOL/L; NPTST129-GGT: 79 [12 - 43] U/L; NPTST213-PCO2: 37.7 [40 - 50] MMHG; NPTST247-PO2: 73.8 [85 - 100] MMHG; NPTST273-RDW: 21.7 [12 - 16] %; PLATELETS: 125 [130 - 450] 10^9/L; PROTEIN: 56 [63 - 82] G/L; [redacted]20[redacted] (RX DAY 107): CREATININE: 35 [46 - 92] UMOL/L; EOSINOPHILS: 0.01 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.2 [1 - 6] %; ERYTHROCYTES: 3.3 [3.8 - 5.2] 10^12/L; GLUCOSE: 8.8 [4.1 - 5.9] MMOL/L; HEMATOCRIT: 0.31 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 98 [120 - 155] G/L; LEUKOCYTES: 4.9 [4 - 11] 10^9/L; LYMPHOCYTES: 0.16 [0.4 - 1.1] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 3.2 [20 - 52] %; MONOCYTES: 0.16 [0.4 - 1.1] 10^9/L; NPTST057-C-REACTIVE PROTEIN (CRP): 93.4 [NOT REPORTED - 5] MG/L; NPTST072-CHCM: 32.1 [33 - 37] G/DL; NPTST149-INDICE DE QUICK: 69 [70 - 100] %; NPTST273-RDW: 20.7 [12 - 16] %; NPTST307-UREA: 10 [15 - 36] MG/DL; NEUTROPHILS/LEUKOCYTES: 92.4 [37 - 72] %; PLATELETS: 88 [130 - 450] 10^9/L; POTASSIUM: 3.4 [3.5 - 5.1] MMOL/L; SODIUM: 136 [137 - 145] MMOL/L; [redacted]20[redacted] (RX DAY 108): EOSINOPHILS: 0.01 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.2 [1 - 6] %; ERYTHROCYTES: 3.2 [3.8 - 5.2] 10^12/L; HEMATOCRIT: 0.3 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 98 [120 - 155] G/L; LEUKOCYTES: 4.1 [4 - 11] 10^9/L; LYMPHOCYTES: 0.35 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 8.4 [20 - 52] %; MONOCYTES: 0.17 [0.4 - 1.1] 10^9/L; NPTST031-APTT: 21.4 [22 - 31] SEC; NPTST072-CHCM: 32.6 [33 - 37] G/DL; NPTST273-RDW: 20.7 [12 - 16] %; NPTST316-VCM: 94.3 [82 - 94] FL; NEUTROPHILS/LEUKOCYTES: 85.4 [37 - 72] %; PLATELETS: 74 [130 - 450] 10^9/L; [redacted]20[redacted] (RX DAY 116): CREATININE: 27 [46 - 92] UMOL/L; NPTST125-GAD ANTICUERPOS: 7.7 [0 - 17] IU/ML; NPTST145-IA2 (TIROSINA FOSFATASA) ANTICU: 7.2 [0 - 28] IU/ML; NPTST307-UREA: 47 [15 - 36] MG/DL

Microbiology

[redacted]20[redacted] (RX DAY 57): URINE UROCULTIVO: NEGATIVE; [redacted]20[redacted] (RX DAY 64): CEREBROSPINAL FLUID CULTIVO BACTERIOLOGICO: NEGATIVE; CEREBROSPINAL FLUID PCR CITOMEGALOVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR CRYPTOCOCCUS NEOFORMANS/GAT: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR ESCHERICHIA COLI K1 (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR HAEMOPHILLUS INFLUENZAE (FI: NEGATIVE; CEREBROSPINAL FLUID PCR LISTERIA MONOCYTOGENES (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR NEISSERIA MENINGITIDIS (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR PARECHOVIRUS HUMANO (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS AGALACTIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS PNEUMONIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES HUMANO 6 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 1 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 2 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA ZOSTER (FIL: NEGATIVE; [redacted]20[redacted] (RX DAY 65): BLOOD CITOMEGALOVIRUS IGG: POSITIVE-IGG (CURED INFECTION); BLOOD CITOMEGALOVIRUS IGM: NEGATIVE; BLOOD IGG BORRELLIA BURGDORGFERI: NEGATIVE; BLOOD IGM BORRELLIA BURGDORGFERI: NEGATIVE; BLOOD PCR VIRUS HERPES SIMPLEX 1: NEGATIVE; BLOOD PCR VIRUS HERPES SIMPLEX 2: NEGATIVE; BLOOD PCR VIRUS VARICELLA-ZOSTER: NEGATIVE; BLOOD ROSA DE

BENGALA (BRUCELLA): NEGATIVE; [redacted]20[redacted] (RX DAY 66): BLOOD AC ANTI-HBS (HEPATITIS B): NEGATIVE; BLOOD AC. HETEROFILOS V. EPSTEIN-BARR: NEGATIVE; BLOOD ANTICUERPOS IGG VHE (HEPATITIS: NEGATIVE; BLOOD ANTICUERPOS IGM VHE (HEPATITIS: NEGATIVE; BLOOD ANTICUERPOS T. PALLIDUM TOTALES: NEGATIVE; BLOOD ANTICUERPOS VHC (HEPATITIS C): POSITIVE-CURED INFECTION; BLOOD ANTICUERPOS VIH 1+2: NEGATIVE; BLOOD CARGA VIRAL VHC: NEGATIVE; BLOOD CITOMEGALOVIRUS IGG: POSITIVE-CURED INFECTION; BLOOD CITOMEGALOVIRUS IGM: NEGATIVE; BLOOD HBSAG (HEPATITIS B): NEGATIVE; BLOOD TOXOPLASMA GONDII IGG: NEGATIVE; BLOOD TOXOPLASMA GONDII IGM: NEGATIVE; BLOOD VCA (V.EPSTEIN-BARR) IGG: POSITIVE-CURED INFECTION; BLOOD VCA (V.EPSTEIN-BARR) IGM: NEGATIVE; BLOOD VHS 1+2 IGG: POSITIVE-CURED INFECTION; BLOOD VHS 1+2 IGM: NEGATIVE; [redacted]20[redacted] (RX DAY 79): CEREBROSPINAL FLUID CARGA VIRAL CMV: NEGATIVE; CEREBROSPINAL FLUID CARGA VIRAL VIRUS BK: NEGATIVE; CEREBROSPINAL FLUID CULTIVO BACTERIOLOGICO: NEGATIVE; CEREBROSPINAL FLUID PCR CITOMEGALOVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR CRYPTOCOCCUS NEOFORMANS/GAT: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS: NEGATIVE; CEREBROSPINAL FLUID PCR ENTEROVIRUS (FILMARRAY): NEGATIVE; CEREBROSPINAL FLUID PCR ESCHERICHIA COLI K1 (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR HAEMOPHILLUS INFLUENZAE (FI: NEGATIVE; CEREBROSPINAL FLUID PCR LISTERIA MONOCYTOGENES (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR NEISSERIA MENINGITIDIS (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR PARECHOVIRUS HUMANO (FILMAR: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS AGALACTIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR STREPTOCOCCUS PNEUMONIAE (F: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES HUMANO 6 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 1 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLE 2 (FILM: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLEX 1: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS HERPES SIMPLEX 2: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA ZOSTER (FIL: NEGATIVE; CEREBROSPINAL FLUID PCR VIRUS VARICELLA-ZOSTER: NEGATIVE

AE Stopped Rx Day	119 (63 DAYS AFTER LAST TREATMENT)
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	GENERAL IMPAIRMENT, PROGRESS IN PARKINSON'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	RESULTS IN DEATH

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，死亡に至った多臓器不全，パーキンソニズム，及びジストニア反応を発現した。

Event 3，5，及び 7 の臨床経過：

関連する病歴は，C 型肝炎ウイルス，不安及びうつ病障害，単純腎摘除術，パーキンソン病，高血圧，レボドパ誘発性ジスキネジア，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 52 日目，被験者はジストニア反応と診断された。投与 53 日目，ジストニア反応は消失した。投与 56 日目，被験者はパーキンソニズムを発現した。投与 119 日目，被験者は多臓器不全を発現した。投与 119 日目，被験者は死亡した。死因は多臓器不全と報告された。剖検は実施されなかった。

本試験開始前の投与から約 3 ヵ月前より，被験者は全身状態の進行性の低下を認めた。

投与 52 日目，被験者は「分離エピソード」のため入院した。徴候及び症状は全身性筋硬直及び「頭位回転」であった。被験者はめまいを感じると報告した。同日，被験者はてんかん発作（非重篤）を発現した。それ以外に運動異常は認められず，括約筋の失禁も認められなかった。被験者はジストニア反応と診断され，投与 53 日目，退院した。

投与 56 日目，被験者は原因不明の全身状態の進行性悪化のため再入院した。被験者は，摂食量の減少，運動の顕著な制限，運動異常の発作性エピソード，便秘（非重篤），及び幻覚（非重篤）の症状を呈した。被験者は高血圧（非重篤）も発現し，高血圧治療薬を投与された。

被験者は全身性ミオクロニー発作を発現し，入院初期より毎日繰り返したため，抗てんかん治療を実施した。投与 58 日目，被験者は脳波測定を実施し，脳症（非重篤）が認められた。投与 59 日目，被験者が重度の栄養障害であったため，経鼻胃チューブが挿管された。投与 64 日目，被験者は肺塞栓症（非重篤）と診断された。投与 65 日目，被験者に経鼻十二指腸チューブを挿管した。投与 66 日目，被験者に再度経鼻胃チューブを挿管した。同日，被験者は栄養障害（非重篤）及び深部静脈血栓症（非重篤）と診断された。脳症治療のため，被験者に prednisone 及びメチルプレドニゾロン経口及び静脈内の交互投与を開始した。被験者の脳症に対してモニタリングを継続した。投与の約 3 ヵ月後，脳症治療のためデキサメタゾンが追加された。

被験者の進行性悪化を判断する特定の診断はなく，当初は自己免疫性脳症や，治療を受け一時的に改善した血管炎の一種など，パーキンソン病とは原因が異なると考えられた。しかし，

多数の検査を行った結果，その他の診断には至らなかった。被験者の状態は悪化し続け，被験者の家族は処方薬による治療を中止することを決めた。投与 109 日目，被験者は緩和療法を開始した。投与 119 日目，被験者は死亡した。

被験者にバルプロ酸，prednisone，デキサメタゾン，免疫グロブリン，クエチアピン，チアプリド，バクロフェン，ラコサミド，ビソプロロール，ウラピジル，ロチゴチン，ドンペリドン，オンダンセトロン，ドキサゾシン，アムロジピン，及びジアゼパムが投与された。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SELEGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Multiple organ failure (10028237) (Multiple organ dysfunction syndrome (10077361)) [v.23.1] [10028237]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Parkinsonism (10034010) (Parkinsonism (10034010)) [v.23.1] [10034010]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Unknown

3) Dystonic reaction (10013986) (Dystonia (10013983)) [v.23.1] [10013986]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of MULTIPLE ORGAN FAILURE

- Investigator: General impairment, progress in Parkinson's disease

- AbbVie: More likely related to a history of Parkinson's disease in a patient with advanced age and a report of E.coli in her urine.

Event of PARKINSONISM

- Investigator: Progressive general deterioration.

- AbbVie: More likely related to a history of Parkinson's disease in a patient with advanced age and a report of E.coli in her urine and on concomitant medication Sertaline.

Event of DYSTONIC REACTION

- Investigator: General deterioration of the subject's Parkinsonism

- AbbVie: More likely related to a history of Parkinson's disease in a patient with advanced age and a report of E.coli in her urine.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] (TIROSINA FOSFATASA) ANTICUERPOS:** 7.2 IU/L (normal 0 to 28)

[redacted] **20[redacted] AC ANTI-HBS (HEPATITIS B) BLOOD:** Negative

[redacted] **20[redacted] AC. HETEROFILOS V. EPSTEIN-BARR BLOOD:** Negative

[redacted] **20[redacted] ALBUMIN:** 3.4 G/DL (normal 3.5 to 5)

[redacted] **20[redacted] ALBUMIN:** 3.3 G/DL (normal 3.5 to 5)

[redacted] 20[redacted] **ANGIO-MAGNETIC RESONANCE IMAGING OF SUPRA-AORTIC TRUNKS:** Study without significant results

[redacted] 20[redacted] **ANGIO-MAGNETIC RESONANCE IMAGING OF WILLIS POLYGON:** No significant results

[redacted] 20[redacted] **ANION GAP:** 6.7 MMOL/L (normal 7 to 16)

[redacted] 20[redacted] **ANTICUERPOS IGG VHE (HEPATITIS E) BLOOD:** Negative

[redacted] 20[redacted] **ANTICUERPOS IGM VHE (HEPATITIS E) BLOOD:** Negative

[redacted] 20[redacted] **ANTICUERPOS T. PALLIDUM TOTALES BLOOD:** Negative

[redacted] 20[redacted] **ANTICUERPOS VHC (HEPATITIS C) BLOOD:** Positive. Cured infection

[redacted] 20[redacted] **ANTICUERPOS VIH 1+2 BLOOD:** Negative

[redacted] 20[redacted] **BODY WEIGHT:** 5[redacted].[redacted] KG

[redacted] 20[redacted] **BRAIN MAGNETIC RESONANCE:** Cortico-subcortical atrophy with frontal predominance stage 1 chronic small vessel ischemia

[redacted] 20[redacted] **BRAIN MAGNETIC RESONANCE:** Unchanged compared to previous study ([redacted] 20[redacted])

[redacted] 20[redacted] **BRAIN MAGNETIC RESONANCE IMAGING:** Unchanged from previous study ([redacted] 20[redacted])

[redacted] 20[redacted] **CALCIUM:** 8.3 mg/dL (normal 8.4 to 10.2)

[redacted] 20[redacted] **CARBOXIHEMOGLOBINA:** 1.1 % (normal 0.5 to 1.5)

[redacted] 20[redacted] **CARGA VIRAL CMV CSF:** Negative

[redacted] 20[redacted] **CARGA VIRAL VHC BLOOD:** Negative

[redacted] 20[redacted] **CARGA VIRAL VIRUS BK CSF:** Negative

[redacted] 20[redacted] **CEREBROSPINAL FLUID:** Negative

[redacted] 20[redacted] **CEREBROSPINAL FLUID RED BLOOD CELLS:** 0 MCL (normal <5)

[redacted] 20[redacted] **CEREBROSPINAL FLUID RED BLOOD CELLS:** 15 MCL (normal <5)

[redacted] 20[redacted] **CEREBROSPINAL FLUID WHITE BLOOD CELLS:** 0 MCL (normal <5)

[redacted] 20[redacted] **CEREBROSPINAL FLUID WHITE BLOOD CELLS:** 0 MCL (normal <5)

[redacted] **20[redacted] CHEST ABDOMEN PELVIS CT SCAN WITH CONTRAST:** Chest: defects in pulmonary vascularization in relation to VTE abdomen; Pelvis: Obstructive lithiasis urinary in distal third (6-7 MM) abundant fecaloid content in rectal ampoule.

[redacted] **20[redacted] CO2:** 33.8 MMOL/L (normal 23 to 28)

[redacted] **20[redacted] CO2 TOTAL:** 32.2 MMOL/L (normal 23 to 28)

[redacted] **20[redacted] CORTISOL:** 29.5 ug/dl (normal 4.5 to 22.7)

[redacted] **20[redacted] CREATIN KINASA:** 21 U/L (normal 30 to 135)

[redacted] **20[redacted] CREATIN KINASA:** <20 U/L (normal 30 to 135)

[redacted] **20[redacted] CREATININE:** 0.7 mg/dL (normal 0.52 to 1.04)

[redacted] **20[redacted] CREATININE:** 0.4 mg/dL (normal 0.52 to 1.04)

[redacted] **20[redacted] CREATININE:** 0.3 mg/dL (normal 0.52 to 1.04)

[redacted] **20[redacted] CULTIVO BACTERIOLOGICO CSF:** Negative

[redacted] **20[redacted] CULTIVO BACTERIOLOGICO CSF:** Negative

[redacted] **20[redacted] CYTOMEGALOVIRUS IGG BLOOD:** Positive. IGG (cured infection).[redacted] 20[redacted] CYTOMEGALOVIRUS IGG BLOOD: Positive. Cured infection

[redacted] **20[redacted] CYTOMEGALOVIRUS IGM BLOOD:** Negative

[redacted] **20[redacted] CYTOMEGALOVIRUS IGM BLOOD:** Negative

[redacted] **20[redacted] DIAGNOSTICO MALDI-TOF URINE:** Positive. Escherichia Coli

[redacted] **20[redacted] DOPPLER COLOR ECHOCARIOGRAPHY:** Mild left ventricular hypertrophy

[redacted] **20[redacted] ESTUDIO GENETICO DEL GEN PRNP CSF:** Negative

[redacted] **20[redacted] GAD ANTIBODIES:** 7.7 IU/mL (normal 0 to 17)

[redacted] **20[redacted] GGT:** 229 U/L (normal 12 to 43)

[redacted] **20[redacted] GLUCOSE:** 97 mg/dL (normal 70 to 110)

[redacted] **20[redacted] GLUCOSE:** 180 mg/dL (normal 74 to 106)

[redacted] **20[redacted] GLUCOSE:** 159 mg/dL (normal 74 to 106)

[redacted] **20[redacted] HBSAG (HEPATITIS B) BLOOD:** Negative

[redacted] **20**[redacted] **HEMATOCRIT:** 30.6% (normal 35 to 45)

[redacted] **20**[redacted] **HEMATOCRIT:** 30.2% (normal 35 to 45)

[redacted] **20**[redacted] **HEMOGLOBIN:** 13.3 G/DL (normal 12 to 16)

[redacted] **20**[redacted] **HEMOGLOBIN:** 10.9 G/DL (normal 12 to 16)

[redacted] **20**[redacted] **HEMOGLOBIN:** 9.8 G/DL (normal 12 to 15.5)

[redacted] **20**[redacted] **HEMOGLOBIN:** 9.8 G/DL (normal 12 to 15.5)

[redacted] **20**[redacted] **IGG BORRELLIA BURGDORGFERI BLOOD:** Negative

[redacted] **20**[redacted] **IGM BORRELLIA BURGDORGFERI BLOOD:** Negative

[redacted] **20**[redacted] **LYMPHOCYTES %:** 15% (normal 20 to 52)

[redacted] **20**[redacted] **LYMPHOCYTES ABS:** 0.16 X10**3/MCL (normal 0.4 to 1.1)

[redacted] **20**[redacted] **NEUTROPHILS %:** 73.3% (normal 37 to 72)

[redacted] **20**[redacted] **NEUTROPHILS %:** 92.4% (normal 37 to 72)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 10.36 X10**3/MCL (normal 1.5 to 7.2)

[redacted] **20**[redacted] **NT-PROBNP:** 905 ph/mL (normal <125)

[redacted] **20**[redacted] **PAROTIDITIS IGG BLOOD:** Positive. Cured Infection

[redacted] **20**[redacted] **PAROTIDITIS IGM BLOOD:** Negative

[redacted] **20**[redacted] **PCO2:** 50.55 mmHg (normal 40 to 50)

[redacted] **20**[redacted] **CRP:** 14.1 MG/L (normal <5)

[redacted] **20**[redacted] **CRP:** 19.3 MG/L (normal <5)

[redacted] **20**[redacted] **CRP:** 38.3 MG/L (normal <5)

[redacted] **20**[redacted] **CRP:** 5.7 MG/L (normal <5)

[redacted] **20**[redacted] **CRP:** 93.4 MG/L (normal <5)

[redacted] **20**[redacted] **PCR CRYPTOCOCCIS NEOFORMANS/GATTI CSF:** Negative

[redacted] **20**[redacted] **PCR CRYPTOCOCCUS NEOFORMANS/GATTI CSF:** Negative

[redacted] **20[redacted] PCR CYTOMEGALOVIRUS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR CYTOMEGALOVIRUS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR ENTEROVIRUS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR ENTEROVIRUS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR ENTEROVIRUS CSF:** Negative

[redacted] **20[redacted] PCR ESCHERICHIA COLI K1 (FILMARRY) CSF:** Negative

[redacted] **20[redacted] PCR ESCHERICHIA COLI K1 (FILMNARRAY) CSF:** Negative

[redacted] **20[redacted] PCR HAEMOPHILLUS INFLUENZAE (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR HAEMOPHILLUS INFULENZA (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR LISTERIA MONOCYTOGENES (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR LISTERIA MONOCYTOGENES (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR NEISSERIA MENINGITIDIS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR NEISSERIA MENINGITIDIS (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR PARECHOVIRUS HUMANO (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR PARECHOVIRUS HUMANO (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR STEPTOCOCCIS AGALACTIAE (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR STREPTOCOCCUS AGALACTIAE(FIMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR STREPTOCOCCUS PNEUMONIAE (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR STREPTOCOCCUS PNEUMONIAE(FIMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES HUMANO 6 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES HUMANO 6 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLE 1 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLE 1 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLE 2 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLE 2 (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLEX 1 BLOOD:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLEX 1 CSF:** Negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLEX 2 BLOOD:** negative

[redacted] **20[redacted] PCR VIRUS HERPES SIMPLEX 2 CSF:** Negative

[redacted] **20[redacted] PCR VIRUS VARICELLA ZOSTER (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS VARICELLA ZOSTER (FILMARRAY) CSF:** Negative

[redacted] **20[redacted] PCR VIRUS VARICELLA ZOSTER BLOOD:** Negative

[redacted] **20[redacted] PCR VIRUS VARICELLAZOSTER CSF:** Negative

[redacted] **20[redacted] PLATELET COUNT:** 116 X10**3/MCL (normal 130 to 450)

[redacted] **20[redacted] PO2:** 21.6 mmHg (normal 85 to 100)

[redacted] **20[redacted] PO2:** 54.8 mmHg (normal 85 to 100)

[redacted] **20[redacted] POTASSIUM:** 3.4 MMOL/L (normal 3.4 to 5)

[redacted] **20[redacted] POTASSIUM:** 3.4 MMOL/L (normal 3.5 to 5.1)

[redacted] **20[redacted] PROTEINA 14-3-3 PRUEBA DE HARRINGTON CSF:** Negative

[redacted] **20[redacted] ROSA DE BENGALA (BRUCELLA) BLOOD:** Negative

[redacted] **20[redacted] SODIUM:** 147 MMOL/L (normal 136 to 146)

[redacted] **20[redacted] SODIUM:** 151 MMOL/L (normal 136 to 146)

[redacted] **20[redacted] SODIUM:** 136 MMOL/L (normal 137 to 145)

[redacted] **20[redacted] TOXOPLASMA GONDII IGG BLOOD:** Negative

[redacted] **20[redacted] TOXOPLASMA GONDII IGM BLOOD:** Negative

[redacted] **20[redacted] TROPHERYMA WHIPPLEI BLOOD:** Negative

[redacted] **20[redacted] TROPONINA I:** < 0.01 NG/ML (normal <0.12)

[redacted] **20[redacted] UREA:** 10 mg/dL (normal 15 to 36)

[redacted] 20[redacted] **UREA:** 47 mg/dL (normal 15 to 36)

[redacted] 20[redacted] **UROCULTIVO:** Negative

[redacted] 20[redacted] **VCA (V.EPSTEIN-BARR) IGG BLOOD:** Positive. Cured infection

[redacted] 20[redacted] **VCA (V.EPSTEIN-BARR) IGM BLOOD:** Negative

[redacted] 20[redacted] **VENOUS DOPPLER LOWER LIMBS:** results compatible with deep vein thrombosis

[redacted] 20[redacted] **VHS 1+2 IGG BLOOD:** Positive. Cured Infection

[redacted] 20[redacted] **VHS 1+2 IGM BLOOD:** Negative

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** Encephalopathy

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** Encephalopathy to a lesser degree than previous study ([redacted] 20[redacted])

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** Encephalopathy to a greater degree with electrophysiological worsening

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** Without electrophysiological changes with respect to previous control ([redacted] 20[redacted])

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** encephalopathy with marked improvement in brain bioelectrical activity

[redacted] 20[redacted] **VIDEO ELECTROENCEPHALOGRAPHY:** Encephalopathy with worsening electrophysiological record

[redacted] 20[redacted] **WBC:** 4.11 X10**3/MCL (normal 4 to 11)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 6.04 X10**3/MCL (normal 4 to 11)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 12.7 X10**3/MCL (normal 4 to 11)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 4.93 X10**3/MCL (normal 4 to 11)

[redacted] 20[redacted] **X-RAY ABDOMEN:** Abundant fecal impaction in rectal ampoule mild distension of the transverse colon nasogastric tube end in gastric chamber.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
心肺停止	X	X	X	
注入部位紅斑				X
注入部位小水疱				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
GIANT HIATAL HERNIA	NOT REPORTED
UTERUS PROLAPSE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
INGUINAL HERNIA SURGERY	20[redacted]
HYSTERECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.3	0.36	0	60	0.3	[redacted]/1
ABBV-951	0.29	0.35	0	60	0.3	[redacted]/2
ABBV-951	0.35	0.42	0	60	0.3	[redacted]/8
ABBV-951	0.48	0.57	0.4	60	0.3	[redacted]/11
ABBV-951	0.48	0.57	0.4	60	0.3	[redacted]/15
ABBV-951	0.61	0.7	0.55	60	0.3	[redacted]/25
ABBV-951	0.65	0.7	0.6	60	0.3	[redacted]/29
ABBV-951	0.65	0.7	0.6	60	0.3	[redacted]/35
ABBV-951	0.75	0.8	0.7	60	0.3	[redacted]/42
ABBV-951	0.7	0.75	0.65	60	0.3	[redacted]/44
ABBV-951	0.75	0.8	0.7	60	0.3	[redacted]/71
ABBV-951	0.75	0.8	0.7	60	0.3	[redacted]/77

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	655.68		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		51.22	SC / ONCE	[redacted] / 3	
ABBV-951	1186.71		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		204.9	SC / ONCE	[redacted] / 6	
ABBV-951	1188.42		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		51.22	SC / ONCE	[redacted] / 7	
ABBV-951	1246.81		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1997.77		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12

ABBV-951	2013.14		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	2277.80		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	2082.12		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2355.32		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2326.12		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2335.86		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2591.13		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2517.70		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1502.6		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	396.99		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ROTIGOTINE	8.000 mg	QD	Y-M: 20[redacted]
TRAZODONE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	700.000 ug	TID	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted]
PRAMIPEXOLE	2100.000 ug	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
SAFINAMIDE	50.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1050.000 ug	QD	Y-M: 20[redacted]
PRAMIPEXOLE	260.000 ug	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	112.000 mg	QD	Y-M: 20[redacted]
SAFINAMIDE	50.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	28.800 mg	QD	Y-M: 20[redacted] / -80
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted] / -76
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted] / -76
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted] / -76

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
TRAZODONE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 108
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 108
LORAZEPAM	1 mg	BID	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 56
SERTRALINE	50 mg	QD	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 108

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA ON THE INFUSION SITE (DOWN-RIGHT).
Preferred term	注入部位紅斑

AE Onset Date / Rx Day	[redacted]20[redacted] / 7
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA (INFUSION SITE)
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 71
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	76
Duration of AE	6 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	VESICULAR ERUPTION (INFUSION SITE)
Preferred term	注入部位小水疱
AE Onset Date / Rx Day	[redacted]20[redacted] / 77
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	CARDIORESPIRATORY ARREST
Preferred term	心肺停止
AE Onset Date / Rx Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	108
Duration of AE	1 DAY

Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	DETERIORATION OF THE GENERAL STATE OF HEALTH
Discontinued Study Drug Due to the Event	YES
SAE Criteria	RESULTS IN DEATH

generated: [redacted] 20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，死亡に至った心肺停止を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 108 日目，被験者は心肺停止を発現した。投与 108 日目，被験者は死亡した。死因は心肺停止と報告された。剖検は実施されなかった。

被験者は，全身状態の悪化及びほとんど何も摂取していない食欲不振の数日目に心肺停止を発現した。

The patient's past medications include:

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

SINEMET CR for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

DUODOPA for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

---

1) Cardio-respiratory arrest (10007617) (Cardio-respiratory arrest (10007617)) [v.23.0] [10007617]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CARDIORESPIRATORY ARREST

- Investigator: deterioration of the general state of health

- AbbVie: More likely related to history of Parkinson's disease in an advanced aged patient with a decreased BMI.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
認知障害	X			
幻覚		X		X
幻視				X
注入部位紅斑				X
精神病性障害	X	X		X
傾眠				X
尿路感染	X			
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
INTERATRIAL SEPTUM ANEURYSM	20[redacted]
MENOPAUSE	20[redacted]
ANXIETY DEPRESSIVE DISORDER	20[redacted]
HYPOTHYROIDISM	20[redacted]
RENAL COLIC	20[redacted]
RENAL COLIC	20[redacted]
RENAL COLIC	20[redacted]
VIT B12 DEFICIENCY	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
APPENDECTOMY	19[redacted]
LITHOTRIPSY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.37	0.45	0.3	60	0.3	[redacted]/1
ABBV-951	0.4	0.45	0.35	60	0.3	[redacted]/2
ABBV-951	0.45	0.5	0.4	60	0.3	[redacted]/8
ABBV-951	0.43	0.47	0.4	60	0.3	[redacted]/17
ABBV-951	0.43	0.47	0.4	60	0.3	[redacted]/24
ABBV-951	0.43	0.47	0.4	60	0.3	[redacted]/31
ABBV-951	0.4	0.43	0.37	60	0.3	[redacted]/85
ABBV-951	0.35	0.4	0.28	60	0.19	[redacted]/95
ABBV-951	0.35	0.4	0.32	60	0.19	[redacted]/107

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	821.30		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1557.24		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		51.22	SC / ONCE	[redacted] / 5	
ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		102.45	SC / ONCE	[redacted] / 6	

ABBV-951	1727.99		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		51.22	SC / ONCE	[redacted] / 7	
ABBV-951	1704.08		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		153.67	SC / ONCE	[redacted] / 8	
ABBV-951	1755.31		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		102.45	SC / ONCE	[redacted] / 9	
ABBV-951	1821.04		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		153.67	SC / ONCE	[redacted] / 10	
ABBV-951	1836.41		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		51.22	SC / ONCE	[redacted] / 12	
ABBV-951	1821.04		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		153.67	SC / ONCE	[redacted] / 13	
ABBV-951	1813.36		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		51.22	SC / ONCE	[redacted] / 14	
ABBV-951	1704.08		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		153.67	SC / ONCE	[redacted] / 15	
ABBV-951	1618.71		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		102.45	SC / ONCE	[redacted] / 16	
ABBV-951	1605.05		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		51.22	SC / ONCE	[redacted] / 17	
ABBV-951	1684.44		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		51.22	SC / ONCE	[redacted] / 18	
ABBV-951	1747.45		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1725.42		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		51.22	SC / ONCE	[redacted] / 21	
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1754.79		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30

ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67

ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 68	[redacted] / 68
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 69	[redacted] / 69
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951	1762.14	SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951	1597.36	SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	1497.30	SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	1516.26	SC / CONTINUOUS	[redacted] / 104	[redacted] / 104

ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1470.15	SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	1386.49	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ESCITALOPRAM	20 mg	QD	Y-M: 20[redacted]-[redacted]
LORAZEPAM	1 mg	BID	Y-M: 20[redacted]-[redacted]
LEVOTHYROXINE SODIUM	25 ug	QD	Y-M: 20[redacted]
ROTIGOTINE	16.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	125.000 mg	QID	Y-M: 20[redacted]-[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	125.000 mg	BID	Y-M: 20[redacted]-[redacted] / -255
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	BID	Y-M: 20[redacted]-[redacted] / -255
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]-[redacted] / -244
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -236
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted]-[redacted] / -46
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]-[redacted] / -46
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted]-[redacted] / -6

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ESCITALOPRAM	20 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
LORAZEPAM	1 mg	BID	Y-M: 20[redacted]-[redacted]	ONGOING
LEVOTHYROXINE SODIUM	25 ug	QD	Y-M: 20[redacted]	ONGOING
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]-[redacted] / -46	Y-M: 20[redacted]-[redacted] / -17
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted]-[redacted] / -6	Y-M: 20[redacted]-[redacted] / -1
CEFUROXIME AXETIL	500 mg	BID	Y-M: 20[redacted]-[redacted] / 17	Y-M: 20[redacted]-[redacted] / 23
CIPROFLOXACIN	400 mg	BID	Y-M: 20[redacted]-[redacted] / 25	Y-M: 20[redacted]-[redacted] / 27
OLANZAPINE	10 mg	PRN	Y-M: 20[redacted]-[redacted] / 25	Y-M: 20[redacted]-[redacted] / 27
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 25	Y-M: 20[redacted]-[redacted] / 27

TIAPRIDE	100 mg	PRN	Y-M: 20[redacted] / 25	Y-M: 20[redacted] / 27
FOSFOMYCIN	3 g	OTHER: Q/48H	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 29
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 107	Y-M: 20[redacted] / 112

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA (INFUSION SITE)
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	16
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Somnolence

Event Description	SLEEPINESS
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	14
Duration of AE	5 DAYS

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	21
Duration of AE	7 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	URINARY TRACT INFECTION
Preferred term	尿路感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 15

Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 17): ALANINE AMINOTRANSFERASE: 20 [14 - 59] U/L; ALBUMIN: 41 [34 - 50] G/L; ALKALINE PHOSPHATASE: 50 [46 - 116] U/L; ASPARTATE AMINOTRANSFERASE: 17 [15 - 37] U/L; BASOPHILS/LEUKOCYTES: 0.5 [0 - 2] %; BILIRUBIN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; CREATININE: 50 [53 - 88] UMOL/L; EOSINOPHILS: 0.13 [0 - 0.7] 10^9/L; EOSINOPHILS/LEUKOCYTES: 2.5 [0.5 - 4] %; ERYTHROCYTES: 10 [0 - 0] /HPF; ERYTHROCYTES: 4 [4.2 - 5.4] 10^12/L; GLUCOSE: NORMAL [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; GLUCOSE: 4.6 [4.1 - 5.9] MMOL/L; HEMATOCRIT: 0.37 [0.37 - 0.47] FRACTION OF 1; HEMOGLOBIN: 124 [125 - 160] G/L; LEUKOCYTES: 5.1 [4.1 - 10] 10^9/L; LEUKOCYTES: 0 [4.5 - 11] 10^9/L; LYMPHOCYTES: 1.27 [1 - 3.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 24.9 [23 - 35] %; MONOCYTES: 0.26 [0 - 0.7] 10^9/L; MONOCYTES/LEUKOCYTES: 5 [4 - 12.1] %; NPTST057-C-REACTIVE PROTEIN (CRP): 0.4 [0 - 0.33] MG/DL; NPTST079-CK: 75 [21 - 215] U/L; NPTST106-DENSITY: 1.02 [1.003 - 1.03] UNIT NOT REPORTED; NPTST129-GGT: 19 [5 - 55] U/L; NPTST156-INR: 0.97 [0.8 - 1.2] RATIO; NPTST159-KETONE BODIES: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST166-LARGE UNSTAINED CELLS (LUC): 0.11 [0 - 0] 10^3/UL; NPTST167-LDH: 159 [81 - 234] U/L; NPTST181-MCH: 31.1 [27 - 31] PG; NPTST182-MCHC: 33.5 [32 - 36] G/DL; NPTST193-MPV: 9.1 [5.9 - 9.9] FL; NPTST199-NITRITES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST271-QUICK INDEX: 99.4 [70 - 130] %; NPTST273-RDW: 12.9 [11.5 - 14] %; NPTST287-SEDIMENT: 8-10 LEUKOCYTES FIE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST297-TP: 10.9 [10 - 15] SEC; NPTST305-TTPA: 25.5 [21.1 - 36.5] SEC; NPTST307-UREA: 44 [15 - 39] MG/DL; NPTST311-UROBILINOGEN: 0.20 [NOT REPORTED - 1] MG/DL; NPTST316-VCM: 92.8 [78 - 100] FL; NEUTROPHILS: 3.32 [1.5 - 6.6] 10^9/L; NEUTROPHILS BAND FORM: 0.03 [0 - 0.1] 10^9/L; NEUTROPHILS BAND FORM/LEUKOCYTES: 2.2 [2 - 6] %; NEUTROPHILS/LEUKOCYTES: 64.9 [55 - 65] %; PLATELETS: 219 [150 - 450] 10^9/L; POTASSIUM: 4.1 [3.5 - 5.1] MMOL/L; PROTEIN: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; SODIUM: 143 [135 - 145] MMOL/L; PH: 6.5 [4.5 - 8] UNIT NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	27
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	MICROBE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERYTHEMA (INFUSION SITE)

Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 17
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	24
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event

Event Description	COGNITIVE DETERIORATION
Preferred term	認知障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 25
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 25): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; ALKALINE PHOSPHATASE: 69 [38 - 126] U/L; ASPARTATE AMINOTRANSFERASE: 23 [14 - 36] U/L; BASOPHILS: 0.03 [0 - 0.2] 10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0 - 2] %; BILIRUBIN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; BILIRUBIN: 14 [2 - 22] UMOL/L; CREATININE: 53 [46 - 92] UMOL/L; EOSINOPHILS: 0.44 [0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 3.6 [1 - 6] %; ERYTHROCYTES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; ERYTHROCYTES: 4.2 [3.8 - 5.2] 10^12/L; GLUCOSE: 5.8 [3.9 - 6.1] MMOL/L; GLUCOSE: 0 [0 - 0.6] MMOL/L; HEMATOCRIT: 0.4 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 133 [120 - 155] G/L; HEMOGLOBIN: 135 [120 - 160] G/L; LEUKOCYTES: 12 [4 - 11] 10^9/L; LYMPHOCYTES: 0.65 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 5.5 [20 - 52] %; MONOCYTES: 0.42 [0.4 - 1.1] 10^9/L; MONOCYTES/LEUKOCYTES: 3.5 [3 - 13] %; NPTST005-ACTUAL BASE EXCESS: 1.2 [-2 - 3] MMOL/L; NPTST014-ANION GAP: 13.1 [7 - 16] MMOL/L; NPTST043-BICARBONATE (STANDAR): 25.4 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST044-BICARBONATO: 25.7 [20 - 30] MMOL/L; NPTST063-CALCIUM OXALATE MONOHYDRATED: MODERATE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST065-CARBOXIHEMOGLOBIN: 0.8 [0.5 - 1.5] %; NPTST072-CHCM: 33.6 [33 - 37] G/DL; NPTST075-CHLORIDE: 105 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 26.9 [23 - 28] MMOL/L;

NPTST106-DENSITY: 1.019 [1.01 - 1.025] UNIT NOT REPORTED; NPTST107-DIHYDRATED CALCIUM OXALATE: FEW [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST115-EXCES BASE (STANDAR): 1.2 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST129-GGT: 11 [12 - 43] U/L; NPTST136-HCM: 31.8 [25 - 33] PG; NPTST157-IONIZED CALCIUM: 4.8 [4.7 - 5.2] MG/DL; NPTST161-KETONIC BODIES: 80 [0 - 0] UNIT NOT REPORTED; NPTST167-LDH: 164 [120 - 246] U/L; NPTST182-MCHC: 33 [NOT REPORTED - NOT REPORTED] G/DL; NPTST188-METAHEMOGLOBIN, WHOLE BLOOD: 0.6 [0 - 1.5] %; NPTST199-NITRITES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST213-PCO2: 39.6 [40 - 50] MMHG; NPTST215-PCR: 12.4 [0 - 5] MG/L; NPTST247-PO2: 94.6 [85 - 100] MMHG; NPTST273-RDW: 13.7 [12 - 16] %; NPTST286-SATURATION O2: 98 [NOT REPORTED - NOT REPORTED] %; NPTST287-SEDIMENT: 4-6 [NOT REPORTED - NOT REPORTED] WBC/FIELD; NPTST307-UREA: 40 [15 - 36] MG/DL; NPTST311-UROBILINOGEN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST316-VCM: 94.8 [82 - 94] FL; NPTST319-VPM: 9.2 [7.4 - 10.4] FL; NPTST321-WHOLE BLOOD LACTATE: 2.1 [0.7 - 2.1] MMOL/L; NEUTROPHILS: 10.39 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 86.7 [37 - 72] %; PLATELETS: 214 [130 - 450] 10^9/L; POTASSIUM: 3.5 [3.4 - 5] MMOL/L; PROTEIN: 300 [0 - 100] MG/L; SODIUM: 144 [136 - 146] MMOL/L; PH: 7.42 [7.35 - 7.5] UNIT NOT REPORTED; PH: 6 [5.5 - 7] UNIT NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 25): URINE URINE CULTURE: NEGATIVE; [redacted]20[redacted] (RX DAY 26): OTHER NASOPHARYNGEAL EXUDATES FLU: NEGATIVE; OTHER NASOPHARYNGEAL EXUDATES RESPIRATORY SYNCYTIAL VIRUS: NEGATIVE; OTHER NASOPHARYNGEAL EXUDATES SARS-CO-V-2 (RT PCR): NEGATIVE

AE Stopped Rx Day	27
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOTIC DISORDER
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 25
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 25): ALANINE AMINOTRANSFERASE: 7 [8 - 30] U/L; ALKALINE PHOSPHATASE: 69 [38 - 126] U/L; ASPARTATE AMINOTRANSFERASE: 23 [14 - 36] U/L; BASOPHILS: 0.03 [0 - 0.2] 10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0 - 2] %; BILIRUBIN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; BILIRUBIN: 14 [2 - 22] UMOL/L; CREATININE: 53 [46 - 92] UMOL/L; EOSINOPHILS: 0.44

[0.04 - 0.5] 10^9/L; EOSINOPHILS/LEUKOCYTES: 3.6 [1 - 6] %; ERYTHROCYTES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; ERYTHROCYTES: 4.2 [3.8 - 5.2] 10^12/L; GLUCOSE: 5.8 [3.9 - 6.1] MMOL/L; GLUCOSE: 0 [0 - 0.6] MMOL/L; HEMATOCRIT: 0.4 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 133 [120 - 155] G/L; HEMOGLOBIN: 135 [120 - 160] G/L; LEUKOCYTES: 12 [4 - 11] 10^9/L; LYMPHOCYTES: 0.65 [1.5 - 4.5] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 5.5 [20 - 52] %; MONOCYTES: 0.42 [0.4 - 1.1] 10^9/L; MONOCYTES/LEUKOCYTES: 3.5 [3 - 13] %; NPTST005-ACTUAL BASE EXCESS: 1.2 [-2 - 3] MMOL/L; NPTST014-ANION GAP: 13.1 [7 - 16] MMOL/L; NPTST043-BICARBONATE (STANDAR): 25.4 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST044-BICARBONATO: 25.7 [20 - 30] MMOL/L; NPTST063-CALCIUM OXALATE MONOHYDRATED: MODERATE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST065-CARBOXIHEMOGLOBIN: 0.8 [0.5 - 1.5] %; NPTST072-CHCM: 33.6 [33 - 37] G/DL; NPTST075-CHLORIDE: 105 [98 - 106] MMOL/L; NPTST087-CO2 TOTAL: 26.9 [23 - 28] MMOL/L; NPTST106-DENSITY: 1.019 [1.01 - 1.025] UNIT NOT REPORTED; NPTST107-DIHYDRATED CALCIUM OXALATE: FEW [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST115-EXCES BASE (STANDAR): 1.2 [NOT REPORTED - NOT REPORTED] MMOL/L; NPTST129-GGT: 11 [12 - 43] U/L; NPTST136-HCM: 31.8 [25 - 33] PG; NPTST157-IONIZED CALCIUM: 4.8 [4.7 - 5.2] MG/DL; NPTST161-KETONIC BODIES: 80 [0 - 0] UNIT NOT REPORTED; NPTST167-LDH: 164 [120 - 246] U/L; NPTST182-MCHC: 33 [NOT REPORTED - NOT REPORTED] G/DL; NPTST188-METAHEMOGLOBIN, WHOLE BLOOD: 0.6 [0 - 1.5] %; NPTST199-NITRITES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST213-PCO2: 39.6 [40 - 50] MMHG; NPTST215-PCR: 12.4 [0 - 5] MG/L; NPTST247-PO2: 94.6 [85 - 100] MMHG; NPTST273-RDW: 13.7 [12 - 16] %; NPTST286-SATURATION O2: 98 [NOT REPORTED - NOT REPORTED] %; NPTST287-SEDIMENT: 4-6 [NOT REPORTED - NOT REPORTED] WBC/FIELD; NPTST307-UREA: 40 [15 - 36] MG/DL; NPTST311-UROBILINOGEN: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST316-VCM: 94.8 [82 - 94] FL; NPTST319-VPM: 9.2 [7.4 - 10.4] FL; NPTST321-WHOLE BLOOD LACTATE: 2.1 [0.7 - 2.1] MMOL/L; NEUTROPHILS: 10.39 [1.5 - 7.2] 10^9/L; NEUTROPHILS/LEUKOCYTES: 86.7 [37 - 72] %; PLATELETS: 214 [130 - 450] 10^9/L; POTASSIUM: 3.5 [3.4 - 5] MMOL/L; PROTEIN: 300 [0 - 100] MG/L; SODIUM: 144 [136 - 146] MMOL/L; PH: 7.42 [7.35 - 7.5] UNIT NOT REPORTED; PH: 6 [5.5 - 7] UNIT NOT REPORTED

Microbiology

[redacted]20[redacted] (RX DAY 25): URINE URINE CULTURE: NEGATIVE; [redacted]20[redacted] (RX DAY 26): OTHER NASOPHARYNGEAL EXUDATES FLU: NEGATIVE; OTHER NASOPHARYNGEAL EXUDATES RESPIRATORY SYNCYTIAL VIRUS: NEGATIVE; OTHER NASOPHARYNGEAL EXUDATES SARS-CO-V-2 (RT PCR): NEGATIVE

AE Stopped Rx Day	27
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 91
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	93
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 97
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	98
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL HALLUCINATIONS
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 97
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	98
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest - Somnolence

Event Description	DROWSINESS
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 107
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	112
Duration of AE	6 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 117
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	118 (1 DAY AFTER LAST TREATMENT)
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #13: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOTIC DISORDER
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 117
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	118 (1 DAY AFTER LAST TREATMENT)
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスペインの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病性障害，認知機能の衰退，及び尿路感染を発現した。

Event 4，6，及び 7 の臨床経過：

関連する病歴は，不安うつ病障害，甲状腺機能低下症，砕石手術，パーキンソン病，腎仙痛，非喫煙者，及び非飲酒者であった。

投与 15 日目，被験者は尿路感染を発現した。投与 25 日目，被験者は精神病性障害及び認知機能の衰退を発現した。投与 27 日目精神病性障害，認知機能の衰退，及び尿路感染は消失した。

投与 17 日目，被験者は頻尿，排尿困難，認知機能の衰退，眠気，及び幻覚（非重篤）を伴い入院した。診断及び臨床検査が実施され，被験者に抗生物質が投与された。投与 18 日目，被験者は臨床的に安定であり退院した。

投与 25 日目，被験者は尿路感染，発熱，攻撃的な態度を伴う行動及び精神病症状の悪化，妄想，及び幻覚のため再入院した。今回は，Zinnat の投与終了後に再度悪化した。そのため，被験者にシプロフロキサシンを投与した結果，精神病症状の消失を含む臨床的な改善が認められた。投与 27 日目，被験者は退院した。

被験者に ZINNAT，チアプリド，オランザピン，シプロフロキサシン，パラセタモール，及びホスホマイシンが投与された。

The patient's past medications include:

ROTIGOTINE for PARKINSON'S DISEASE ([redacted])

SINEMET for PARKINSON'S DISEASE ([redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1) Cognitive deterioration (10009843) (Cognitive disorder (10057668)) [v.23.1] [10009843]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Psychotic disorder (10061920) (Psychotic disorder (10061920)) [v.23.1] [10061920]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

3) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.1] [10046571]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOTIC DISORDER, COGNITIVE DETERIORATION

- Investigator: Not applicable

- AbbVie: More likely related to history of anxiety depressive disorder in a 6[redacted] year old female with Parkinson's disease and urinary tract infection

Event of URINARY TRACT INFECTION

- **Investigator:** Infection

- **AbbVie:** More likely related to history of Parkinson's disease in a 6[redacted] year old female

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BANDS ABS:** 0.11 X10**3/MCL

[redacted] **20[redacted] BANDS ABS:** 0.03 X10**3/MCL (normal 0.0 to 0.1)

[redacted] **20[redacted] BASOPHILS %:** 0.5% (normal 0 to 2)

[redacted] **20[redacted] BASOPHILS %:** 0.2% (normal 0 to 2)

[redacted] **20[redacted] CREATININE:** 0.57 mg/dL (normal 0.6 to 1)

[redacted] **20[redacted] EOSINOPHILS %:** 2.5% (normal 0.5 to 4)

[redacted] 20[redacted] **EOSINOPHILS %:** 3.6% (normal 1 to 6)

[redacted] 20[redacted] **EOSINOPHILS ABS:** 0.13 X10**3/MCL (normal 0.0 to 0.7)

[redacted] 20[redacted] **HEMOGLOBIN:** 12.4 G/DL (normal 12.5 to 16)

[redacted] 20[redacted] **LYMPHOCYTES %:** 24.9% (normal 23.0 to 35.0)

[redacted] 20[redacted] **LYMPHOCYTES %:** 5.5% (normal 20 to 52)

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 1.27 X10**3/MCL (normal 1.0 to 3.5)

[redacted] 20[redacted] **MONOCYTES %:** 5.0% (normal 4.0 to 12.1)

[redacted] 20[redacted] **MONOCYTES %:** 3.5% (normal 3 to 13)

[redacted] 20[redacted] **MONOCYTES ABS:** 0.26 X10**3/MCL (normal 0.0 to 0.7)

[redacted] 20[redacted] **NASOPHARYNGEAL EXUDATES (GRIPE A):** Negative

[redacted] 20[redacted] **NASOPHARYNGEAL EXUDATES (GRIPE B):** Negative

[redacted] 20[redacted] **NASOPHARYNGEAL EXUDATES SARS-CO-V-2 (RT PCR):** Negative

[redacted] 20[redacted] **NASOPHARYNGEAL EXUDATES VRS (PCR RAPID):** Negative

[redacted] 20[redacted] **NEUTROPHILS %:** 64.9% (normal 55.0 to 65.0)

[redacted] 20[redacted] **NEUTROPHILS %:** 86.7% (normal 37 to 72)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 3.32 X10**3/MCL (normal 1.5 to 6.6)

[redacted] 20[redacted] **UREA:** 44 mg/dL (normal 15 to 39)

[redacted] 20[redacted] **UREA:** 40 mg/dL (normal 15 to 39)

[redacted] 20[redacted] **URINE ANALYSIS:** CUERPOS CETONICOS: 80 no units (normal negative), SEDIMENTO: 4-6 no units (normal negative), SEDIMENTO: BACTERIAS MODERADAS.

[redacted] 20[redacted] **URINE CULTURE:** Negative

[redacted] 20[redacted] **URINE DENSIDAD:** 1.02 no unit (normal 1.003 to 1.03)

[redacted] 20[redacted] **URINE NITRITOS:** Negative

[redacted] 20[redacted] **URINE PH:** 6.5 no unit (normal 4.5 to 8)

[redacted] 20[redacted] **URINE PROTEIN:** INDICIOS (normal <15)

[redacted] **20[redacted] URINE PROTEIN:** 30 mg/dL (normal 0 to 10)

[redacted] **20[redacted] URINE WBCS:** APR15.00 MCL

[redacted] **20[redacted] WEIGHT:** 5[redacted] KG

[redacted] **20[redacted] WHITE BLOOD CELLS:** 5.11 X10**3/MCL (normal 4.1 to 10)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 11.9 X10**3/MCL (normal 4 to 11)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想	X			X
幻聴				X
注入部位血腫				X
注入部位疼痛				X
** Disc. due to lack of efficacy				X
** Disc. due to other: other				X
** Disc. due to withdrawal by subject				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
B12 DEFICIENCY	NOT REPORTED
GAMBLING PROBLEM	NOT REPORTED
HEREDITARY ESSENTIAL TREMOR	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
SUICIDAL IDEATION	20[redacted]
ISCHIADIC LEG PAIN	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.38	0.41	0.33	60	0.24	[redacted]/1
ABBV-951	0.38	0.41	0.33	60	0.24	[redacted]/2
ABBV-951	0.45	0.5	0.41	60	0.3	[redacted]/8
ABBV-951	0.5	0.55	0.45	60	0.3	[redacted]/15
ABBV-951	0.5	0.55	0.45	60	0.3	[redacted]/23
ABBV-951	0.5	0.55	0.45	60	0.3	[redacted]/30
ABBV-951	0.5	0.55	0.45	60	0.3	[redacted]/44
ABBV-951	0.55	0.62	0.5	60	0.3	[redacted]/93
ABBV-951	0.38	0.45	0.31	60	0.3	[redacted]/191

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	979.76		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		40.98	SC / ONCE	[redacted] / 2	
ABBV-951	1550.75		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		122.94	SC / ONCE	[redacted] / 3	
ABBV-951	1531.28		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1550.75		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		81.96	SC / ONCE	[redacted] / 5	
ABBV-951	1550.75		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		40.98	SC / ONCE	[redacted] / 6	
ABBV-951	1531.28		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		81.96	SC / ONCE	[redacted] / 7	

ABBV-951	1537.77		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		102.45	SC / ONCE	[redacted] / 8	
ABBV-951	1607.26		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		102.45	SC / ONCE	[redacted] / 9	
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		51.22	SC / ONCE	[redacted] / 10	
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		153.67	SC / ONCE	[redacted] / 11	
ABBV-951	1836.41		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		153.67	SC / ONCE	[redacted] / 12	
ABBV-951	1790.31		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		153.67	SC / ONCE	[redacted] / 13	
ABBV-951	1821.04		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		153.67	SC / ONCE	[redacted] / 14	
ABBV-951	1828.73		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		102.45	SC / ONCE	[redacted] / 15	
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		102.45	SC / ONCE	[redacted] / 16	
ABBV-951	1873.98		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		153.67	SC / ONCE	[redacted] / 17	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		102.45	SC / ONCE	[redacted] / 18	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		51.22	SC / ONCE	[redacted] / 19	
ABBV-951	1989.23		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		51.22	SC / ONCE	[redacted] / 20	
ABBV-951	1996.92		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		51.22	SC / ONCE	[redacted] / 21	
ABBV-951	1927.76		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		51.22	SC / ONCE	[redacted] / 22	
ABBV-951	1932.03		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		51.22	SC / ONCE	[redacted] / 23	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		51.22	SC / ONCE	[redacted] / 25	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2003.75		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26

ABBV-951	1992.65		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2043.87		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 33	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1980.7		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	1956.79		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 40	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 45	
ABBV-951	1997.77		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 47	
ABBV-951	1673.35		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	341.5		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48

ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 50	
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	1946.55		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 52	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 54	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 56	
ABBV-951	1864.59		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2195.84		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1929.47		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 61	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	2014.85		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 64	
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 65	
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1920.93		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1997.77		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 69	
ABBV-951	1920.93		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1989.23		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 71	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 73	
ABBV-951	1784.33		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73

ABBV-951		51.22	SC / ONCE	[redacted] / 74	
ABBV-951	1758.72		SC / CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	1980.7		SC / CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951		51.22	SC / ONCE	[redacted] / 76	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	1938.01		SC / CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	2031.92		SC / CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	2138.64		SC / CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951		51.22	SC / ONCE	[redacted] / 80	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	2235.11		SC / CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	2225.72		SC / CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951		51.22	SC / ONCE	[redacted] / 84	
ABBV-951	2047.29		SC / CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951		51.22	SC / ONCE	[redacted] / 85	
ABBV-951	2188.16		SC / CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	2244.50		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	2197.55		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	2253.9		SC / CONTINUOUS	[redacted] / 105	[redacted] / 105

ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	2156.57		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 136	
ABBV-951	2077.17		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141

ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
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ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
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ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
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ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
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ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
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ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178

ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	1754.62	SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PRAMIPEXOLE	0.260 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.520 mg	5 TIMES PER DAY	Y-M: 20[redacted]
PRAMIPEXOLE	0.780 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
ENTACAPONE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
PARACETAMOL	1 g	QID	Y-M: 20[redacted]-[redacted] / -66
DICLOFENAC	50 mg	BID	Y-M: 20[redacted]-[redacted] / -43
DICLOFENAC	50 mg	TID	Y-M: 20[redacted]-[redacted] / -23
CYANOCOBALAMIN	4 mg	QD	Y-M: 20[redacted]-[redacted] / -19
GABAPENTIN	300 mg	PRN	Y-M: 20[redacted]-[redacted] / -19
CYANOCOBALAMIN	1 mg	QD	Y-M: 20[redacted]-[redacted] / -3

GABAPENTIN	600 mg	TID	Y-M: 20[redacted] / -3
PRAMIPEXOLE	0.260 mg	PRN	Y-M: 20[redacted] / -2

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PARACETAMOL	1 g	QID	Y-M: 20[redacted] / -66	Y-M: 20[redacted] / 43
DICLOFENAC	50 mg	TID	Y-M: 20[redacted] / -23	Y-M: 20[redacted] / 5
CYANOCOBALAMIN	4 mg	QD	Y-M: 20[redacted] / -19	Y-M: 20[redacted] / -4
GABAPENTIN	300 mg	PRN	Y-M: 20[redacted] / -19	Y-M: 20[redacted] / -4
CYANOCOBALAMIN	1 mg	QD	Y-M: 20[redacted] / -3	ONGOING
GABAPENTIN	600 mg	TID	Y-M: 20[redacted] / -3	Y-M: 20[redacted] / 23
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 1	Y-M: 20[redacted] / 82
NAPROXEN	250 mg	BID	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 136
GABAPENTIN	900 mg	TID	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 28
GABAPENTIN	600 mg	TID	Y-M: 20[redacted] / 29	Y-M: 20[redacted] / 160
PROPRANOLOL HYDROCHLORIDE	20 mg	PRN	Y-M: 20[redacted] / 44	ONGOING
PARACETAMOL	1 g	TID	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 136
OXAZEPAM	5 mg	PRN	Y-M: 20[redacted] / 93	ONGOING
DULOXETINE	60 mg	QD	Y-M: 20[redacted] / 93	Y-M: 20[redacted] / 137
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 135	Y-M: 20[redacted] / 145
NAPROXEN	250 mg	PRN	Y-M: 20[redacted] / 136	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 136	ONGOING
ZOPICLONE	7.5 mg	QD	Y-M: 20[redacted] / 141	ONGOING
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 146	ONGOING
MELATONIN	5 mg	QD	Y-M: 20[redacted] / 151	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAIN AT INFUSION SITE
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 12
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	13

Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	HEMATOMA AT INFUSION SITE
Preferred term	注入部位血腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 41
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	93
Duration of AE	53 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	PARANOID DELUSIONS AT NIGHT
Preferred term	妄想

AE Onset Date / Rx Day	[redacted]20[redacted] / 130
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	148
Duration of AE	19 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Hallucinations/Psychosis

Event Description	ACOUSTIC HALLUCINATIONS AT NIGHT
Preferred term	幻聴
AE Onset Date / Rx Day	[redacted]20[redacted] / 130
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	159
Duration of AE	30 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PARANOID DELUSIONS
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 149
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	159
Duration of AE	11 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	MARITIAL CRISIS IN COMBINATION WITH A GAMBLING WIN AND POOR SLEEP MAY HAVE CONTRIBUTED BUT MAIN REASON IS BELIEVED TO BE THE START OF ROPINIROL, POSSIBLY IN COMBINATION WITH DULOXETINE.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, PERSIST OR SIGNIF DISABILITY/INCAPACITY, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスウェーデンの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，偏執性妄想を発現した。

Event 5 の臨床経過：

関連する病歴は，パーキンソン病，自殺念慮，ギャンブル癖，ビタミン B12 欠乏症，遺伝性本態性振戦，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 149 日目，被験者は偏執性妄想を発現した。投与 159 日目，偏執性妄想は消失した。

投与 149 日目，被験者は被験者の妻と治験薬投与者と治験責任医師が共謀しているという考えを含む偏執性妄想による精神病のため精神科に入院した。被験者はセンサーによって監視されていると信じていたため，自殺することができなかった。被験者は注入ポンプから包囲する人の声を聞いた。また，被験者は夜間の睡眠が断片的で少なくなっていた。被験者は自殺すると脅したため，被験者の妻が救急車を呼び，その後精神科に措置入院した。日時不明で実施された被験者の身体所見に異常は認められなかった。

投与 155 日目，被験者は電気痙攣療法（以下「ECT」）による治療を開始した。ECT を 2 回実施した後，被験者の精神症状は消失した。本事象に対する治験薬の注入によって，被験者のパーキンソン病の症状が増強し始めた。入院中，基礎精神障害は診断されなかった。投与 159 日目，被験者は退院した。

被験者の過去の病歴である自殺念慮，結婚生活の危機，及びギャンブル癖は，すべて本事象に関連したリスク因子と考えられた。被験者の母親も詳細不明の精神障害に苦しんでいた。

被験者にメラトニン及びクエチアピンが投与された。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted], 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON DISEASE (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Paranoid delusions (10033867) (Delusion (10012239)) [v.24.1] [10033867]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of PARANOID DELUSIONS

- Investigator: Marital crisis in combination with a gambling win and poor sleep may have contributed but main reason is believed to be the start of ropinirole, possibly in combination with duloxetine.

- AbbVie: More likely related to life stressors, concomitant medication ropinirole and a history of suicidal ideation in an advanced aged subject. The event did not reappear with re-introduction of study drug.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] WEIGHT:** 7[redacted] KG

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
錯覚				X
注入部位紅斑				X
直腸腺癌	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
MILD COGNITIVE IMPAIRMENT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.43	0.47	0.34	60	0.24	[redacted]/1
ABBV-951	0.43	0.47	0.34	60	0.24	[redacted]/2
ABBV-951	0.43	0.47	0.34	60	0.24	[redacted]/9
ABBV-951	0.43	0.5	0.34	60	0.24	[redacted]/16
ABBV-951	0.43	0.5	0.34	60	0.24	[redacted]/23
ABBV-951	0.43	0.5	0.34	60	0.24	[redacted]/30
ABBV-951	0.43	0.5	0.34	60	0.24	[redacted]/45
ABBV-951	0.43	0.5	0.34	60	0.24	[redacted]/88
ABBV-951	0.45	0.5	0.34	60	0.24	[redacted]/184
ABBV-951	0.5	0.55	0.34	60	0.24	[redacted]/275

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		40.98	SC / ONCE	[redacted] / 1	
ABBV-951	821.30		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1654.56		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		40.98	SC / ONCE	[redacted] / 3	
ABBV-951	1755.82		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		40.98	SC / ONCE	[redacted] / 4	
ABBV-951	1748.99		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		40.98	SC / ONCE	[redacted] / 5	
ABBV-951	1572.77		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1640.73		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1670.78		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		40.98	SC / ONCE	[redacted] / 8	
ABBV-951	1583.19		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		40.98	SC / ONCE	[redacted] / 9	
ABBV-951	1630.66		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		40.98	SC / ONCE	[redacted] / 14	

ABBV-951	1691.96		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	1641.41		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1664.98		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1604.70		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1635.10		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
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ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1718.59		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1619.90		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1717.40		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1632.54		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 45	

ABBV-951	1725.42	SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
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ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
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ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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ABBV-951	1762.14	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
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ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 273	
ABBV-951	1819.34		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 274	
ABBV-951	1753.60		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 275	
ABBV-951	2115.59		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	1.750 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]-[redacted]
ROPINIROLE	10.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted]
ENTACAPONE	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: DOSE BAG	PRN	Y-M: 20[redacted]-[redacted]
CYANOCOBALAMIN	1 mg	QD	Y-M: 20[redacted]-[redacted] / -33

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: DOSE BAG	PRN	Y-M: 20[redacted]	ONGOING
CYANOCOBALAMIN	1 mg	QD	Y-M: 20[redacted] / -33	ONGOING
FLUCLOXACILLIN SODIUM	1 g	TID	Y-M: 20[redacted] / 17	Y-M: 20[redacted] / 27
RADIOTHERAPY	UNKNOWN Bq	OTHER: ADMINISTERED FOR 5 DAYS	Y-M: 20[redacted] / 259	Y-M: 20[redacted] / 263

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 17
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	45
Duration of AE	29 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	ILUSIONS

Preferred term	錯覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 74
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event

Event Description	RECTAL ADENOCARCINOMA
Preferred term	直腸腺癌
AE Onset Date / Rx Day	[redacted]20[redacted] / 120
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	AGE AND SEX ARE THE STRONGEST RISK FACTORS FOR RECTAL CANCER.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	LIFE THREATENING

generated: [redacted] 20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスウェーデンの 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に直腸腺癌を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 120 日目，被験者は直腸腺癌を発現した。

被験者は時折血便を認めていたと報告した。被験者は投与を開始した年の夏から秋の間に直腸出血を発現した。投与 218 日目，結腸内視鏡検査を実施し，直腸癌が認められた。病変部位の生検により直腸癌と確定された。精密検査（詳細不明）では転移は認められなかった。投与 259 日目から投与 263 日目まで，被験者に放射線療法を実施した。

The patient's past medications include:

LEVODOPA/BENSERAZIDE DISPERIABLE for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE STANDARD for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROPINIROLE for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], Started [redacted] 20[redacted])

CARBIDOPA/LEVODOPA SUSTAINED RELEASE for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Rectal adenocarcinoma (10038019) (Rectal adenocarcinoma (10038019)) [v.24.1] [10038019]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of RECTAL ADENOCARCINOMA

- Investigator: Age and sex are the strongest risk factors for rectal cancer.

- AbbVie: Event is more likely related to underlying risk factors in a 6[redacted] year old subject with Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

20[redacted] COLOSCOPY: Rectal Cancer.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
不安	X			
注入部位紅斑				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
PULMONARY EMBOLISM	19[redacted]
CELIAC DISIEASE	19[redacted]
HYPECHOLESTEROLEMIA	20[redacted]
DEPRESSION	20[redacted]
TRANSITORY ISCHEMIC ATTACK	20[redacted]
HALLUX VALGUS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.37	0.44	0.3	60	0.24	[redacted]/1
ABBV-951	0.37	0.44	0.3	60	0.24	[redacted]/2
ABBV-951	0.37	0.42	0.3	60	0.19	[redacted]/8
ABBV-951	0.37	0.42	0.3	60	0.19	[redacted]/15
ABBV-951	0.37	0.42	0.3	60	0.19	[redacted]/22
ABBV-951	0.38	0.42	0.3	60	0.19	[redacted]/30
ABBV-951	0.4	0.44	0.3	60	0.19	[redacted]/44
ABBV-951	0.4	0.44	0.3	60	0.19	[redacted]/100
ABBV-951	0.42	0.45	0.3	60	0.19	[redacted]/142
ABBV-951	0.4	0.44	0.3	60	0.19	[redacted]/184
ABBV-951	0.47	0.5	0.36	60	0.19	[redacted]/246
ABBV-951	0.48	0.5	0.36	60	0.19	[redacted]/275

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		40.98	SC / ONCE	[redacted] / 1	
ABBV-951	807.98		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1344.14		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		40.98	SC / ONCE	[redacted] / 3	
ABBV-951	1386.49		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		40.98	SC / ONCE	[redacted] / 4	
ABBV-951	1386.31		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		40.98	SC / ONCE	[redacted] / 5	
ABBV-951	1436.17		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		40.98	SC / ONCE	[redacted] / 7	
ABBV-951	1501.91		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		32.44	SC / ONCE	[redacted] / 8	
ABBV-951	1033.37		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		32.44	SC / ONCE	[redacted] / 9	

ABBV-951	1461.27		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 10	
ABBV-951	1408.68		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1449.83		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1426.95		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	1423.03		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1157.68		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 15	
ABBV-951	539.91		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 16	
ABBV-951	1419.44		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 17	
ABBV-951	1407.49		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	1408.68		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1446.93		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1427.81		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1431.05		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1414.66		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	1419.27		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1401.68		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1397.58		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1432.59		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1500.72		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 28	
ABBV-951	1457.86		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1429.00		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1446.59		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 31	
ABBV-951	1442.49		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 32	
ABBV-951	1460.93		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 33	

ABBV-951	1411.07		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1429.17		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1442.49		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1432.93		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1457.52		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 38	
ABBV-951	1435.66		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 39	
ABBV-951	1502.25		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1461.62		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1444.88		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1435.32		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1372.48		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1459.91		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1523.09		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1546.31		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1482.11		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1471.86		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1534.35		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1544.60		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1556.89		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1461.62		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1493.37		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 54	
ABBV-951	1461.62		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 55	
ABBV-951	1497.13		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1468.45		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1506.01		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 58	
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1510.79		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1495.77		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61

ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 63	
ABBV-951	1501.23		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 64	
ABBV-951	1498.16		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 65	
ABBV-951	1474.25		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1497.47		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1500.89		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1518.65		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1512.84		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1521.38		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1494.06		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 72	
ABBV-951	1485.52		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1487.23		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1471.86		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1511.13		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1456.49		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1497.47		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1528.21		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1511.13		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1471.86		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1521.38		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1488.94		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1482.11		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1483.81		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1617.00		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1521.38		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 88	
ABBV-951	1487.23		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1490.64		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1504.30		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1497.47		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1502.6		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1512.84		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93

ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1517.96		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	1488.94		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1499.18		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1553.82		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1511.13		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 102	
ABBV-951	1557.92		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1647.73		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1720.13		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1511.13		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 106	
ABBV-951	1502.6		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	1492.35		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1515.91		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1502.6		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	1485.52		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1502.6		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	1490.64		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	1519.67		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	1483.81		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 116	
ABBV-951	1515.23		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	1482.11		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1551.43		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1500.89		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	1510.45		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 121	
ABBV-951	1461.62		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 122	
ABBV-951	1492.01		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1468.45		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 124	
ABBV-951	1479.03		SC / CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124

ABBV-951	1498.84		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1539.48		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1528.21		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	1566.80		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1548.01		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1525.82		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1522.40		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 132	
ABBV-951	1507.72		SC / CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1502.94		SC / CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	1582.51		SC / CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	1511.82		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1536.75		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 142	
ABBV-951	1674.03		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1348.24		SC / CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 144	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 145	
ABBV-951	1541.36		SC / CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 146	
ABBV-951	1553.65		SC / CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 147	
ABBV-951	1573.63		SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 148	
ABBV-951	1469.64		SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 149	
ABBV-951	1543.92		SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 150	
ABBV-951	1551.09		SC / CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 151	
ABBV-951	1569.02		SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151

ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 152	
ABBV-951	1559.80		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 153	
ABBV-951	1597.70		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 154	
ABBV-951	1545.45		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 155	
ABBV-951	1547.50		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 156	
ABBV-951	1569.53		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 157	
ABBV-951	1558.77		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 158	
ABBV-951	1555.19		SC / CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 159	
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 160	
ABBV-951	1545.97		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 161	
ABBV-951	1535.21		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 162	
ABBV-951	1564.41		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 163	
ABBV-951	1541.36		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 164	
ABBV-951	1580.29		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 165	
ABBV-951	1558.77		SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 166	
ABBV-951	1697.08		SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 167	
ABBV-951	1566.97		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 168	
ABBV-951	1555.70		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 169	
ABBV-951	1595.14		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 170	

ABBV-951	1608.97		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 171	
ABBV-951	1544.94		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 172	
ABBV-951	1560.31		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 173	
ABBV-951	1580.80		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1536.75		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 175	
ABBV-951	1555.19		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 176	
ABBV-951	1520.35		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 177	
ABBV-951	1558.26		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 178	
ABBV-951	1570.55		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 179	
ABBV-951	1575.16		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 180	
ABBV-951	1586.95		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 181	
ABBV-951	1489.11		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 182	
ABBV-951	1556.72		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 183	
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 185	
ABBV-951	1486.54		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 186	
ABBV-951	1517.96		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 187	
ABBV-951	1524.11		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	1587.97		SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	1511.13		SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 190	
ABBV-951	1473.57		SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190

ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 191	
ABBV-951	1524.45		SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 192	
ABBV-951	1476.98		SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 193	
ABBV-951	1503.96		SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 194	
ABBV-951	1478.35		SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951	1498.84		SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	913.85		SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	266.37		SC / CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951	271.49		SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	347.81		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951		194.65	SC / ONCE	[redacted]20[redacted] / 273	
ABBV-951	1825.14		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 274	
ABBV-951	1787.06		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 275	
ABBV-951	1842.05		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CYANOCOBALAMIN	1 mg	OTHER: ! TABLET MONDAYS AND THURSDAYS	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	8.000 mg	QD	Y-M: 20[redacted]-[redacted]
ENTACAPONE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted]
ETORICOXIB	90 mg	QD	Y-M: 20[redacted]-[redacted]
VENLAFAXINE HYDROCHLORIDE	150 mg	QD	Y-M: 20[redacted]-[redacted]
ROSUVASTATIN	20 mg	QD	Y-M: 20[redacted]-[redacted] / -313
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -232

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CYANOCOBALAMIN	1 mg	OTHER: ! TABLET MONDAYS AND THURSDAYS	Y-M: 20[redacted]	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ETORICOXIB	90 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 212
VENLAFAXINE HYDROCHLORIDE	150 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ROSUVASTATIN	20 mg	QD	Y-M: 20[redacted] / -313	NOT REPORTED
FLUCLOXACILLIN	1 g	TID	Y-M: 20[redacted] / 18	Y-M: 20[redacted] / 27
ZOPICLONE	7.5 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / 189	NOT REPORTED
HYDROXYZINE HYDROCHLORIDE	10 mg	OTHER: AS NEEDED	Y-M: 20[redacted] / 200	Y-M: 20[redacted] / 275
QUETIAPINE FUMARATE	25 mg	OTHER: 0.5 IN THE MORNING AND 1 AT NIGHT PLANNED END DOSE START WIT A QUARTER OF A TABLETT	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 275
OXAZEPAM	5 mg	OTHER: 0.5-1 TABL AS NEEDED	Y-M: 20[redacted] / 252	Y-M: 20[redacted] / 275
HYDROXYZINE HYDROCHLORIDE	10 mg	BID	Y-M: 20[redacted] / 275	NOT REPORTED
OXAZEPAM	5 mg	BID	Y-M: 20[redacted] / 275	NOT REPORTED
QUETIAPINE FUMARATE	25 mg	BID	Y-M: 20[redacted] / 275	NOT REPORTED

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED

Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	ANXIETY
Preferred term	不安
AE Onset Date / Rx Day	[redacted]20[redacted] / 188
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	189
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	ANXIETY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45

program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はスウェーデンの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に不安を発現した。

Event 2 の臨床経過：

関連する病歴は，肺塞栓症，セリアック病，高コレステロール血症，うつ病，一過性脳虚血発作，及び外反母趾であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 188 日目，被験者は不安を発現した。投与 189 日目，不安は消失した。

投与 188 日目，被験者は浮動性めまい，悪心，及び失神寸前の状態の症状及び徴候を伴って入院した。被験者は入院し，テレメトリーにて一晩観察された。バイタルサイン及び連続心電図はすべて正常であった。頭部 CT スキャンは正常で，生化学検査も正常であった。

被験者にゾピクロン及びクエチアピンが投与された。

The patient's past medications include:

LEVODOPA/BENSERAZIDE (MADOPAR HBS) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE HYDROCHLORIDE (MADOPAR) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ENTACAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE HYDROCHLORIDE (MADOPAR DISPERSIBLE) for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Anxiety (10002855) (Anxiety (10002855)) [v.24.1] [10002855]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ANXIETY

- Investigator: Anxiety

- AbbVie: More likely related to a history of Parkinson's disease and depression in an elderly patient

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ECG:** No pathological findings

[redacted] **20[redacted] HEAD CT:** No pathological findings

[redacted] **20[redacted] HEART ULTRASOUND:** No pathological findings

[redacted] **20[redacted] MRI HEAD:** No pathological findings

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
投与部位内出血				X
カテーテル留置部位出血				X
胸部不快感	X			
呼吸困難	X			
ジストニア	X			
注入部位内出血				X
注入部位結節				X
注入部位疼痛				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	WHITE

Medical History	Onset Year
RECURRENT TONSILLITIS	19[redacted]
ULCERATIVE COLITIS	19[redacted]
URINARY RETENTION	20[redacted]
LEFT INGUINAL HERNIA	20[redacted]
FEMORAL HERNIA	20[redacted]
PERNICIOUS ANAEMIA	20[redacted]
VIVID DREAMS	20[redacted]
INSOMNIA	20[redacted]
RIGHT BUNDLE BRANCH BLOCK	20[redacted]
SINUS BRADYCARDIA	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
TONILECTOMY AND ADENOIDECTOMY	19[redacted]
VASECTOMY	20[redacted]
OPTICAL URETHROTOMY	20[redacted]
FEMORAL HERNIA REPAIR	20[redacted]
LEFT INGUINAL HERNIA REPAIR	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.47	0.48	0.46	60	0.19	[redacted]20[redacted]/1
ABBV-951	0.47	0.48	0.46	60	0.19	[redacted]20[redacted]/2
ABBV-951	0.47	0.48	0.46	60	0.19	[redacted]20[redacted]/8
ABBV-951	0.47	0.48	0.46	60	0.19	[redacted]20[redacted]/15
ABBV-951	0.49	0.5	0.48	60	0.24	[redacted]20[redacted]/22
ABBV-951	0.49	0.5	0.48	60	0.24	[redacted]20[redacted]/27
ABBV-951	0.5	0.51	0.48	60	0.24	[redacted]20[redacted]/44
ABBV-951	0.51	0.52	0.5	60	0.3	[redacted]20[redacted]/62
ABBV-951	0.51	0.52	0.5	60	0.3	[redacted]20[redacted]/93
ABBV-951	0.52	0.53	0.51	60	0.3	[redacted]20[redacted]/101
ABBV-951	0.53	0.54	0.52	60	0.3	[redacted]20[redacted]/175
ABBV-951	0.55	0.56	0.54	60	0.3	[redacted]20[redacted]/183
ABBV-951	0.58	0.59	0.57	60	0.3	[redacted]20[redacted]/213
ABBV-951	0.6	0.61	0.58	60	0.3	[redacted]20[redacted]/239
ABBV-951	0.62	0.63	0.59	60	0.3	[redacted]20[redacted]/266
ABBV-951	0.62	0.63	0.59	60	0.3	[redacted]20[redacted]/274
ABBV-951	0.63	0.64	0.62	60	0.3	[redacted]20[redacted]/309

ABBV-951	0.64	0.65	0.63	60	0.3	[redacted]/316
ABBV-951	0.65	0.66	0.64	60	0.3	[redacted]/357
ABBV-951	0.65	0.66	0.64	60	0.3	[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	952.10		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		97.32	SC / ONCE	[redacted] / 2	
ABBV-951	1917.52		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		32.44	SC / ONCE	[redacted] / 3	
ABBV-951	1893.95		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		32.44	SC / ONCE	[redacted] / 4	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		64.88	SC / ONCE	[redacted] / 5	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		64.88	SC / ONCE	[redacted] / 6	
ABBV-951	1877.90		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		129.77	SC / ONCE	[redacted] / 7	
ABBV-951	1893.95		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		32.44	SC / ONCE	[redacted] / 8	
ABBV-951	1901.98		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1918.03		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		64.88	SC / ONCE	[redacted] / 10	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		64.88	SC / ONCE	[redacted] / 11	
ABBV-951	1910.00		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		32.44	SC / ONCE	[redacted] / 12	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		97.32	SC / ONCE	[redacted] / 13	
ABBV-951	1922.64		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1940.40		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		64.88	SC / ONCE	[redacted] / 15	
ABBV-951	1951.16		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1957.13		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		162.21	SC / ONCE	[redacted] / 17	
ABBV-951	1958.84		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17

ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 18	
ABBV-951	1958.84		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 19	
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		194.65	SC / ONCE	[redacted]20[redacted] / 20	
ABBV-951	1958.84		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 21	
ABBV-951	1917.86		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1943.81		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 23	
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 24	
ABBV-951	1982.91		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 25	
ABBV-951	2003.06		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 26	
ABBV-951	1979.33		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 41	
ABBV-951	1969.77		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	2023.21		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44

ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1909.49		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2084.85		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 59	
ABBV-951	2056.34		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1675.39		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	322.71		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 62	
ABBV-951	2049.51		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79

ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	2088.44		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	2073.58		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 92	
ABBV-951	2022.53		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 93	
ABBV-951	2019.97		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 94	
ABBV-951	2115.42		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2099.54		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 96	
ABBV-951	2028.85		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 97	
ABBV-951	2021.68		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 98	
ABBV-951	2045.24		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 99	
ABBV-951	2064.70		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 100	
ABBV-951	2108.42		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107

ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	2130.96	SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
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ABBV-951	2540.76	SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2540.76	SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2540.76	SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2527.27	SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2205.57	SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	354.98	SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2377.86	SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2600.69	SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324

ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2622.72	SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361

ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 362	
ABBV-951	2643.38		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 363	
ABBV-951	2659.77		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2683.33		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMIN B12 NOS	1 mg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted]
DOMPERIDONE	10 mg	QD	Y-M: 20[redacted]
MELATONIN	2 mg	QD	Y-M: 20[redacted] / -280
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]-[redacted] / -189
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]-[redacted] / -128
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted]-[redacted] / -128

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
VITAMIN B12 NOS	1 mg	OTHER: EVERY 8 WEEKS	Y-M: 20[redacted]-[redacted]	ONGOING
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted]	ONGOING
DOMPERIDONE	10 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 15
MELATONIN	2 mg	QD	Y-M: 20[redacted] / -280	Y-M: 20[redacted]-[redacted] / 7
CYCLIZINE	50 mg	PRN	Y-M: 20[redacted]-[redacted] / 2	Y-M: 20[redacted]-[redacted] / 2
MELATONIN	4 mg	QD	Y-M: 20[redacted]-[redacted] / 8	Y-M: 20[redacted]-[redacted] / 14
MELATONIN	6 mg	QD	Y-M: 20[redacted]-[redacted] / 15	Y-M: 20[redacted]-[redacted] / 272
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 76	ONGOING
SODIUM PHOSPHATE	1 L	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 169	Y-M: 20[redacted]-[redacted] / 170
IBUPROFEN	200 mg	QD	Y-M: 20[redacted]-[redacted] / 176	Y-M: 20[redacted]-[redacted] / 176
LOW MOLECULAR WEIGHT HEPARIN	60 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 176	Y-M: 20[redacted]-[redacted] / 177

LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 211	Y-M: 20[redacted] / 239
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 233
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted] / 226	Y-M: 20[redacted] / 233
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 237
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 237
ACETYLSALICYLIC ACID	300 mg	OTHER: ONCE	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 249
GLYCERYL TRINITRATE	400 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 249
MORPHINE SULFATE	10 mg	OTHER: ONCE	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 249
PARACETAMOL	1 g	OTHER: ONCE	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 249
SODIUM CHLORIDE	1 L	OTHER: ONCE	Y-M: 20[redacted] / 249	Y-M: 20[redacted] / 249
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 265	ONGOING
MELATONIN	6 mg	BID	Y-M: 20[redacted] / 273	ONGOING
COLECALCIFEROL	4000 IU	QD	Y-M: 20[redacted] / 295	ONGOING
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 295	ONGOING
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 295	ONGOING
TADALAFIL	20 mg	PRN	Y-M: 20[redacted] / 332	ONGOING
FERROUS SULFATE	200 mg	QD	Y-M: 20[redacted] / 337	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	27
Duration of AE	26 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAIN AT INFUSION SITE WHEN UTILISING THE BOOST FUNCTION ON PUMP
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 2
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	27
Duration of AE	24 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	27
Duration of AE	24 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE

Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	27
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 14
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	15
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	27
Duration of AE	13 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	NODULE AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 20
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	27
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SPURT OF BLOOD FROM CANNULA SITE WHEN ROUTINELY REMOVING CANNULA.
Preferred term	カテーテル留置部位出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 39
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	42
Duration of AE	4 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 81
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	82
Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Serious Adverse Event

Event Description	FEELING OF PRESSURE ON CHEST
Preferred term	胸部不快感
AE Onset Date / Rx Day	[redacted]20[redacted] / 169
Age at AE Onset	5[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 169): NPTST104-D DIMERS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST242-PHOSPHATE: 0.2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	171
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #12: Serious Adverse Event

Event Description	DIFFICULTY BREATHING
Preferred term	呼吸困難
AE Onset Date / Rx Day	[redacted]20[redacted] / 169
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 169): NPTST104-D DIMERS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST242-PHOSPHATE: 0.2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	171
Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #13: Serious Adverse Event

Event Description	DYSTONIA
Preferred term	ジストニア

AE Onset Date / Rx Day	[redacted]20[redacted] / 169
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 169): NPTST104-D DIMERS: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST242-PHOSPHATE: 0.2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: <2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

NOT REPORTED

AE Stopped Rx Day	170
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #14: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE - APPROX 4MM.
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 220
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	222
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAIN AT INFUSION SITE (STINGING)
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 234
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	234
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Serious Adversary Event

Event Description	CHEST DYSTONIA
Preferred term	ジストニア
AE Onset Date / Rx Day	[redacted]20[redacted] / 249
Age at AE Onset	5[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 249): ALANINE AMINOTRANSFERASE: 8 [0 - 55] U/L; ALBUMIN: 40 [35 - 50] G/L; ALKALINE PHOSPHATASE: 70 [30 - 130] U/L; BASOPHILS/LEUKOCYTES: 1 [0 - 2] %; CALCIUM: 2.4 [2.2 - 2.6] MMOL/L; CREATININE: 90 [64 - 111] UMOL/L; EOSINOPHILS: 0.17 [0.03 - 0.46] 10^9/L; ERYTHROCYTES: 4.1

[4.3 - 5.7] 10^12/L; HEMATOCRIT: 0.38 [0.39 - 0.5] FRACTION OF 1; HEMOGLOBIN: 125 [135 - 180] G/L; LEUKOCYTES: 7.3 [3.7 - 9.5] 10^9/L; LYMPHOCYTES: 2.39 [1 - 3.2] 10^9/L; NPTST008-ADJUSTED CALCIUM: 2.5 [2.2 - 2.6] MMOL/L; NPTST011-AMYLASE: 23 [25 - 125] IU/L; NPTST014-ANION GAP: 10 [8 - 12] MMOL/L; NPTST030-APPT: 29.5 [25 - 38] S; NPTST032-APTT RATIO: 1 [0.8 - 1.2] NOT RECORDED ON REPORT; NPTST038-BASOPHILS: 0.07 [0.02 - 0.1] 10^9/L; NPTST042-BICARBONATE: 23 [22 - 29] MMOL/L; NPTST075-CHLORIDE: 104 [95 - 108] UMOL/L; NPTST081-CKD EPI GFR: 86 [90 - 99999] ML/MIN; NPTST097-CRP: 1 [0 - 5] MG/L; NPTST105-D-DIMERS: 172 [0 - 231] NG/ML; NPTST130-GLOBULIN: 29 [20 - 35] G/L; NPTST156-INR: 1 [0.8 - 1.2] NONE RECORDED; NPTST181-MCH: 30.9 [27.3 - 32.6] PG; NPTST182-MCHC: 333 [316 - 349] G/L; NPTST183-MCV: 92.6 [77 - 98] FL; NPTST192-MONOCYTES: 0.56 [0.2 - 0.6] 10^9/L; NPTST198-NEUTROPHILS: 4.15 [1.7 - 7.5] 10^9/L; NPTST242-PHOSPHATE: 0.4 [0.8 - 1.5] MMOL/L; NPTST261-PROCALCITONIN: 0.03 [NOT REPORTED - NOT REPORTED] NG/ML; NPTST266-PROTHROMBIN TIME: 12 [10 - 15] S; NPTST294-TOTAL BILIRUBIN: 9 [0 - 21] UMOL/L; NPTST301-TROPONIN 1: <2 [NOT REPORTED - 0.34] NG/ML; NPTST307-UREA: 4.4 [2.5 - 7.8] MMOL/L; PLATELETS: 295 [150 - 400] 10^9/L; POTASSIUM: 3.4 [3.5 - 5.3] MMOL/L; PROTEIN: 69 [60 - 80] G/L; SODIUM: 137 [133 - 146] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	250
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #17: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SMALL BRUISE FROM FROM PREVIOUS INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 269
Age at AE Onset	5[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	280
Duration of AE	12 DAYS

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #18: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	TINY BRUISE FROM PREVIOUS INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 273
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	280
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #19: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 280

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	309
Duration of AE	30 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #20: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SMALL BRUISE AT INSERTION SITE
Preferred term	投与部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 360
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	368 (4 DAYS AFTER LAST TREATMENT)
Duration of AE	9 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE

Discontinued Study Drug Due to the Event NO
SAE Criteria NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，ジストニア，呼吸困難，及び胸部圧迫感を発現した。

Event 11，12，及び 13 の臨床経過：

関連する病歴は，潰瘍性大腸炎，悪性貧血，パーキンソン病，不眠症，非喫煙者，元葉巻タバコ喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 169 日目，被験者はジストニア，呼吸困難，及び胸部圧迫感を発現した。投与 170 日目，ジストニアは消失した。投与 171 日目，呼吸困難，及び胸部圧迫感は消失した。

投与 169 日目，被験者は胸の重苦しさ，息切れ，上肢及び下肢の痙攣及び硬直感のため入院した。診断検査の結果，右脚ブロックを伴う徐脈が認められた。血液検査は低リン酸血症を示しており，リン酸濃度を改善するための治療を行った。本エピソードはパニック発作の二次的な事象と考えられた。投与 170 日目，被験者は退院し，症状は改善した。

被験者にリン酸，低分子ヘパリン，及びレボドパ / ベンセラジド分散剤（速溶錠）が投与された。

The patient's past medications include:

DOMPERIDONE for ASSIST WITH PARKINSON'S SWALLOWING (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Dystonia (10013983) (Dystonia (10013983)) [v.23.1] [10013983]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction recurred

2) Difficulty breathing (10012791) (Dyspnoea (10013968)) [v.23.1] [10012791]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

3) Chest pressure sensation (10008487) (Chest discomfort (10008469)) [v.23.1] [10008487]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of DYSTONIA

- Investigator: Not applicable

- AbbVie: More likely related to reported panic attack in an advanced aged patient with a history of Parkinson's disease

Event of DIFFICULTY BREATHING, FEELING OF PRESSURE ON CHEST

- Investigator: Not applicable

- **AbbVie:** More likely related to reported panic attack in an advanced aged patient with a history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 6[redacted] KG

[redacted] **20[redacted] CHEST X-RAY:** No known problems

[redacted] **20[redacted] D-DIMER:** Negative

[redacted] **20[redacted] ECG:** Sinus bradycardia and RBBB noted

[redacted] **20[redacted] PHOSPHATE:** 0.2 no units

[redacted] **20[redacted] TROPONIN:** <2 no units

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，胸部ジストニアを発現した。

Event 16 の臨床経過：

関連する病歴は，悪性貧血，パーキンソン病，右脚ブロック，洞性徐脈，非喫煙者，元葉巻タバコ喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 249 日目，被験者は胸部ジストニアを発現した。投与 250 日目，胸部ジストニアは消失した。

本事象発現前の投与 169 日目から投与 171 日目まで，被験者は重篤な呼吸困難を発現した。

投与 249 日目，被験者は胸部中央の痛み及び息切れのため入院した。被験者はジストニア及びジスキネジアの症状も認められた。臨床検査及び画像検査が実施され，結果は正常であった。投与 249 日目，息切れは消失した。投与 250 日目，胸部痛，ジストニア，及びジスキネジアの症状も消失した。同日，被験者は退院した。

被験者にグリセリルトリニトラートスプレー，モルヒネ硫酸塩，パラセタモール，アスピリン，及び生理食塩水が投与された。

The patient's past medications include:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE DISPERSIBLE for PARKINSON'S DISEASE and RESCUE MEDICINE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE STANDARD for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

---

1) Dystonia (10013983) (Dystonia (10013983)) [v.24.0] [10013983]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CHEST DYSTONIA

- Investigator: Possibly related to ABBV-951 and to infusion pump

- AbbVie: More likely related to history of Parkinson's disease in an elderly patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ADJUSTED CALCIUM:** 2.5 MMOL/L (normal 2.2 to 2.6)

[redacted] **20[redacted] ALANINE AMINO TRANSFERASE:** 8 IU/L (normal 0 to 55)

[redacted] **20[redacted] ALBUMIN:** 40 G/L (normal 35 to 50)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 70 IU/L (normal 30 to 130)

[redacted] **20[redacted] AMYLASE:** 23 IU/L (normal 25 to 125)

[redacted] **20[redacted] ANION GAP:** 10 MMOL/L (normal 8 to 12)

[redacted] **20[redacted] BICARBONATE:** 23 MMOL/L (normal 22 to 29)

[redacted] **20[redacted] BLOOD PRESSURE:** normal

[redacted] **20[redacted] CALCIUM:** 2.4 MMOL/L (normal 2.2 to 2.6)

[redacted] **20[redacted] CHEST X RAY:** THE HEART SIZE AND MEDIASTINAL CONTOURS ARE NORMAL. THE LUNGS ARE CLEAR.

[redacted] **20[redacted] CHLORIDE:** 104 MCMOL/L (normal 95 to 108)

[redacted] **20[redacted] CKD EPI GFR:** 86 ML/Min (normal 90 to 99999)

[redacted] **20[redacted] CREATININE:** 90 MCMOL/L (normal 64 to 111)

[redacted] **20[redacted] CRP:** <1 mg/L

[redacted] **20[redacted] D-DIMERS:** 172 NG/ML (normal 0 to 231)

[redacted] **20[redacted] ECG:** normal

[redacted] **20[redacted] ECHO:** SINUS RHYTHM WITH RIGHT BRANCH BUNDLE BLOCK (NOT NEW)

[redacted] **20[redacted] GLOBULIN:** 29 G/L (normal 20 to 35)

[redacted] **20[redacted] HEART ECHO:** SHOWED EF 71% AND NO STRUCTURAL HEART PROBLEMS. NORMAL VALVE FUNCTION.

[redacted] **20[redacted] PHOSPHATE:** 0.4 MMOL/L (normal 0.8 to 1.5)

[redacted] **20[redacted] POTASSIUM:** 3.4 MMOL/L (normal 3.5 to 5.3)

[redacted] **20[redacted] PROCALCITONIN:** 0.03 NG/ML

[redacted] **20[redacted] SODIUM:** 137 MMOL/L (normal 133 to 146)

[redacted] **20**[redacted] **TOTAL BILIRUBIN:** 9 MCMOL/L (normal 0 to 21)

[redacted] **20**[redacted] **TOTAL PROTEIN:** 69 G/L (normal 60 to 80)

[redacted] **20**[redacted] **UREA:** 4.4 MMOL/L (normal 2.5 to 7.8)

[redacted] **20**[redacted] **WHITE BLOOD CELLS:** 7.3 X10**9/L (normal 3.7 to 9.5)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
すくみ現象				X
注入部位膿瘍	X			X
注入部位蜂巣炎		X		X
注入部位疼痛				X
注入部位反応		X		X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
CRAMPS	NOT REPORTED
DYSPEPSIA	NOT REPORTED
HYPERCHOLESTEROLAEMIA	NOT REPORTED
HYPERTENSION	NOT REPORTED
OTEOPOROSIS	NOT REPORTED
SEVERE SCOLIOSIS	NOT REPORTED
DEPRESSION - NOT CLINICALLY RELEVANT	19[redacted]
PARKINSONS DISEASE	19[redacted]
EPILEPSY - ABSENCE SEIZURES	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	5 CIGARETTE	15	
CIGARS	FORMER			
E-CIGARETTES	CURRENT	10 SESSIONS	2	
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.4	0	0	0	0	[redacted]/1
ABBV-951	0.5	0	0	0	0	[redacted]/2
ABBV-951	0.65	0	0	60	0.11	[redacted]/9
ABBV-951	0.65	0	0	60	0.11	[redacted]/16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
DULOXETINE	30 mg	QD	Y-M: 20[redacted]
GABAPENTIN	600 mg	BID	Y-M: 20[redacted]
LAMOTRIGINE	100 mg	BID	Y-M: 20[redacted]
LANSOPRAZOLE	30 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	2.620 mg	QD	Y-M: 20[redacted]
QUININE SULFATE	200 mg	QD	Y-M: 20[redacted]
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]
COLECALCIFEROL	NOT REPORTED	QD	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
DULOXETINE	30 mg	QD	Y-M: 20[redacted]	ONGOING
GABAPENTIN	600 mg	BID	Y-M: 20[redacted]	ONGOING
LAMOTRIGINE	100 mg	BID	Y-M: 20[redacted]	ONGOING
LANSOPRAZOLE	30 mg	QD	Y-M: 20[redacted]	ONGOING
QUININE SULFATE	200 mg	QD	Y-M: 20[redacted]	ONGOING
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL		QD	Y-M: 20[redacted]	ONGOING
CLARITHROMYCIN	250 mg	BID	Y-M: 20[redacted] / 22	Y-M: 20[redacted] / 29

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	4
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	FREEZING EPISODE

Preferred term	すくみ現象
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	4
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ABDOMEN INFUSION SITE PAIN
Preferred term	注入部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 7
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	7
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	RIGHT UPPER ARM INFUSION SITE REACTION
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 9
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE LEFT ARM - ABSCESS
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	

AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #6: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	LEFT FLANK INFUSION SITE WITH SIGNS OF CELLULITIS
Preferred term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #7: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ADDITIONAL INFUSION SITE REACTION ON THE LEFT FLANK
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #8: AE Leading to Discontinuation of Study Drug, Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION RIGHT FLANK INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 22
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左腕の注入部位膿瘍を発現した。

Event 5 の臨床経過：

関連する病歴は，パーキンソン病，紙巻タバコ喫煙者（1 日 5 本を 15 年），現電子タバコ喫煙者（1 日 10 回を 2 年間），元葉巻タバコ喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 15 日目，被験者は左腕の注入部位膿瘍を発現した。

被験者は左腕に直径約 7 cm の大きな感染膿瘍を呈した重度の皮膚反応を発現した。また，他の注入部位（腹部）では皮膚反応が認められたが明瞭ではなく，局所的な赤み及び光沢のある外見であった。投与 22 日目，被験者は試験を中止した。投与 31 日目，皮膚反応は大幅に改善し，以降の治療は不要であった。

被験者にクラリスロマイシンが投与された。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.22.1] [10058464]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of INFUSION SITE LEFT ARM-ABSCESS

- Investigator: Not applicable

- AbbVie: Not applicable

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
譫妄	X			
妄想				X
幻覚	X			X
幻視				X
低体温	X			
注入部位膿瘍				X
注入部位紅斑				X
注入部位皮膚剥脱				X
注入部位結節				X
注入部位浮腫				X
注入部位反応				X
注射部位反応				X
肺炎	X			
精神病性障害	X			X
敗血症	X			
敗血症性ショック	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
OVERWEIGHT (BMI 33.6 KG/M2)	NOT REPORTED
CARPAL TUNNEL SYNDROME	19[redacted]
ARTHRITIS	20[redacted]
MENOPAUSE	20[redacted]
DEPRESSION (PART OF NMS PD)	20[redacted]
FUSION OF LEFT MID FOOT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED

PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
ULNAR NERVE TRANSPOSITION	19[redacted]
HYSTERECTOMY	19[redacted]
FUSION L3.L4 AND L4/L5, L5S1	20[redacted]
KNEE REPLACEMENT BILATERAL	20[redacted]
TOTAL HIP REPLACEMENT	20[redacted]
FUSION C3/C4 AND C4/C5	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.45	0	0	60	0.15	[redacted]20[redacted]/1
ABBV-951	0.55	0	0	60	0.15	[redacted]20[redacted]/2
ABBV-951	0.55	0	0	60	0.15	[redacted]20[redacted]/42
ABBV-951	0.45	0.55	0.35	61	0.15	[redacted]20[redacted]/43
ABBV-951	0.4	0.5	0.3	60	0.15	[redacted]20[redacted]/209
ABBV-951	0.3	0.25	0.35	360	0.11	[redacted]20[redacted]/306
ABBV-951	0.3	0.25	0.35	360	0.11	[redacted]20[redacted]/387
ABBV-951	0.3	0.25	0.35	360	0.11	[redacted]20[redacted]/393

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		25.61	SC / ONCE	[redacted] / 1	
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	1844.1		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33

ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 43	
ABBV-951	1031.33		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1097.06		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	683		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232

ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 233	
ABBV-951	1717.74		SC / CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 234	
ABBV-951	1287.45		SC / CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 235	
ABBV-951	947.66		SC / CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	1669.93		SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	1497.47		SC / CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2013.14		SC / CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	2031.92		SC / CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 240	
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 241	
ABBV-951	1615.29		SC / CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	1897.03		SC / CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 245	
ABBV-951	1473.57		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	1951.67		SC / CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	1748.48		SC / CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	1673.35		SC / CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 249	
ABBV-951	1509.43		SC / CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 250	
ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	1540.16		SC / CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 252	
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	1613.58		SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	1929.47		SC / CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1632.37		SC / CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 259	
ABBV-951	1632.37		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259

ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 260	
ABBV-951	1632.37		SC / CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 261	
ABBV-951	1611.88		SC / CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 262	
ABBV-951	1611.88		SC / CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 263	
ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	1632.37		SC / CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1618.71		SC / CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 266	
ABBV-951	1763.84		SC / CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1625.54		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	1058.65		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	332.96		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 307	
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 308	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 313	
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 315	
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 316	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 323	

ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	1167.93		SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 331	
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1198.66		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 335	
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1126.95		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 337	
ABBV-951	87.08		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	281.73		SC / CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 342	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1203.78		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1224.27		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1208.91		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1214.03		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355

ABBV-951		18.78	SC / ONCE	[redacted] / 356	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted] / 356	[redacted] / 356
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 357	[redacted] / 357
ABBV-951		37.56	SC / ONCE	[redacted] / 358	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted] / 358	[redacted] / 358
ABBV-951	1219.15		SC / CONTINUOUS	[redacted] / 359	[redacted] / 359
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 360	[redacted] / 360
ABBV-951	1214.03		SC / CONTINUOUS	[redacted] / 361	[redacted] / 361
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 362	[redacted] / 362
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951		37.56	SC / ONCE	[redacted] / 364	
ABBV-951	1224.27		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365
ABBV-951		18.78	SC / ONCE	[redacted] / 366	
ABBV-951	1219.15		SC / CONTINUOUS	[redacted] / 366	[redacted] / 366
ABBV-951	1214.03		SC / CONTINUOUS	[redacted] / 367	[redacted] / 367
ABBV-951	1208.91		SC / CONTINUOUS	[redacted] / 368	[redacted] / 368
ABBV-951	1214.03		SC / CONTINUOUS	[redacted] / 369	[redacted] / 369
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 370	[redacted] / 370
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 371	[redacted] / 371
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 372	[redacted] / 372
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 373	[redacted] / 373
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 374	[redacted] / 374
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 375	[redacted] / 375
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 376	[redacted] / 376
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 377	[redacted] / 377
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 378	[redacted] / 378
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 379	[redacted] / 379
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 380	[redacted] / 380
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 381	[redacted] / 381
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 382	[redacted] / 382
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 383	[redacted] / 383
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 384	[redacted] / 384
ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 385	[redacted] / 385
ABBV-951	1070.60		SC / CONTINUOUS	[redacted] / 386	[redacted] / 386
ABBV-951	824.72		SC / CONTINUOUS	[redacted] / 389	[redacted] / 389
ABBV-951	1150.00		SC / CONTINUOUS	[redacted] / 390	[redacted] / 390

ABBV-951	1140.61	SC / CONTINUOUS	[redacted] / 391	[redacted] / 391
ABBV-951	1219.15	SC / CONTINUOUS	[redacted] / 392	[redacted] / 392
ABBV-951	496.88	SC / CONTINUOUS	[redacted] / 393	[redacted] / 393

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CODEINE PHOSPHATE HEMIHYDRATE;PARACETAMOL	500 mg	TID	Y-M: 20[redacted]
SERTRALINE	150 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	8 TIMES PER DAY	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	12.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CODEINE PHOSPHATE HEMIHYDRATE;PARACETAMOL	500 mg	TID	Y-M: 20[redacted]	ONGOING
SERTRALINE	150 mg	QD	Y-M: 20[redacted]	ONGOING
QUETIAPINE	25 mg	BID	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 30
AMOXICILLIN;CLAVULANATE POTASSIUM	UNKNOWN OTHER: UNKNOWN	OTHER: INFUSION	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 31
CLARITHROMYCIN	UNKNOWN OTHER: UNKNOWN	OTHER: UNKNOWN	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 31
NITROFURANTOIN	100 mg	QID	Y-M: 20[redacted] / 30	Y-M: 20[redacted] / 36
ERYTHROMYCIN	500 mg	BID	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 256
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 268	Y-M: 20[redacted] / 370
PYRIDOXINE HYDROCHLORIDE	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / 306	ONGOING
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 370	Y-M: 20[redacted] / 373
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 373	ONGOING
PARACETAMOL	1000 mg	QD	Y-M: 20[redacted] / 387	ONGOING

Event #1: Serious Adverse Event

Event Description	HYPOTHERMIA
Preferred term	低体温
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434] UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	28 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	PREVIOUS EPISODES OF HYPOTHERMIA (PRIOR TO STUDY COMMENCEMENT) WERE RELATED TO AN INFECTION.THE PI FEELS THIS WAS DUE TO INFECTION WHICH HAS BEEN CLASSIFIED AS PNEUMONIA; PATHOGEN UNKNOWN AT THIS TIME
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	PNEUMONIA
Preferred term	肺炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED]

UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434] UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	28 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	PATHOGEN UNKNOWN, BACTERIAL CULTURES NO GROWTH.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #3: Serious Adverse Event

Event Description	SEPSIS
Preferred term	敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434] UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	28 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	PREVIOUS EPISODES OF HYPOTHERMIA (PRIOR TO STUDY COMMENCEMENT) WERE RELATED TO AN INFECTION.THE PI FEELS THIS WAS DUE TO INFECTION WHICH HAS BEEN CLASSIFIED AS PNEUMONIA; PATHOGEN UNKNOWN AT THIS TIME
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event

Event Description	SEPTIC SHOCK
Preferred term	敗血症性ショック
AE Onset Date / Rx Day	[redacted]20[redacted] / 3
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434] UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	28 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other cause of event	PNEUMONIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #5: Serious Adverse Event

Event Description	DELIRIUM
Preferred term	譫妄
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434] UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other cause of event	MOST LIKELY CAUSE OF EVENT IS THE SEPSIS AND ICU ADMISSION FOR ALMOST A WEEK.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #6: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 10
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 27): CALCIUM: 2.19 [2.2 - 2.55] MMOL/L; CREATININE: 39 [53 - 106] UMOL/L; HEMOGLOBIN: 119 [117 - 161] G/L; LEUKOCYTES: 4.1 [4.5 - 11] 10^9/L; NPTST051-BNP: 275 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST097-CRP: 10.8 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] UNKNOWN; NPTST300-TROPONIN: 19 [NOT REPORTED - NOT REPORTED] UNKNOWN; SODIUM: 143 [136 - 145] MMOL/L; URATE: 3900 [208 - 434]

UMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 19): URINE MICROBIOLOGY: POSITIVE-E.COLI

AE Stopped Rx Day	30
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	UTI
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT

Event #7: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONS
Preferred term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #8: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL HALLUCINATION
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Infusion Site Related Infections

Event Description	REGRESSING ABSCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Infusion Site Related Infections

Event Description	REGRESSING ABSCESS AT INFUSION SITE
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

Event #13: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PEELING AT THE INFUSION SITE
Preferred term	注入部位皮膚剥脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #14: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION (NODULE) AT INFUSION SITE
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY

SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #15: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION (NODULE) AT INFUSION SITE - RIGHT LOWER ABDOMEN SITE 2
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION (NODULE) AT INFUSION SITE - RIGHT ABDOMEN SITE 3
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 232

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #17: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION (NODULE) AT INFUSION SITE - LEFT LOWER ABDOMEN SITE 1
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #18: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SKIN REACTION (NODULE) AT INFUSION SITE - LEFT LOWER ABDOMEN SITE 2
Preferred term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #19: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DEFINITE OEDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393

Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #20: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	GLAZING AND CRACKING AT INFUSION SITE
Preferred term	注入部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #21: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT GLAZED APPEARANCE AT INFUSION SITE
Preferred term	注入部位反応

AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #22: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	SLIGHT GLAZED APPEARANCE AT INJECTION SITE
Preferred term	注射部位反応
AE Onset Date / Rx Day	[redacted]20[redacted] / 232
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
Duration of AE	162 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #23: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 268
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 271): ALANINE AMINOTRANSFERASE: <5 [NOT REPORTED - NOT REPORTED] IU/L; ALBUMIN: 32 [32 - 46] G/L; ALKALINE PHOSPHATASE: 82 [NOT REPORTED - NOT REPORTED] IU/L; BILIRUBIN: 10 [3 - 19] UMOL/L; CALCIUM: 2.16 [2.2 - 2.55] MMOL/L; CREATININE: 40 [53 - 106] UMOL/L; HEMOGLOBIN: 122 [117 - 161] G/L; LEUKOCYTES: 4.4 [4.5 - 11] 10^9/L; NPTST097-CRP: 22.1 [18.8 - 23.6] MG/L; NPTST109-EGFR: >90 [NOT REPORTED - NOT REPORTED] ML/MIN; NPTST183-MCV: 85.4 [NOT REPORTED - NOT REPORTED] FL; NPTST244-PHOSPHORUS BLOOD TEST: 1.29 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST307-UREA: 2.7 [NOT REPORTED - NOT REPORTED] MMOL/L; PLATELETS: 185 [150 - 400] 10^9/L; POTASSIUM: 3.9 [3.4 - 4.4] MMOL/L; SODIUM: 141 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	370
Duration of AE	103 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #24: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 370
Age at AE Onset	6[redacted]

Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，敗血症性ショック，肺炎，譫妄，低体温，敗血症，及び幻覚を発現した。

Event 1，2，3，4，5，及び 6 の臨床経過：

関連する病歴は，関節炎，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 3 日目，被験者は敗血症性ショック，肺炎，低体温，及び敗血症を発現した。投与 10 日目，被験者は譫妄及び幻覚を発現した。投与 30 日目，敗血症性ショック，肺炎，譫妄，低体温，敗血症，及び幻覚は消失した。

投与 3 日目，被験者は 30.5℃の低体温，感染，及び集中治療室への入院が必要な敗血症及び呼吸不全のため入院した。低体温の原因は，その後の呼吸障害にもつながった感染と考えられた。敗血症について検査が行われた。投与 4 日目，被験者は呼吸不全のため人工呼吸器を介した呼吸

補助を必要とした。投与 6 日目，呼吸不全は改善し，非侵襲的な換気から離脱した。投与 8 日目，被験者は集中治療室から一般病棟に移送され，そこで譫妄（感染が原因である可能性あり）を発現した。治験責任医師は必要に応じてロチゴチンを 10 mg に減量し，クエチアピンを導入するよう指導した。投与 15 日目，譫妄によってポンプを抜き取りがちになる重度の落ち着きのなさを認めたため，被験者は治験薬投与を中止した。被験者は抗生物質治療によって安定化し，譫妄の治療のためクエチアピンが投与され，同時にロチゴチンを 4 mg に減量した。投与 30 日目，被験者は退院した。

被験者にアモキシシリン / クラブラン酸，クラリスロマイシン，クエチアピン，NITROFURANTOIN，レボドパ / ベンセラジド速溶錠，クエチアピン及びレボドパ / カルビドパ速放剤が投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA for PARKINSON'S (20[redacted] - [redacted] 20[redacted])

MODOPAR for PARKINSON'S ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Septic shock (10040070) (Septic shock (10040070)) [v.24.0] [10040070]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.24.0] [10035664]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

3) Delirium (10012218) (Delirium (10012218)) [v.24.0] [10012218]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

4) Sepsis (10040047) (Sepsis (10040047)) [v.24.0] [10040047]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

5) Hypothermia (10021113) (Hypothermia (10021113)) [v.24.0] [10021113]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

6) Hallucinations (10019077) (Hallucination (10019063)) [v.24.0] [10019077]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of SEPTIC SHOCK

- Investigator: Pneumonia.

- AbbVie: More likely related to concurrent event of pneumonia in an advanced age subject with Parkinson's disease and elevated BMI.

Event of PNEUMONIA

- Investigator: Pathogen unknown. Bacterial cultures no growth.

- AbbVie: More likely related to coincidental occurrence in an advanced age subject with Parkinson's disease and elevated BMI.

Event of DELIRIUM

- Investigator: Most likely cause of event is the sepsis and ICU admission for almost a week.

- AbbVie: More likely related to concurrent event of pneumonia with sepsis in an advanced age subject with Parkinson's disease.

Event of HYPOTHERMIA, SEPSIS

- Investigator: Previous episodes of hypothermia (prior to study commencement) were related to an infection. The P.I feels this was due to infection which has been classified as pneumonia. Pathogen unknown at this time.

- AbbVie: More likely related to concurrent event of pneumonia in an advanced age subject with Parkinson's disease.

Event of HALLUCINATIONS

- Investigator: UTI

- AbbVie: More likely related to concurrent event of pneumonia with sepsis in an advanced age subject with Parkinson's disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BNP:** 275 No unit

[redacted] **20[redacted] BODY TEMPERATURE:** 30.5 Degrees C

[redacted] **20[redacted] CALCIUM:** 2.10 No unit

[redacted] **20[redacted] CREATININE:** 39 MCMOL/L

[redacted] **20[redacted] CRP:** 10.8 No unit

[redacted] **20[redacted] EGFR:** >90 No unit

[redacted] **20[redacted] HEMOGLOBIN:** 119 G/L

[redacted] **20[redacted] SODIUM:** 143 MMOL/L

[redacted] **20[redacted] TROPONIN:** 19 No unit

[redacted] **20[redacted] URIC ACID:** 3.9 MMOL/L

[redacted] **20[redacted] URINE MICROBIOLOGY:** Positive; E. Coli

[redacted] **20[redacted] WHITE BLOOD CELLS:** 4.10 X10**9/L

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病性障害の悪化及び精神病性障害を発現した。

Event 23 及び 24 の臨床経過：

関連する病歴は，パーキンソン病，閉経，うつ病（パーキンソン病の非運動性症状の一部），非喫煙者，及び非飲酒者であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 268 日目，被験者は精神病性障害を発現した。投与 370 日目，被験者は精神病性障害の悪化を発現した。投与 370 日目，精神病性障害は消失した。

本事象発現前に，被験者は非重篤な幻覚（投与 232 日目）及び昼夜逆転（投与 265 日目）を発現した。

投与 268 日目，被験者は錯乱，幻覚（非重篤），及び昼夜逆転（非重篤）と関連のある睡眠サイクルの乱れのため入院した。また，精神病性障害及び攻撃的行動も認められた。血液検査には感染の徴候がなく，観察では安定しており，頭部 CT スキャンでは急性所見は認められなかった。投与 274 日目，被験者は退院した。治験責任医師は，被験者に対してクエチアピンの用量を 1 日 25 mg に増量した。

投与 370 日目，被験者は精神病性障害の悪化を発現し，幻覚の悪化及び妄想様観念のため入院した。運動症状は安定していた。精密検査の結果は正常であった。精神病性障害はパーキンソン病によるものと結論付けられた。被験者は退院できる程度まで回復したが，精神病性障害は継続中であった。投与 373 日目，被験者は退院した。

治験責任医師によると，関連するリスク因子として進行性パーキンソン病が挙げられた。

被験者にクエチアピンが投与された。

The patient's past medications include:

QUETIAPINE for DELIRIUM ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Psychosis aggravated (10048343) (Psychotic disorder (10061920)) [v.24.0] [10048343]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: No

2) Psychosis (10037234) (Psychotic disorder (10061920)) [v.24.0] [10037234]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to advanced Parkinson’s disease, history of depression and menopause.

Event of PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to advanced Parkinson’s disease, history of depression and menopause.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALANINE AMINOTRANSFERASE:** <5 IU/L

[redacted] **20[redacted] ALBUMIN:** 32 G/L

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 82 IU/L

[redacted] **20[redacted] BILIRUBIN:** 10 umol/L

[redacted] **20[redacted] BMI:** 33.10 kg/m11 [redacted] 20[redacted] BODY WEIGHT: 10[redacted] KG

[redacted] **20[redacted] CALCIUM:** 2.16 MMOL/L

[redacted] **20[redacted] COVID-19 VIRUS TEST:** PCR - negative

[redacted] **20[redacted] CREATININE:** 40 umol/L

[redacted] **20[redacted] CRP:** 22.1 MG/L

[redacted] **20[redacted] CT HEAD:** normal

[redacted] **20[redacted] EGFR:** >90 ML/MIN

[redacted] **20[redacted] HEMOGLOBIN:** 122 G/L

[redacted] **20[redacted] MCV:** 85.4 FL

[redacted] **20[redacted] PHOSPHATE:** 1.29 no units

[redacted] **20[redacted] PLATELET COUNT:** 185 X10**9/L

[redacted] **20[redacted] POTASSIUM:** 3.9 MMOL/L

[redacted] **20[redacted] UREA:** 2.7 MMOL/L

[redacted] **20[redacted] WBC:** 4.40 X10**9/L

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
幻覚				X
片側感覚消失	X			
不全片麻痺	X			
注入部位膿瘍				X
精神病性障害	X	X		X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	8[redacted]	FEMALE	WHITE

Medical History	Onset Year
ABDOMINAL HERNIA	NOT REPORTED
ALLERGY	19[redacted]
HYPOVITAMINOSIS C	19[redacted]
POSTMENOPAUSAL	19[redacted]
ANAEMIA	20[redacted]
HYPERCHOLESTEROLAEMIA	20[redacted]
MILD DEPRESSIVE SYMPTOMS	20[redacted]
HYPOVITAMINOSIS B12	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.33	0.27	0.4	60	0.15	[redacted]/1
ABBV-951	0.4	0.27	0.33	60	0.15	[redacted]/2
ABBV-951	0.45	0.27	0.4	60	0.15	[redacted]/8
ABBV-951	0.45	0.27	0.4	60	0.15	[redacted]/15
ABBV-951	0.5	0.4	0.27	60	0.15	[redacted]/22
ABBV-951	0.5	0.4	0.33	60	0.15	[redacted]/27
ABBV-951	0.5	0.4	0.33	60	0.15	[redacted]/48
ABBV-951	0.5	0.4	0.33	60	0.15	[redacted]/92

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	698.70		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1220.00		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1459.40		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	1208.56		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	1450.35		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1439.42		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	477.07		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		51.22	SC / ONCE	[redacted] / 8	
ABBV-951	1658.15		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8

ABBV-951	1613.58		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1506.01		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1628.95		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 12	
ABBV-951	1647.39		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 13	
ABBV-951	1456.32		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1611.88		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	635.19		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	748.73		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1579.60		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1748.48		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1697.42		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1765.55		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1500.72		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1843.07		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 29	
ABBV-951	1854.51		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 30	
ABBV-951	1837.44		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1796.80		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1799.70		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 33	
ABBV-951	1808.41		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1825.82		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 35	
ABBV-951	1805.51		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1817.12		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 37	
ABBV-951	1822.92		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1817.12		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1709.71		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39

ABBV-951	1756.50		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1802.60		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 42	
ABBV-951	1814.38		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1823.09		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
ABBV-951	1797.14		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1805.51		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 46	
ABBV-951	1831.63		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 47	
ABBV-951	1796.80		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
ABBV-951	1854.85		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 49	
ABBV-951	1811.48		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 50	
ABBV-951	1837.44		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 51	
ABBV-951	1837.27		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1857.93		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1794.07		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1837.27		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1851.78		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1570.38		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2003.06		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1808.58		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1532.31		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1538.28		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1531.11		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1535.89		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1538.28		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1524.28		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1799.70		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1688.20		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1782.28		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1811.31		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68

ABBV-951	1802.60		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1799.87		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1834.70		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1851.78		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1802.60		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1820.02		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1837.27		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1796.80		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 77	
ABBV-951	1799.87		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 78	
ABBV-951	1819.85		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1782.28		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1796.46		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1805.51		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1808.24		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 83	
ABBV-951	1779.21		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1782.11		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1819.85		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 86	
ABBV-951	1799.53		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1822.92		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1802.60		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 89	
ABBV-951	1828.56		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 90	
ABBV-951	1790.99		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 91	
ABBV-951	1799.70		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 92	
ABBV-951	1834.53		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1822.92		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 94	
ABBV-951	1761.96		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1767.60		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1787.92		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96

ABBV-951	1782.11		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 98	
ABBV-951	1825.65		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1825.82		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1802.60		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1796.97		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 102	
ABBV-951	1845.97		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1840.17		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 104	
ABBV-951	1808.41		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1840.34		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	1808.41		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 107	
ABBV-951	1799.53		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1814.21		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1837.44		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 110	
ABBV-951	1799.70		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 111	
ABBV-951	1813.87		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 112	
ABBV-951	1808.07		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 113	
ABBV-951	1814.21		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 114	
ABBV-951	1831.46		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 115	
ABBV-951	1820.02		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 116	
ABBV-951	1845.97		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 117	
ABBV-951	1817.12		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 118	
ABBV-951	1808.41		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 119	
ABBV-951	1822.75		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119

ABBV-951		25.61	SC / ONCE	[redacted] / 120
ABBV-951	1816.95		SC / CONTINUOUS	[redacted] / 120 [redacted] / 120
ABBV-951	1842.90		SC / CONTINUOUS	[redacted] / 121 [redacted] / 121
ABBV-951	1808.41		SC / CONTINUOUS	[redacted] / 122 [redacted] / 122
ABBV-951		25.61	SC / ONCE	[redacted] / 123
ABBV-951	1822.75		SC / CONTINUOUS	[redacted] / 123 [redacted] / 123
ABBV-951		25.61	SC / ONCE	[redacted] / 124
ABBV-951	1811.14		SC / CONTINUOUS	[redacted] / 124 [redacted] / 124
ABBV-951		25.61	SC / ONCE	[redacted] / 125
ABBV-951	1828.56		SC / CONTINUOUS	[redacted] / 125 [redacted] / 125
ABBV-951		25.61	SC / ONCE	[redacted] / 126
ABBV-951	1805.33		SC / CONTINUOUS	[redacted] / 126 [redacted] / 126
ABBV-951		51.22	SC / ONCE	[redacted] / 127
ABBV-951	1814.04		SC / CONTINUOUS	[redacted] / 127 [redacted] / 127

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
FERROUS SULFATE	210 mg	QD	Y-M: 20[redacted]
SERTRALINE	50 mg	QD	Y-M: 20[redacted]
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]
ROPINIROLE	12.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	49.000 mg	QD	Y-M: 20[redacted]-[redacted]
APOMORPHINE	4.000 mg	QD	Y-M: 20[redacted]-[redacted]
ASCORBIC ACID	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -330
FEXOFENADINE	180 mg	QD	Y-M: 20[redacted] / -330
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	150.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -35
CYANOCOBALAMIN	1 mg	OTHER: THREE TIMES PER WEEK	Y-M: 20[redacted]-[redacted] / -31
PARACETAMOL	500 mg	TID	Y-M: 20[redacted]-[redacted] / -25
VITAMIN B COMPLEX	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted] / -16
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -1

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
FERROUS SULFATE	210 mg	QD	Y-M: 20[redacted]	ONGOING
SERTRALINE	50 mg	QD	Y-M: 20[redacted]	ONGOING
SIMVASTATIN	20 mg	QD	Y-M: 20[redacted]	ONGOING
ASCORBIC ACID	UNKNOWN OTHER: UNKNOWN	QD	Y-M: 20[redacted] / -330	ONGOING
FEXOFENADINE	180 mg	QD	Y-M: 20[redacted] / -330	ONGOING
CYANOCOBALAMIN	1 mg	OTHER: THREE TIMES PER WEEK	Y-M: 20[redacted] / -31	Y-M: 20[redacted] / -16
PARACETAMOL	500 mg	TID	Y-M: 20[redacted] / -25	ONGOING
VITAMIN B COMPLEX	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -16	ONGOING
ACETYLSALICYLIC ACID	75 mg	QD	Y-M: 20[redacted] / 19	ONGOING
FLUCLOXACILLIN	UNKNOWN mg	BID	Y-M: 20[redacted] / 139	Y-M: 20[redacted] / 146
CLARITHROMYCIN	UNKNOWN mg	BID	Y-M: 20[redacted] / 150	Y-M: 20[redacted] / 158
METRONIDAZOLE	400 mg	TID	Y-M: 20[redacted] / 158	ONGOING
SULFAMETHOXAZOLE;TRIMETHOPRIM	80/400 mg	TID	Y-M: 20[redacted] / 158	Y-M: 20[redacted] / 164

Event #1: Event of Interest -Falls And Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 13
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	13
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	TRANSIENT RIGHT-SIDED HEMIHYPO-AESTHESIA
Preferred term	片側感覚消失
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	15
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Serious Adverse Event

Event Description	HEMIPARESIS RIGHT SIDE
Preferred term	不全片麻痺
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	

AE Stopped Rx Day	15
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event

Event Description	TRANSIENT RIGHT-SIDED HEMIPARESIS
Preferred term	不全片麻痺
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	15
Duration of AE	1 DAY
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 139
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	144
Duration of AE	6 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE ABSCESS
Preferred term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 144
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 144
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Event of Interest -Falls And Associated Injuries

Event Description	RECURRENT FALLS
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 157
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 8[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，右半身不全片麻痺，一過性の右半身不全片麻痺，及び一過性の右半身片側感覚消失を発現した。

Event 2，3 及び 4 の臨床経過：

関連する病歴は，パーキンソン病，高コレステロール血症，ビタミン B12 欠乏症，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 15 日目，被験者は右半身不全片麻痺，一過性の右半身不全片麻痺，及び一過性の右半身片側感覚消失を発現した。投与 15 日目，右半身不全片麻痺，一過性の右半身不全片麻痺，及び一過性の右半身片側感覚消失は消失した。

本事象発現前の投与 13 日目に，被験者は落下事故（非重篤）にあった。

投与 15 日目，被験者は一過性脳虚血発作又は軽微な脳卒中の疑いがあり，精密検査のため入院した。被験者には右半身に不全片麻痺が認められた。実施された脳 CT の結果は年齢相応の正常範囲内であった。入院中，被験者に新たな症状は認められなかった。投薬に変更はなかった。投与 16 日目，被験者は退院した。

The patient's past medications include:

SINEMET IR for PARKINSON'S DISEASE (20[redacted] - [redacted] 20[redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE GO for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

MADOPAR RAPID for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

COCABALAMINE for HYPOVITAMINOSIS B12 ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hemiparesis (10019465) (Hemiparesis (10019465)) [v.23.1] [10019465]

Causality asper reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

2) Hemihypoesthesia (10077205) (Hemianaesthesia (10077170)) [v.23.1] [10077205]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

3) Hemiparesis (right) (10019467) (Hemiparesis (10019465)) [v.23.1] [10019467]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of HEMIPARESIS RIGHT SIDE, TRANSIENT RIGHT-SIDED HEMIPARESIS, TRANSIENT RIGHT-SIDED HEMIHYPO-AESTHESIA

- Investigator: Not applicable

- AbbVie: More likely related to a history of hypercholesterolemia in an advanced aged patient

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CEREBRAL CT:** Some age appropriate atrophy, no signs of ischemia, no haemorrhage, normal white-grey matter differentiation.

[redacted] **20[redacted] CHEST X-RAY:** Large hiatus hernia, no abnormalities in the lungs.

[redacted] **20[redacted] CT SPINE:** Degenerative changes throughout the cervical spine with multilevel disc narrowing and anterior slip C7/T1. Mild narrowing of canal C4 to T1 but no compression of spinal cord. Superior end-plate fracture T3 with Schmorls node. No fractures or prevertebral tissue swelling.

[redacted] **20[redacted] WEIGHT:** 5[redacted] KG
Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 8[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病性障害を発現した。

Event 7 の臨床経過：

関連する病歴は，閉経，パーキンソン病，貧血，高コレステロール血症，軽度の抑うつ症状，ビタミン B12 欠乏症，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。

本期間を通してABBV-951の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与144日目，被験者は精神病性障害を発現した。

本事象発現前の投与から約7ヵ月前に，被験者は非重篤な事象として，尿路感染，譫妄，幻覚，及び注入部位膿瘍を発現した。

投与166日目，被験者は病識を伴わない重度の精神病性障害のため入院した。精神病性障害は数週間前から徐々に悪化していた。被験者の精神病性障害の症状は，治験薬投与の休止後に急速に改善した。精神病性障害を改善するための追加の薬剤は必要ではなかった。投与175日目，被験者は退院した。

治験責任医師によると，関連するリスク因子として進行性パーキンソン病及び年齢が挙げられた。

本事象によって治験薬投与が中止された。

The patient's past medications include:

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON’S DISEASE (20[redacted] - [redacted] 20[redacted])

ROPINIROLE for PARKINSON’S DISEASE (20[redacted] - [redacted] 20[redacted])

APOMORPHINE CONTNFUSION for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

APOMORPHINE GO for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVODOPA/BENSERAZIDE DISPERSIBLE for PARKINSON’S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Psychosis (10037234) (Psychotic disorder (10061920)) [v.24.0] [10037234]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): Reasonable possibility

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOSIS

- **Investigator:** Not Applicable

- **AbbVie:** Not Applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 5[redacted] KG

[redacted] **20[redacted] BRAIN CT:** Normal

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
寄生虫妄想		X		X
浮動性めまい	X			X
転倒	X			X
幻視		X		X
注入部位紅斑				X
注入部位浮腫				X
注射部位疼痛				X
傾眠				X
体重減少				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
DYSPHAGIA	19[redacted]
GORD	19[redacted]
DEPRESSION	20[redacted]
MIXED AORTIC VALVE DISEASE	20[redacted]
MENINGIOMA NOS	20[redacted]
HYPERTENSION	20[redacted]
BACK PAIN	20[redacted]
BLADDER PROBLEMS	20[redacted]
CONSTIPATION	20[redacted]
OSTEOARTHRITIS	20[redacted]
ANGINA	20[redacted]
ISCHAEMIC HEART DISEASE (IHD)	20[redacted]
INSOMNIA	20[redacted]

BILATERAL CATARACTS	20[redacted]
VITREOUS DETACHMENT	20[redacted]
MACULAR DEGENERATION	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
CRANIOTOMY FOR REMOVAL OF MENINGIOMA	20[redacted]
TOTAL HIP REPLACEMENT LEFT	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	40 CIGARETTE	10	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (Min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.32	0.24	60	0.19	[redacted]20[redacted]/1
ABBV-951	0.27	0.32	0.22	60	0.19	[redacted]20[redacted]/4
ABBV-951	0.3	0.33	0.27	60	0.19	[redacted]20[redacted]/11
ABBV-951	0.3	0.33	0.27	60	0.19	[redacted]20[redacted]/15
ABBV-951	0.33	0.37	0.27	60	0.19	[redacted]20[redacted]/25
ABBV-951	0.37	0.43	0.33	60	0.19	[redacted]20[redacted]/32
ABBV-951	0.37	0.43	0.33	60	0.19	[redacted]20[redacted]/40
ABBV-951	0.37	0.43	0.33	60	0.19	[redacted]20[redacted]/89

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		32.44	SC / ONCE	[redacted] / 24	
ABBV-951	800.13		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1043.11		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	694.95		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	84.52		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	1447.96		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	1458.20		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		32.44	SC / ONCE	[redacted] / 49	
ABBV-951	1231.96		SC / CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951	631.77		SC / CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62

ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1516.26	SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1494.06	SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1508.74	SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1462.30	SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1457.52	SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]-[redacted]
BOTULINUM TOXIN TYPE A	1 mL	PRN	Y-M: 20[redacted]-[redacted]
ACETYLSALICYLIC ACID	75 mg	QD	Y-M: 20[redacted]
BISOPROLOL FUMARATE	5 mg	QD	Y-M: 20[redacted]

BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
FESOTERODINE FUMARATE	8 mg	QD	Y-M: 20[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]
MELATONIN	2 mg	QD	Y-M: 20[redacted]
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted]
SELEGILINE	10.000 mg	QD	Y-M: 20[redacted]

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted]	ONGOING
BOTULINUM TOXIN TYPE A	1 mL	PRN	Y-M: 20[redacted]	ONGOING
ACETYLSALICYLIC ACID	75 mg	QD	Y-M: 20[redacted]	ONGOING
BISOPROLOL FUMARATE	5 mg	QD	Y-M: 20[redacted]	ONGOING
FESOTERODINE FUMARATE	8 mg	QD	Y-M: 20[redacted]	ONGOING
MELATONIN	2 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 153
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted]	ONGOING
CODEINE PHOSPHATE;PARACETAMOL	30/500 mg	PRN	Y-M: 20[redacted] / 25	ONGOING
AFLIBERCEPT	40 OTHER: MG/ML	OTHER: 2 MONTHLY	Y-M: 20[redacted] / 26	ONGOING
AMOXICILLIN	500 mg	TID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 122
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 131	ONGOING

Event #1: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	PAIN AT INJECTION SITE
Preferred term	注射部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 4
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	11
Duration of AE	8 DAYS

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERTHYMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 15
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	22
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, Event of Interest -Falls And Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	DIZZINESS
Preferred term	浮動性めまい

AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 25): ALANINE AMINOTRANSFERASE: 9 [5 - 55] U/L; ALBUMIN: 34 [35 - 50] G/L; ALKALINE PHOSPHATASE: 68 [30 - 130] U/L; BASOPHILS: 0.1 [0 - 0.1] 10^9/L; BILIRUBIN: 8 [0 - 21] UMOL/L; CREATININE: 66 [62 - 106] UMOL/L; EOSINOPHILS: 0.23 [0 - 0.4] 10^9/L; ERYTHROCYTES: 5 [4.5 - 6] 10^12/L; GLUCOSE: 5.9 [3.3 - 5.8] MMOL/L; HEMATOCRIT: 0 [0 - 0.01] FRACTION OF 1; HEMOGLOBIN: 145 [130 - 180] G/L; LEUKOCYTES: 5.1 [4 - 11] 10^9/L; LYMPHOCYTES: 1.3 [1.5 - 4] 10^9/L; MONOCYTES: 0.4 [0.2 - 0.8] 10^9/L; NPTST004-ACTIVATED PARTIAL THROMBOPLASTI: 1.2 [NOT REPORTED - NOT REPORTED] RATIO; NPTST004-ACTIVATED PARTIAL THROMBOPLASTI: 34.5 [24.3 - 35.2] SEC; NPTST056-C-REACTIVE PROTEIN: 4 [0 - 10] MG/L; NPTST114-ESTIMATED GFR: 60 [NOT REPORTED - NOT REPORTED] ML/MIN; NPTST184-MEAN CORPUSCULAR HAEMOGLOBIN: 29.1 [27 - 32] PG; NPTST185-MEAN CORPUSCULAR HAEMOGLOBIN CO: 329 [320 - 360] G/L; NPTST187-MEAN CORPUSCULAR VOLUME: 88.3 [85 - 105] FL; NPTST266-PROTHROMBIN TIME: 11.8 [9.5 - 14] SEC; NPTST268-PT RATIO: 1.0 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST307-UREA: 8 [2.5 - 7.8] MMOL/L; NEUTROPHILS: 3.2 [2 - 7.5] 10^9/L; PLATELETS: 180 [150 - 400] 10^9/L; POTASSIUM: 4.1 [3.5 - 5.3] MMOL/L; SODIUM: 141 [133 - 146] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	23
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Serious Adverse Event, Event of Interest -Falls And Associated Injuries

Event Description	FALL (ACCIDENTAL), NO TRIP OR SLIP.
Preferred term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 25): ALANINE AMINOTRANSFERASE: 9 [5 - 55] U/L; ALBUMIN: 34 [35 - 50] G/L; ALKALINE PHOSPHATASE: 68 [30 - 130] U/L; BASOPHILS: 0.1 [0 - 0.1] 10^9/L; BILIRUBIN: 8 [0 - 21] UMOL/L; CREATININE: 66 [62 - 106] UMOL/L; EOSINOPHILS: 0.23 [0 - 0.4] 10^9/L; ERYTHROCYTES: 5 [4.5 - 6] 10^12/L; GLUCOSE: 5.9 [3.3 - 5.8] MMOL/L; HEMATOCRIT: 0 [0 - 0.01] FRACTION OF 1; HEMOGLOBIN: 145 [130 - 180]

G/L; LEUKOCYTES: 5.1 [4 - 11] 10^9/L; LYMPHOCYTES: 1.3 [1.5 - 4] 10^9/L; MONOCYTES: 0.4 [0.2 - 0.8] 10^9/L; NPTST004-ACTIVATED PARTIAL THROMBOPLASTI: 1.2 [NOT REPORTED - NOT REPORTED] RATIO; NPTST004-ACTIVATED PARTIAL THROMBOPLASTI: 34.5 [24.3 - 35.2] SEC; NPTST056-C-REACTIVE PROTEIN: 4 [0 - 10] MG/L; NPTST114-ESTIMATED GFR: 60 [NOT REPORTED - NOT REPORTED] ML/MIN; NPTST184-MEAN CORPUSCULAR HAEMOGLOBIN: 29.1 [27 - 32] PG; NPTST185-MEAN CORPUSCULAR HAEMOGLOBIN CO: 329 [320 - 360] G/L; NPTST187-MEAN CORPUSCULAR VOLUME: 88.3 [85 - 105] FL; NPTST266-PROTHROMBIN TIME: 11.8 [9.5 - 14] SEC; NPTST268-PT RATIO: 1.0 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST307-UREA: 8 [2.5 - 7.8] MMOL/L; NEUTROPHILS: 3.2 [2 - 7.5] 10^9/L; PLATELETS: 180 [150 - 400] 10^9/L; POTASSIUM: 4.1 [3.5 - 5.3] MMOL/L; SODIUM: 141 [133 - 146] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	23
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other cause of event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	MINIMAL ERETHYMA AT INFUSION SITE
Preferred term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 25
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	32
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Somnolence

Event Description	DAYTIME SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	153
Duration of AE	123 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Somnolence

Event Description	SOMNOLENCE
Preferred term	傾眠
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	153
Duration of AE	123 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Weight Loss

Event Description	UNEXPLAINED WEIGHT LOSS
Preferred term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	153
Duration of AE	123 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest -Infusion Site Related Non Infection Reactions

Event Description	DEFINITE EDEMA AT INFUSION SITE
Preferred term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 40
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	47
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONS OF INFESTATION
Preferred term	寄生虫妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 121
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	153
Duration of AE	33 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Event #11: AE Leading to Discontinuation of Study Drug, Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL HALLUCINATION
Preferred term	幻視
AE Onset Date / Rx Day	[redacted]20[redacted] / 121
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	153
Duration of AE	33 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other cause of event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

generated: [redacted]20[redacted]:10:45
program source code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は英国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，浮動性めまい及び躓きや滑りを伴わない転倒（偶発的）を発現した。

Event 3 及び 4 の臨床経過：

関連する病歴は，パーキンソン病，混合性大動脈弁疾患，髄膜腫除去のための開頭術，髄膜腫 NOS，高血圧，左全人工股関節置換術，狭心症，虚血性心疾患，運動機能変動，不眠症，両側性白内障，硝子体剥離，黄斑変性，レボドパ誘発性ジスキネジア，元喫煙者（1 日 40 本を 10 年間），及び非飲酒者であった。

投与 23 日目，被験者は浮動性めまい及び躓きや滑りを伴わない転倒（事故）を発現した。投与 23 日目，浮動性めまい及び躓きや滑りを伴わない転倒（事故）は消失した。

本事象発現前に，被験者は非重篤なパーキンソン病症状の悪化を発現した。

投与 23 日目，被験者は転倒し，その後浮動性めまいを発現した。被験者は入院した。身体所見，詳細不明の血液検査，及び起立性血圧はいずれも異常ではなかった。血圧の上昇が認められた（結果の報告なし）。投与 23 日目，被験者は退院した。

The patient's past medications include:

MADOPAR for PARKINSON'S DISEASE (Started 20[redacted], Started 20[redacted])

MADOPAR HBS for PARKINSON'S DISEASE (Started 20[redacted])

ROPINIROLE for PARKINSON'S DISEASE (Started [redacted] 20[redacted])

SELEGILINE for PARKINSON'S DISEASE (Started [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Dizziness (10013573) (Dizziness (10013573)) [v.24.0] [10013573]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

2) Fall (10016173) (Fall (10016173)) [v.24.0] [10016173]

Causality as per reporter (Drug/Vaccine): Reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of DIZZINESS

- Investigator: Not applicable

- AbbVie: More likely related to a history of mixed aortic valve disease and report of increased blood pressure in an advanced aged patient.

Event of FALL (ACCIDENTAL) NO TRIP OR SLIP

- Investigator: Not applicable

- AbbVie: More likely related to a history of Parkinson's disease and macular degeneration in an advanced age patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALBUMIN:** 34 G/L (normal 35 to 50)

[redacted] **20[redacted] BLOOD PRESSURE:** 146/79 mmHg

[redacted] **20[redacted] BLOOD PRESSURE (SCREENING):** 152/75 mmHg

[redacted] **20[redacted] CHEST XRAY:** Unremarkable.

[redacted] **20[redacted] ECG:** Unremarkable

[redacted] **20[redacted] GLUCOSE:** 5.9 MMOL/L (normal 3.3 to 5.8)

[redacted] **20[redacted] HEMATOCRIT:** 0.441% (normal 0.40 to 0.52)

[redacted] **20[redacted] HGB:** 145 G/L (normal 130 to 180)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 1.3 X10**9/L (normal 1.5 to 4.0)

[redacted] **20[redacted] PLATELET COUNT:** 180 X10**9/L (normal 150 to 400)

[redacted] **20[redacted] POTASSIUM:** 4.1 MMOL/L (normal 3.5 to 5.3)

[redacted] **20[redacted] SODIUM:** 141 MMOL/L (normal 133 to 146)

[redacted] **20[redacted] UREA:** 8.0 MMOL/L (normal 2.5 to 7.8)

[redacted] **20[redacted] BODY WEIGHT:** 7[redacted].[redacted] KG

ADVERSE EVENTS OF SPECIAL INTEREST AND **OTHER AREAS OF SAFETY INTEREST

Weight Decreased: Day 1 weight 7[redacted].[redacted] kg. Weight at time of event 6[redacted] kg. Weight loss occurred over a period of 2 months. Change in diet reported as "healthier diet with cut down on sweets and savory treats." Onset of weight loss coincided with worsening PD symptoms and non-motor symptoms. Subject experienced a temporal episode of depression and/or other psychiatric symptoms, previous and temporal episode of loss of appetite, and tooth problems causing a general feeling of unwell. Pump catheter found to be leaking on inspection by wife. Days when patient is most unwell are thought to be related to a lack of dopamine.

M15-737 試験

治験の標題： パーキンソン病患者を対象とした ABBV-951 の持続皮下注入による 1 日 24 時間投与時の安全性及び忍容性を評価する M15-741 試験の非盲検継続試験	
施設数 / 実施国名： 41 施設 / オーストラリア，ベルギー，カナダ，デンマーク，イタリア，日本，オランダ，スペイン，イギリス及び米国	
治験責任医師： [redacted], MD，他	
公表文献 (参考資料) ： なし	
治験期間： 最初の被験者の初回来院日：20[redacted] 年 [redacted] 月 [redacted] 日 最後の被験者の最終来院日：20[redacted] 年 [redacted] 月 [redacted] 日（データカットオフ日）	開発のフェーズ：III
目的： 持続皮下注入（以下「CSCI」）として 1 日 24 時間，ABBV-951 を持続投与した場合の局所及び全身の安全性及び忍容性の評価	
被験者数 (計画時と解析時) ： 計画時：約 130 例，解析時：105 例	
診断と主要な組入れ基準： 親試験（M15-741 試験）の完了時に治験薬を継続中のパーキンソン病患者	
治験方法： 本試験は，親試験である M15-741 試験を完了したパーキンソン病患者を対象とし，ABBV-951 を 1 日 24 時間 CSCI 投与した場合の局所及び全身の安全性及び忍容性の評価を継続する非盲検，単群，多施設共同継続試験であった。 本試験にスクリーニング期は設定しなかった。親試験（M15-741 試験）の最終来院を本継続試験（M15-737 試験）の組入れ来院（投与 1 日目）とした。親試験の最終来院は，本継続試験の投与 1 日目と同日に実施し，被験者は直ちに M15-737 試験の投与期を開始することとした。投与 1 日目に適格性が確認された後，被験者は親試験の未使用の治験薬及び付属品を返却した。M15-737 試験用の治験薬のバイアルが入った箱及び注入セットが新たに提供された。何らかの理由で交換が必要でない限り，ポンプは交換されなかった（被験者は親試験で提供されたポンプを使用し続けた）。投与期間中，被験者は 1 日 24 時間，最適治療用量の ABBV-951 の CSCI 投与を受けた。試験期間を通じて，ABBV-951 の投与量は治験責任医師の判断に基づき調節してもよいこととした。投与期は最大 96 週間で，5 回の治験来院と 4 回の遠隔評価から構成された。	
被験薬，用量，投与方法及びバッチ番号： ABBV-951 12/240 mg/mL（カルビドパ-4′-リン酸塩 / レボドパ-4′-リン酸塩）注入用溶液を個々の患者に合わせた用量でポンプに接続した注入セットを介して 1 日 24 時間 CSCI 投与 バルクロット番号：[redacted] 治療期間：最大 96 週間	

対照薬，用量，投与方法及びバッチ番号：
該当なし

評価基準：

有効性：

有効性評価項目は本試験における副次評価項目であり，パーキンソン病日誌により評価した標準化した 1 日あたりの平均オフ時間及びオン時間，国際パーキンソン病・運動障害学会統一パーキンソン病評価尺度（以下「MDS-UPDRS」）Part I-IV により評価したパーキンソン病症状，パーキンソン病質問票（以下「PDQ-39」）により評価した生活の質，EuroQol 5 項目質問票（以下「EQ-5D-5L」）により評価した健康に関連した生活の質並びにミニメンタルステート検査（以下「MMSE」）により評価した認知障害のベースラインから試験終了時までの変化を評価した。

安全性：

安全性評価項目は本試験における主要評価項目であり，有害事象の発現割合並びに臨床検査値，バイタルサイン測定値及び心電図のベースラインから試験終了時までの変化量により評価した。局所刺激性についても注入部位評価尺度により評価した。自殺傾向及び衝動的強迫性行動をそれぞれコロンビア自殺評価スケール（以下「C-SSRS」）及びパーキンソン病における衝動制御障害の評価尺度（以下「QUIP-RS」）により評価した。

統計手法：

有効性：

すべての有効性解析は，ABBV-951 を注入し，1 つ以上の有効性評価項目に関してベースライン及び投与後の所見が得られているすべての被験者から構成された最大の解析対象集団（以下「FAS」）を用いて実施した。

各被験者は，投与期における 1 日あたりの最頻投与量に基づき用量群別に分類された。すべての有効性評価項目について，各用量群及び被験者全体における各評価時点でのベースラインからの変化量を記述的に要約した。統計量には観測数，平均値，標準偏差，最小値，中央値及び最大値を含めた。

安全性：

すべての安全性解析は，ABBV-951 を注入したすべての被験者から構成された安全性解析対象集団を用いて実施した。有害事象は，ABBV-951 の CSCI 投与開始日以降に発現又は悪化した，最終注入後 30 日までに報告されたすべての事象と定義した。有害事象及び注入部位評価尺度を除く安全性評価項目に関するすべての解析は，ABBV-951 の注入終了後 1 日目までに収集されたデータを用いて実施した。すべての有害事象は ICH 国際医薬用語集（以下「MedDRA」）version 24.0 を用いて要約した。

安全性転帰に関する連続変数について，各用量群及び被験者全体におけるベースラインからの変化を評価時点別に記述的に解析した。安全性転帰に関するカテゴリー変数について，各用量群及び被験者全体における各カテゴリーの数及び割合を評価時点別に要約した。仮説検定は実施しなかった。

表 1. 治験実施スケジュール

実施項目	投与期				
	組入れ来院 (D1)	**遠隔評価 (W12,W36, W60,W84)**	**治験来院 (W24,W48, W72)**	**最終治験来院 (W96) 又は 治験の早期中止 [a]**	**交付のための来院 [b]**
問診及び質問票					
被験者への情報提供及び同意取得	√				
適格基準	√				
最新の病歴聴取	√				
注入部位の評価 (適切な場合は皮膚科学的評価)	M15-741 試験の評価		√	√	
有害事象の評価		√	√	√	
特に注目すべき有害事象		√	√	√	
製品の苦情・不具合		√	√	√	
前治療 / 併用療法		√	√	√	
患者報告アウトカム： 患者報告による評価 (特定の時点)					
被験者投与日誌		評価の 2 日前 √	来院の 2 日前 √	来院の 2 日前 √	
パーキンソン病日誌		評価の 2 日前 √	来院の 2 日前 √	来院の 2 日前 √	
EQ-5D-5L	M15-741 試験の評価		√	√	
患者報告アウトカム： 評価者報告による評価 (特定の時点)					
C-SSRS	M15-741 試験の評価		√	√	
QUIP-RS			√	√	
MDS-UPDRS			√	√	
MMSE	√		√	√	
PDQ-39	M15-741 試験の評価		√	√	

表 1. 治験実施スケジュール（続き）

実施項目	投与期				
	組入れ来院 (D1)	遠隔評価 (W12,W36, W60,W84)	治験来院 (W24,W48, W72)	最終治験来院 (W96) 又は 治験の早期中止 [a]	交付のための来院 [b]
検査及び診察					
臨床検査	M15-741 試験の評価		√	√	
特殊な臨床検査 (ビタミン B_6 及び B_{12}, 葉酸，メチルマロン酸，ホモシステイン)			√	√	
12 誘導心電図			√	√	
体重			√	√	
バイタルサイン			√	√	
身体検査			√	√	
神経学的検査			√	√	
妊娠検査 (尿) [c]			√	√	
治療					
治験薬投与システムに関するトレーニング	必要に応じて				
治験薬の注入	√		√		
薬剤，治験機器，及び付属品の供給の確認	√		√		√
薬剤及び治験機器処方の確認			√	√	√
治験薬投与システムの交付 / 返却	√		√	√	√
治験薬の処方記録	√		√	√	

D = 投与日，W = 投与週

a. 被験者が早期中止し，被験者から了承が得られた場合，治験薬の注入終了 30 日後にも治験実施医療機関スタッフから電話することとした。

b. 治験来院を実施したか否かに関わらず，治験薬は最低でも 2 週間に 1 回交付された。

c. 妊娠可能な女性には，妊娠検査（尿）を月 1 回実施した。治験来院の予定がある場合，検査は実施医療機関で実施することとした。治験来院の予定がない場合，規定外の治験来院又は自宅で実施してもよいこととした。

被験者の内訳

被験者の内訳を表 2 に示す。

本試験では，M15-741 試験を完了した 105 例が登録された。

解析対象集団については，FAS が 81 例であった。
治験薬の投与を完了した被験者はおらず，治験薬投与継続中は 97 例（92.4%），治験薬投与中止は 8 例（7.6%）であった。治験薬の投与を中止した主な理由で最も多かったのは有害事象 5 例（4.8%）であった。

日本人部分集団における被験者の内訳を表 3 に示す。
本試験には M15-741 試験を完了した 11 例の日本人が登録され，日本人解析対象集団の FAS は 7 例であった。
治験薬の投与を完了した被験者はおらず，治験薬投与継続中は 10 例（90.9%），治験薬投与中止は 1 例（9.1%）であり，治験薬の投与を中止した主な理由は有害事象であった。

被験者背景

人口統計学的特性及びその他のベースラインの特性

人口統計学的特性及びその他のベースラインの特性を表 4 に，パーキンソン病の病歴を表 5 に示す。
安全性解析対象集団では，年齢の平均値が 62.4 歳（範囲：34～86 歳），65 歳以上の割合が 42.9%，体重の平均値が 74.50 kg（範囲：38.9～110.9 kg），居住地域は欧米及びオーストラリア合わせて 89.5%，女性が 35.2%，民族は非ヒスパニック（非ラテン含む）が 93.3%，人種は白人が 85.7%，アジア人が 13.3%，パーキンソン病罹病期間は 10 年以上が 41.0%であった。

日本人部分集団における人口統計学的特性及びその他のベースラインの特性を表 6 に示す。
安全性解析対象集団では，年齢の平均値が 61.0 歳（範囲：47～72 歳），65 歳以上の割合が 36.4%，体重の平均値が 61.45 kg（範囲：38.9～82.5 kg），女性が 36.4%であった。

併用薬

パーキンソン病の前治療歴は，親試験（M15-741 試験）のスクリーニング期に収集した。ベースラインのデータは，M15-741 試験における投与 1 日目の ABBV-951 の注入開始前までに収集されたものである。
治験実施計画書の規定に基づき，すべての被験者は親試験（M15-741 試験）の登録時に経口パーキンソン病治療薬を使用していた。
M15-737 試験の試験期間中，他のパーキンソン病治療薬を使用していなかった被験者は 30 例（28.6%），1 種類の他のパーキンソン病治療薬を使用していた被験者は 47 例（44.8%），2 種類の他のパーキンソン病治療薬を使用していた被験者は 22 例（21.0%），3 種類の他のパーキンソン病薬を使用していた被験者は 5 例（4.8%）であった（M15-737 試験 CSR Table 14.1__3.2.3）。

曝露状況

処方用量

本試験における開始時の標準及び追加の持続注入速度，追加投与量並びに追加投与間のロックアウト時間は，調節が必要であると治験責任医師が判断しない限り，親試験である M15-741 試験の最終投与日に処方されたものと同様とした。

特に明記されていない限り，ABBV-951 の投与量は，ホスレボドパを分子量に基づきレボドパに換算したレボドパ換算投与量として示す（ホスレボドパ 100 mg はレボドパ 71 mg に相当）。

1 日あたりの総投与量，標準注入速度及び追加の注入速度を表 7 及び表 8 に示す。また，追加の高い注入速度及び追加の低い注入速度を標準注入速度の割合として表したものを M15-737 試験 CSR Table 14.1__6.2 に示す。データカットオフ時点で，標準注入速度の変化量は小さかった（レボドパの平均変化量は 2.1 mg/時間又は 50.7 mg/日に相当）。

日本人部分集団における 1 日あたりの総投与量，標準注入速度及び追加の注入速度を表 9 に示す。全体集団と同様に，標準注入速度の変化量は小さかった（レボドパの平均変化量は 1.6 mg/時間又は 37.3 mg/日に相当）。

1 日あたりの総投与量

救済療法が必要となった場合に備え，治験責任医師又はかかりつけ医によりレボドパ及びドパ脱炭酸酵素阻害薬の速放性経口錠剤又はレボドパ吸入パウダーがすべての被験者に処方されることとした。ABBV-951 の投与期間中，ABBV-951 の追加投与又は注入速度の増加では反応がないような急激な運動症状の悪化など，重大な医療上の必要性が生じた場合のみ，救済療法を使用することとした。

ABBV-951 及び併用薬のレボドパ換算 1 日投与量を表 10 に示す。また，レボドパの 1 日あたりの最頻投与量の分布を表 11 及び M15-737 試験 CSR Figure 14.1__13.2 に示す。レボドパ換算投与量を 100 mg 間隔で表した各被験者の 1 日あたりの最頻投与量を，被験者が実際に使用した注入速度及び注入持続時間から計算し，レボドパ換算投与量として示した。1 日あたりの最頻レボドパ換算投与量は約 700 mg から 4200 mg の範囲で分布しており，第 I 相試験及び他の第 III 相試験でみられた投与量の分布と同様であることから，ABBV-951 が進行期パーキンソン病患者における運動症状を十分にコントロールするために必要な広範囲のレボドパ投与量に対応できることが確認された。

治験薬の曝露期間及び投与中断

データカットオフ時点（20[redacted] 年 [redacted] 月 [redacted] 日）で，治験薬への平均曝露日数は 239.1 日であった（表 12）。約 69.5%の被験者が治験薬の曝露を 169 日以上受けた。

投与中断した被験者は 11 例であった。投与中断理由はその他（6 例），ポンプの故障（4 例）及び COVID-19 以外の有害事象（2 例）であった（表 13）。投与中断期間は 1 日未満から 30 日以上までの日数間隔により分類された。投与中断した 11 例中 8 例（72.7%）の投与中断期間は，

1 日未満であった（表 14）。いずれの時点においても，経口負荷投与した被験者は 3 例以下であった（表 15）。

日本人部分集団における治験薬への平均曝露日数は 185.5 日であった（表 16）。約 45.5%の被験者が治験薬の曝露を 169 日以上受けた。

投与中断した日本人被験者は 1 例で，投与中断理由はその他であった（表 17）。投与中断期間は 1 日未満であった（M15-737 試験 CSR Table 14.1__12.2.J）。経口負荷投与した被験者はいなかった（表 18）。

有効性の結果

パーキンソン病日誌

各被験者は，起床時及び起きている時間は 30 分ごとに，睡眠，ジスキネジアを伴わないオン時間，日常生活に支障のないジスキネジアを伴うオン時間，日常生活に支障のあるジスキネジアを伴うオン時間又はオフ時間をパーキンソン病日誌に記録した。パーキンソン病日誌は 24 時間を 1 日と定義し（午前 6 時から翌日の午前 5 時 30 分まで），各被験者は 1 日に 48 回，各記録が 0.5 時間に相当するように各規定日に記入することとした。被験者ごとに睡眠パターンが異なることを考慮し，1 日あたりのオン時間とオフ時間を一般的な覚醒期間（16 時間）に標準化した。

標準化した 1 日あたりの平均オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間の M15-737 試験のベースライン（親試験である M15-741 試験の最終評価）からの変化量は小さく，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も，治療効果の経時的な低下は認められなかった（表 19）。1 日あたりの時間を絶対値で解析した場合の結果も同様であった（M15-737 試験 CSR Table 14.2__1.2）。

日本人部分集団においても同様に，標準化した 1 日あたりの平均オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間のベースラインからの変化量は小さかった（M15-737 試験 CSR Figure 14.2__6.1.J）。

部分集団解析結果（用量別［低用量又は高用量］，性別［男性又は女性］，人種別［白人又はアジア人］，年齢別［65 歳未満又は 65 歳以上］，地域別［北米，欧州及びオーストラリア，又は日本］，パーキンソン病罹病期間［10 年未満又は 10 年以上］）は全体集団の結果とおおむね同様であった（表 20）。

ベースライン（親試験である M15-741 試験の最終評価）から投与 72 週時までの期間に早朝の非睡眠症状を報告した被験者の割合を表 21 に示す。データカットオフ時点において，投与 60 週時及び投与 72 週時まで達している被験者数は少なかった。

日本人部分集団においてベースラインから投与 60 週時までの期間に早朝の非睡眠症状を報告した被験者の割合を表 22 に示す。データカットオフ時点において，投与 60 週時まで達している被験者数は 1 例であった。投与 72 週時まで達している被験者はいなかった。

MDS-UPDRS

MDS-UPDRS は以下の項から構成される。

- Part I：日常生活における非運動症状
- Part II：日常生活における運動症状
- Part III：運動症状の検査（Hoehn-Yahr 重症度分類を含む）
- Part IV：運動合併症

MDS-UPDRS の総スコア（Part I～III）は 0 から 236 の範囲であり，236 が最も重症度の高い（合計）障害を示し，0 は障害がないことを示す。MDS-UPDRS は，ABBV-951 の投与開始前に被験者の実質的なオフ状態で実施された親試験（M15-741 試験）の投与 1 日目を除き，被験者の最良のオン状態で実施することとした。

MDS-UPDRS スコアはベースラインから投与 48 週時まで安定しており，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も治療効果が持続することを示した（表 23）。

日本人部分集団においても同様に，MDS-UPDRS スコアはベースラインから投与 48 週時まで安定していた（表 24）。

全体集団及び日本人部分集団の MDS-UPDRS スコア（Hoehn-Yahr 重症度分類）をそれぞれ表 25 及び表 26 に示す。

生活の質

PDQ-39 は，パーキンソン病患者に関連する健康面を評価するためにデザインされた 39 項目の疾患特異的評価尺度である。要約指標及び各構成要素のスコアは 0 から 100 までの点数で評価され，スコアが低いほど健康状態が良好であることを意味する。

EQ-5D-5L は，EQ-5D 記述式評価と EQ 視覚的評価尺度（以下「EQ VAS」）の 2 部から構成された標準化尺度である。記述式評価は「移動の程度」，「身の回りの管理」，「ふだんの活動」，「痛み / 不快感」及び「不安 / ふさぎ込み」の 5 項目から構成される。5 項目の機能状態それぞれを 5 段階尺度（1 = 問題はない，2 = 少し問題がある，3 = 中程度の問題がある，4 = かなり問題がある，5 = 極度の問題がある）で評価する。健康状態は，米国固有の重み付けをした評価アルゴリズム（最低値–0.109～最高値 1）を用いて要約指標に変換した。EQ VAS は，被験者の自己評価による健康状態を，「想像できる最良の健康状態」から「想像できる最悪の健康状態」までの範囲が表記された縦軸視覚的評価尺度に記録する。

PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 48 週時まで安定しており，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も治療効果が持続することを示した（表 27 及び表 28）。

日本人部分集団においても同様に，PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 48 週時まで安定していた（表 29 及び表 30）。

認知機能障害

MMSE は，成人の認知機能を定量的に評価するための 30 点満点の質問票であり，認知機能障害のスクリーニング又は特定時点の認知機能障害の重症度を推定し，患者の認知機能の経時的な変化を追跡し，治療への反応を記録するために広く使用されている。MMSE のスコアは 0 から 30 点の範囲であり，低いスコアほど認知機能障害が大きいことを示す。

MMSE 評価の結果は，M15-737 試験のベースラインから投与 48 週時までの MMSE 総スコアに変化がないことを示し，ABBV-951 の作用機序から期待されるとおりであった（表 31）。

日本人部分集団においても同様に，ベースラインから投与 48 週時までの MMSE 総スコアに大きな変化は認められなかった（表 32）。

安全性の結果

全体集団の有害事象の発現状況を以下に示す。

有害事象の発現割合は 62.9%（66 / 105 例）であった。ほとんどの有害事象は非重篤で，軽度又は中等度であった。有害事象の全体的な発現割合は，ABBV-951 の用量別及び部分集団間で同様であった。発現割合が 10%以上の有害事象は，注入部位紅斑（12.4%［13 / 105 例］），転倒及び注入部位蜂巣炎（各 11.4%［12 / 105 例］）であった。ほとんどの注入部位の有害事象は回復した。

治験薬と関連ありの有害事象の発現割合は 41.9%（44 / 105 例）であった。発現割合が 5%以上の治験薬と関連ありの有害事象は，注入部位蜂巣炎（10.5%［11 / 105 例］），注入部位紅斑（9.5%［10 / 105 例］）であった。

死亡に至った有害事象を発現した被験者は 3 例であった。死亡に至った有害事象はいずれも，治験責任医師により治験薬と関連なしと判断された。

重篤な有害事象の発現割合は 16.2%（17 / 105 例）であった。2 例以上に発現した重篤な有害事象は，注入部位蜂巣炎，転倒，股関節部骨折，パーキンソン病及び精神病性障害（各 1.9%［2 / 105 例］）であった。

中止に至った有害事象の発現割合は 4.8%（5 / 105 例）であった。中止に至った有害事象は，パーキンソン病（1.9%［2 / 105 例］），注入部位発疹，注入部位蜂巣炎，窒息及び誤嚥（各 1.0%［1 / 105 例］）であった。

有害事象の 90 日間ごとの初回発現割合は，投与開始後 90 日までが 41.0%（43 / 105 例）と最も高く，その後，発現割合は減少した。90 日間ごとの有病割合は，投与開始後 90 日までが 41.0%（43 / 105 例），91 日～180 日が 58.7%（44 / 75 例），181 日～270 日が 65.8%（48 / 73 例），271 日～360 日が 59.7%（37 / 62 例）であった。

臨床検査値，バイタルサイン，心電図，C-SSRS 又は QUIP-RS の評価において，安全性の懸念は認められなかった。

日本人部分集団の有害事象の発現状況を以下に示す。

日本人部分集団の有害事象の発現割合は 72.7%（8 / 11 例）であった。認められた有害事象は，眼充血，便秘，注入部位皮膚炎，注入部位硬結，注射部位紅斑，注射部位硬結，注入部位蜂巣炎，転倒，肩甲骨骨折，血中ホモシステイン増加，ビタミンＢ１２欠乏，腱鞘炎，感覚鈍麻，幻覚，窒息，誤嚥，痰貯留及び湿疹（各 9.1%［1 / 11 例］）であった。

治験薬と関連ありの有害事象の発現割合は 45.5%（5 / 11 例）であった。認められた治験薬と関連ありの有害事象は，注入部位皮膚炎，注入部位硬結，注射部位紅斑，注射部位硬結，注入部位蜂巣炎，血中ホモシステイン増加，ビタミンＢ１２欠乏及び幻覚（各 9.1%［1 / 11 例］）であった。

死亡に至った有害事象を発現した被験者は 1 例であった。認められた死亡に至った有害事象は窒息及び誤嚥で，いずれも治験責任医師により治験薬と関連なしと判断された。

重篤な有害事象の発現割合は 18.2%（2 / 11 例）であった。認められた重篤な有害事象は，肩甲骨骨折，窒息及び誤嚥（各 9.1%［1 / 11 例］）であった。

中止に至った有害事象の発現割合は 9.1%（1 / 11 例）であった。認められた中止に至った有害事象は，窒息及び誤嚥（各 9.1%［1 / 11 例］）であった。

本試験で発現した有害事象を以下のとおり示す。

項目	全体集団	日本人部分集団
有害事象の概要	表 33	表 41
すべての有害事象	表 34	表 42
治験薬との因果関係別の有害事象	表 35	表 43
死亡した被験者一覧	表 36	–
重篤な有害事象	表 37	表 44
中止に至った有害事象	表 38	表 45
有害事象の 90 日間ごとの初回発現割合の推移	表 39	–
有害事象の 90 日間ごとの有病割合の推移	表 40	–

結論

データカットオフ時点（20[redacted]年[redacted]月[redacted]日）で，オフ時間，日常生活に支障のないジスキネジアを伴うオン時間及び日常生活に支障のあるジスキネジアを伴うオン時間の M15-737 試験のベースライン（親試験である M15-741 試験の最終評価）からの平均変化量は小さかった。PDQ-39 及び EQ-5D-5L 評価の全体的な結果は，ベースラインから投与 48 週時まで安定していた。MMSE 評価の結果は，M15-737 試験のベースラインから投与 48 週時までの MMSE 総スコアに大きな変化がなかったことを示した。これらの結果は，M15-741 試験における 12 ヵ月間の ABBV-951 投与後も有効性が持続することを示した。

ABBV-951 はおおむね安全で，忍容性は良好であった。ABBV-951 の全身性の安全性プロファイルは，レボドパ / カルビドパ薬剤の確立された安全性プロファイルとおおむね一致していた。ほとんどの注入部位の有害事象は非重篤で，軽度又は中等度であり，回復した。ABBV-951 に関する新たな安全性の懸念は認められなかった。

表2　被験者の内訳　（All Enrolled Subjects）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=45) n (%)	High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Total subjects enrolled	45 (100)	60 (100)	105 (100)
Analysis population			
Full analysis set	33 (73.3)	48 (80.0)	81 (77.1)
Safety analysis set	45 (100)	60 (100)	105 (100)
ABBV-951 ongoing	44 (97.8)	53 (88.3)	97 (92.4)
ABBV-951 completed	0	0	0
ABBV-951 prematurely discontinued	1 (2.2)	7 (11.7)	8 (7.6)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=45) n (%)	Dose Category: High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	1 (2.2)	4 (6.7)	5 (4.8)
Infusion site related infections	0	1 (1.7)	1 (1.0)
Infusion site related non infection reactions	0	1 (1.7)	1 (1.0)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.7)	1 (1.0)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	2 (3.3)	2 (1.9)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=45) n (%)	Dose Category: High Dose (N=60) n (%)	All Subjects (N=105) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	1 (2.2)	4 (6.7)	5 (4.8)
Infusion site related infections	0	1 (1.7)	1 (1.0)
Infusion site related non infection reactions	0	1 (1.7)	1 (1.0)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.7)	1 (1.0)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	4 (6.7)	4 (3.8)
Study ongoing	44 (97.8)	53 (88.3)	97 (92.4)
Study completed	0	0	0
Study prematurely discontinued	1 (2.2)	7 (11.7)	8 (7.6)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=45) n (%)	High Dose (N=60) n (%)	All Subjects (N=105) n (%)
Primary reasons for study discontinuation #			
Adverse event	1 (2.2)	4 (6.7)	5 (4.8)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.7)	1 (1.0)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	2 (3.3)	2 (1.9)
All reasons for study discontinuation $			
Adverse event	1 (2.2)	4 (6.7)	5 (4.8)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	1 (2.2)	7 (11.7)	8 (7.6)
COVID-19 infection	1 (2.2)	7 (11.7)	8 (7.6)
COVID-19 logistical restrictions	1 (2.2)	7 (11.7)	8 (7.6)
Difficulty with drug delivery system	0	0	0
Other	0	5 (8.3)	5 (4.8)
Number of sites that enrolled at least 1 subject			41
Number of country that enrolled at least 1 subject			10

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

表3　被験者の内訳（All Enrolled Subjects，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=7) n (%)	High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Total subjects enrolled	7 (100)	4 (100)	11 (100)
Analysis population			
Full analysis set	4 (57.1)	3 (75.0)	7 (63.6)
Safety analysis set	7 (100)	4 (100)	11 (100)
ABBV-951 ongoing	6 (85.7)	4 (100)	10 (90.9)
ABBV-951 completed	0	0	0
ABBV-951 prematurely discontinued	1 (14.3)	0	1 (9.1)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=7) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	1 (14.3)	0	1 (9.1)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	0	0	0
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=7) n (%)	Dose Category: High Dose (N=4) n (%)	All Subjects (N=11) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	1 (14.3)	0	1 (9.1)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	0	0	0
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	0	0	0
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0
Study ongoing	6 (85.7)	4 (100)	10 (90.9)
Study completed	0	0	0
Study prematurely discontinued	1 (14.3)	0	1 (9.1)

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

TABLE 14.1 1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=7) n (%)	High Dose (N=4) n (%)	All Subjects (N=11) n (%)
Primary reasons for study discontinuation #			
Adverse event	1 (14.3)	0	1 (9.1)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	0	0	0
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	0	0	0
All reasons for study discontinuation $			
Adverse event	1 (14.3)	0	1 (9.1)
Withdrew consent	0	0	0
Lost to follow-up	0	0	0
Lack of efficacy	1 (14.3)	0	1 (9.1)
COVID-19 infection	1 (14.3)	0	1 (9.1)
COVID-19 logistical restrictions	1 (14.3)	0	1 (9.1)
Difficulty with drug delivery system	0	0	0
Other	0	0	0
Number of sites that enrolled at least 1 subject			3
Number of country that enrolled at least 1 subject			1

One subject can be only counted once.
$ All reasons that are contributing to the disposition event, including the primary reason. One subject can be counted multiple times.

Program Source Code: [redacted]

表4　人口統計学的特性及びその他のベースラインの特性（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Age (year)			
n	45	60	105
Mean (SD)	61.3 (8.83)	63.3 (9.77)	62.4 (9.38)
Median	63.0	63.0	63.0
Min, Max	34, 78	43, 86	34, 86
Age (year) - n (%)			
< 65	26 (57.8)	34 (56.7)	60 (57.1)
>= 65	19 (42.2)	26 (43.3)	45 (42.9)
Age (year) - n (%)			
< 75	44 (97.8)	51 (85.0)	95 (90.5)
>= 75	1 (2.2)	9 (15.0)	10 (9.5)
Weight (kg)			
n	45	60	105
Mean (SD)	70.59 (17.968)	77.43 (16.349)	74.50 (17.315)
Median	72.00	79.05	75.80
Min, Max	38.9, 110.6	44.5, 110.9	38.9, 110.9
Height (cm)			
n	45	60	105
Mean (SD)	166.82 (11.407)	173.95 (9.413)	170.90 (10.859)
Median	165.00	174.15	172.00
Min, Max	140.1, 187.9	154.0, 196.0	140.1, 196.0

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
BMI (kg/m^2)			
n	45	60	105
Mean (SD)	25.16 (5.312)	25.47 (4.555)	25.34 (4.871)
Median	23.94	25.22	24.68
Min, Max	18.0, 39.9	16.1, 35.0	16.1, 39.9
BMI (kg/m^2) - n (%)			
< 18.5	1 (2.2)	3 (5.0)	4 (3.8)
18.5 - < 25.0	25 (55.6)	25 (41.7)	50 (47.6)
25.0 - < 30.0	10 (22.2)	20 (33.3)	30 (28.6)
>= 30.0	9 (20.0)	12 (20.0)	21 (20.0)
Mini-Mental State Examination (MMSE) total score			
n	45	59	104
Mean (SD)	29.02 (1.138)	28.58 (1.905)	28.77 (1.626)
Median	29.00	29.00	29.00
Min, Max	26.0, 30.0	21.0, 30.0	21.0, 30.0
Country - n (%)			
AUSTRALIA	7 (15.6)	8 (13.3)	15 (14.3)
BELGIUM	2 (4.4)	2 (3.3)	4 (3.8)
CANADA	1 (2.2)	3 (5.0)	4 (3.8)
DENMARK	1 (2.2)	5 (8.3)	6 (5.7)
ITALY	2 (4.4)	0	2 (1.9)
JAPAN	7 (15.6)	4 (6.7)	11 (10.5)
NETHERLANDS	2 (4.4)	0	2 (1.9)
SPAIN	5 (11.1)	6 (10.0)	11 (10.5)
UNITED KINGDOM	2 (4.4)	5 (8.3)	7 (6.7)
UNITED STATES	16 (35.6)	27 (45.0)	43 (41.0)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Geographic region - n (%)			
North America	17 (37.8)	30 (50.0)	47 (44.8)
Europe and Australia	21 (46.7)	26 (43.3)	47 (44.8)
Japan	7 (15.6)	4 (6.7)	11 (10.5)
Sex - n (%)			
Female	22 (48.9)	15 (25.0)	37 (35.2)
Male	23 (51.1)	45 (75.0)	68 (64.8)
Ethnicity - n (%)			
Hispanic or Latino	4 (8.9)	3 (5.0)	7 (6.7)
Not Hispanic or Latino	41 (91.1)	57 (95.0)	98 (93.3)
Race - n (%)			
White	35 (77.8)	55 (91.7)	90 (85.7)
Black or African American	0	0	0
Asian	9 (20.0)	5 (8.3)	14 (13.3)
American Indian or Alaska Native	1 (2.2)	0	1 (1.0)
Native Hawaiian or Other Pacific Islander	0	0	0
Tobacco - n (%)			
Current	2 (4.4)	2 (3.3)	4 (3.8)
Former	9 (20.0)	20 (33.3)	29 (27.6)
Never	34 (75.6)	38 (63.3)	72 (68.6)
Unknown	0	0	0

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Alcohol - n (%)			
Current	32 (71.1)	35 (58.3)	67 (63.8)
Former	5 (11.1)	11 (18.3)	16 (15.2)
Never	8 (17.8)	14 (23.3)	22 (21.0)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	45 (100)	58 (96.7)	103 (98.1)
Abnormal	0	2 (3.3)	2 (1.9)
Cranial nerves - n (%)			
Normal	42 (93.3)	55 (91.7)	97 (92.4)
Abnormal	3 (6.7)	5 (8.3)	8 (7.6)
Motor system - n (%)			
Normal	22 (48.9)	40 (66.7)	62 (59.0)
Abnormal	23 (51.1)	20 (33.3)	43 (41.0)
Sensory system - n (%)			
Normal	40 (90.9)	53 (88.3)	93 (89.4)
Abnormal	4 (9.1)	7 (11.7)	11 (10.6)
Missing	1	0	1
Reflexes - n (%)			
Normal	41 (93.2)	51 (85.0)	92 (88.5)
Abnormal	3 (6.8)	9 (15.0)	12 (11.5)
Missing	1	0	1

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2

Demographic and Baseline Characteristics
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Coordination - n (%)			
Normal	36 (81.8)	50 (83.3)	86 (82.7)
Abnormal	8 (18.2)	10 (16.7)	18 (17.3)
Missing	1	0	1
Gait - n (%)			
Normal	19 (42.2)	29 (48.3)	48 (45.7)
Abnormal	26 (57.8)	31 (51.7)	57 (54.3)
Station - n (%)			
Normal	33 (76.7)	44 (75.9)	77 (76.2)
Abnormal	10 (23.3)	14 (24.1)	24 (23.8)
Missing	2	2	4

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

表5　パーキンソン病の病歴（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Duration of PD since diagnosis - n (%)			
< 10 years	27 (60.0)	35 (58.3)	62 (59.0)
>= 10 years	18 (40.0)	25 (41.7)	43 (41.0)
History of levodopa induced dyskinesia - n (%)			
Yes	35 (77.8)	42 (70.0)	77 (73.3)
No	10 (22.2)	18 (30.0)	28 (26.7)
Levodopa response for more than 5 years - n (%)			
Yes	40 (88.9)	46 (76.7)	86 (81.9)
No	5 (11.1)	14 (23.3)	19 (18.1)
Baseline parkinson's disease Hoehn and Yahr Stage (MDS-UPDRS) - n (%)			
0	0	0	0
1	0	0	0
2	27 (60.0)	33 (55.0)	60 (57.1)
3	12 (26.7)	11 (18.3)	23 (21.9)
4	4 (8.9)	8 (13.3)	12 (11.4)
5	2 (4.4)	8 (13.3)	10 (9.5)
Age at PD onset (years)			
n	45	60	105
Mean (SD)	50.0 (9.49)	52.3 (9.29)	51.3 (9.40)
Median	52.0	53.0	52.9
Min, Max	21, 66	34, 70	21, 70

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Duration of PD since onset (years)			
n	45	60	105
Mean (SD)	11.96 (5.179)	11.56 (5.246)	11.73 (5.196)
Median	11.78	10.34	11.09
Min, Max	3.1, 29.7	2.1, 24.8	2.1, 29.7
Age at first diagnosis by a physician (years)			
n	45	60	105
Mean (SD)	52.2 (9.36)	53.9 (8.92)	53.1 (9.10)
Median	55.0	54.0	54.7
Min, Max	27, 66	37, 70	27, 70
Duration of PD since first diagnosis by a physician (years)			
n	45	60	105
Mean (SD)	9.79 (4.776)	9.97 (4.898)	9.89 (4.823)
Median	9.20	9.07	9.07
Min, Max	1.6, 23.7	2.1, 20.9	1.6, 23.7
Age at onset of motor fluctuation (years)			
n	45	59	104
Mean (SD)	55.7 (8.98)	57.4 (9.86)	56.6 (9.48)
Median	58.0	57.6	57.9
Min, Max	34, 71	40, 77	34, 77
Duration since onset of motor fluctuation (years)			
n	45	59	104
Mean (SD)	6.26 (3.830)	6.51 (4.196)	6.40 (4.024)
Median	6.29	5.62	5.98
Min, Max	1.0, 17.1	0.4, 20.4	0.4, 20.4

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1 3.1

Parkinson's Disease History
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
MDS-UPDRS - Part III score during 'Off' state			
n	45	60	105
Mean (SD)	45.2 (14.29)	45.4 (13.87)	45.3 (13.98)
Median	44.0	42.0	43.0
Min, Max	11, 87	19, 81	11, 87

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

表6　人口統計学的特性及びその他のベースラインの特性（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
Age (year)			
n	7	4	11
Mean (SD)	61.4 (8.34)	60.3 (10.75)	61.0 (8.76)
Median	61.0	61.0	61.0
Min, Max	49, 72	47, 72	47, 72
Age (year) - n (%)			
< 65	5 (71.4)	2 (50.0)	7 (63.6)
>= 65	2 (28.6)	2 (50.0)	4 (36.4)
Age (year) - n (%)			
< 75	7 (100)	4 (100)	11 (100)
>= 75	0	0	0
Weight (kg)			
n	7	4	11
Mean (SD)	52.53 (13.308)	77.05 (4.665)	61.45 (16.305)
Median	44.20	77.15	66.90
Min, Max	38.9, 67.7	71.4, 82.5	38.9, 82.5
Height (cm)			
n	7	4	11
Mean (SD)	158.84 (14.991)	168.15 (4.276)	162.23 (12.742)
Median	151.30	167.55	165.10
Min, Max	140.1, 177.4	164.2, 173.3	140.1, 177.4

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
BMI (kg/m^2)			
n	7	4	11
Mean (SD)	20.47 (1.673)	27.29 (2.140)	22.95 (3.857)
Median	20.39	26.82	22.46
Min, Max	18.0, 22.6	25.2, 30.3	18.0, 30.3
BMI (kg/m^2) - n (%)			
< 18.5	1 (14.3)	0	1 (9.1)
18.5 - < 25.0	6 (85.7)	0	6 (54.5)
25.0 - < 30.0	0	3 (75.0)	3 (27.3)
>= 30.0	0	1 (25.0)	1 (9.1)
Mini-Mental State Examination (MMSE) total score			
n	7	4	11
Mean (SD)	29.57 (0.787)	29.00 (0.816)	29.36 (0.809)
Median	30.00	29.00	30.00
Min, Max	28.0, 30.0	28.0, 30.0	28.0, 30.0
Country - n (%)			
JAPAN	7 (100)	4 (100)	11 (100)
Geographic region - n (%)			
Japan	7 (100)	4 (100)	11 (100)
Sex - n (%)			
Female	4 (57.1)	0	4 (36.4)
Male	3 (42.9)	4 (100)	7 (63.6)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
Ethnicity - n (%)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7 (100)	4 (100)	11 (100)
Race - n (%)			
White	0	0	0
Black or African American	0	0	0
Asian	7 (100)	4 (100)	11 (100)
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Tobacco - n (%)			
Current	0	0	0
Former	1 (14.3)	2 (50.0)	3 (27.3)
Never	6 (85.7)	2 (50.0)	8 (72.7)
Unknown	0	0	0
Alcohol - n (%)			
Current	4 (57.1)	2 (50.0)	6 (54.5)
Former	1 (14.3)	1 (25.0)	2 (18.2)
Never	2 (28.6)	1 (25.0)	3 (27.3)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	7 (100)	3 (75.0)	10 (90.9)
Abnormal	0	1 (25.0)	1 (9.1)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

TABLE 14.1 2.J

Demographic and Baseline Characteristics
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
Cranial nerves - n (%)			
Normal	7 (100)	4 (100)	11 (100)
Abnormal	0	0	0
Motor system - n (%)			
Normal	5 (71.4)	2 (50.0)	7 (63.6)
Abnormal	2 (28.6)	2 (50.0)	4 (36.4)
Sensory system - n (%)			
Normal	7 (100)	4 (100)	11 (100)
Abnormal	0	0	0
Reflexes - n (%)			
Normal	6 (85.7)	4 (100)	10 (90.9)
Abnormal	1 (14.3)	0	1 (9.1)
Coordination - n (%)			
Normal	3 (42.9)	3 (75.0)	6 (54.5)
Abnormal	4 (57.1)	1 (25.0)	5 (45.5)
Gait - n (%)			
Normal	2 (28.6)	1 (25.0)	3 (27.3)
Abnormal	5 (71.4)	3 (75.0)	8 (72.7)
Station - n (%)			
Normal	4 (57.1)	2 (50.0)	6 (54.5)
Abnormal	3 (42.9)	2 (50.0)	5 (45.5)

Note: Percentages calculated on non-missing or non-unknown values.
For categorical variables, 'Missing' row is only presented when there are missing data presented.

Program Source Code: [redacted]

表7　レボドパの1日あたりの規定投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__6.1

Daily Prescribed Dose
(Safety Analysis Set)

	N	Mean	SD	25% Quantile	Median	75% Quantile	Min / Max
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	105	80.9	30.75	56.3	78.5	97.3	30.7 / 163.9
Final prescription in study	105	83.0	31.57	56.3	82.0	102.5	30.7 / 162.2
Change from initial to final	105	2.1	7.07	0.0	0.0	3.4	-17.1 / 35.9
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	95	87.9	33.03	63.2	83.7	107.6	34.2 / 177.6
Final prescription in study	95	89.5	33.64	63.2	90.5	109.3	34.2 / 174.2
Change from initial to final	94	1.8	7.42	0.0	0.0	3.4	-25.6 / 34.2
ABBV-951 continuous infusion rate ('low') & - LD mg/HR							
Initial CSCI prescription	94	72.3	29.83	47.8	67.4	90.5	25.6 / 141.7
Final prescription in study	94	75.3	30.81	47.8	76.8	99.0	25.6 / 153.7
Change from initial to final	93	2.3	6.94	0.0	0.0	1.7	-12.0 / 37.6
Extra dose $ - LD mg/use							
Initial prescription	99	33.08	11.746	25.61	32.44	40.98	18.78 / 51.23
Final prescription in study	98	32.70	11.859	25.61	32.44	40.98	18.78 / 51.23
Change from initial to final	97	-0.46	5.289	0.00	0.00	0.00	-32.44 / 22.20
Total daily dose # - LD mg/day							
Initial prescription	105	1941.3	737.89	1352.3	1885.1	2335.9	737.6 / 3934.1
Final prescription in study	105	1992.0	757.78	1352.3	1967.0	2458.8	737.6 / 3893.1
Change from initial to final	105	50.7	169.68	0.0	0.0	82.0	-409.8 / 860.6

& Only for subjects whose 'high' or 'low' flow rates are allowed, non-zero and different from 'base'.
$ Only for subjects whose extra dose function is allowed (volume > 0 mL).
# Calculated as 'base' (mL/HR) * 24 HR/day * 170.75 mg LD/mL.

Program Source Code: [redacted]

表8　規定注入速度（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__6.3

Prescribed Pump Infusion Flow Rate by Category
(Safety Analysis Set)

	Base n (%)	High n (%)	Low n (%)
Modal prescribed pump infusion flow rate	N=105	N=96	N=94
FLOW RATE < 0.17 mL/hr	0	0	1 (1.1)
0.17 <= FLOW RATE < 0.20 mL/hr	1 (1.0)	0	6 (6.4)
0.20 <= FLOW RATE < 0.23 mL/hr	5 (4.8)	2 (2.1)	2 (2.1)
0.23 <= FLOW RATE < 0.26 mL/hr	2 (1.9)	4 (4.2)	9 (9.6)
0.26 <= FLOW RATE < 0.29 mL/hr	9 (8.6)	5 (5.2)	7 (7.4)
0.29 <= FLOW RATE < 0.32 mL/hr	6 (5.7)	6 (6.3)	4 (4.3)
0.32 <= FLOW RATE < 0.35 mL/hr	9 (8.6)	2 (2.1)	3 (3.2)
0.35 <= FLOW RATE < 0.38 mL/hr	4 (3.8)	6 (6.3)	6 (6.4)
0.38 <= FLOW RATE < 0.41 mL/hr	5 (4.8)	8 (8.3)	7 (7.4)
0.41 <= FLOW RATE < 0.44 mL/hr	4 (3.8)	2 (2.1)	6 (6.4)
0.44 <= FLOW RATE < 0.47 mL/hr	6 (5.7)	7 (7.3)	6 (6.4)
0.47 <= FLOW RATE < 0.50 mL/hr	6 (5.7)	5 (5.2)	6 (6.4)
0.50 <= FLOW RATE < 0.53 mL/hr	8 (7.6)	4 (4.2)	6 (6.4)
0.53 <= FLOW RATE < 0.56 mL/hr	11 (10.5)	6 (6.3)	3 (3.2)

Note: High and low columns only contain subjects whose high/low prescription is not 0.

Program Source Code: [redacted]

TABLE 14.1 6.3

Prescribed Pump Infusion Flow Rate by Category
(Safety Analysis Set)

	Base n (%)	High n (%)	Low n (%)
0.56 <= FLOW RATE < 0.59 mL/hr	3 (2.9)	8 (8.3)	3 (3.2)
0.59 <= FLOW RATE < 0.62 mL/hr	5 (4.8)	5 (5.2)	3 (3.2)
0.62 <= FLOW RATE < 0.65 mL/hr	2 (1.9)	5 (5.2)	2 (2.1)
0.65 <= FLOW RATE < 0.68 mL/hr	4 (3.8)	1 (1.0)	3 (3.2)
0.68 <= FLOW RATE < 0.71 mL/hr	5 (4.8)	5 (5.2)	4 (4.3)
0.71 <= FLOW RATE < 0.74 mL/hr	0	5 (5.2)	0
0.74 <= FLOW RATE < 0.77 mL/hr	0	0	3 (3.2)
0.77 <= FLOW RATE < 0.80 mL/hr	2 (1.9)	0	0
0.80 <= FLOW RATE < 0.83 mL/hr	1 (1.0)	2 (2.1)	2 (2.1)
0.83 <= FLOW RATE < 0.86 mL/hr	2 (1.9)	2 (2.1)	2 (2.1)
0.86 <= FLOW RATE < 0.89 mL/hr	3 (2.9)	0	0
0.89 <= FLOW RATE < 0.92 mL/hr	0	2 (2.1)	0
0.92 <= FLOW RATE < 0.95 mL/hr	0	0	0
0.95 <= FLOW RATE < 0.98 mL/hr	2 (1.9)	0	0
0.98 <= FLOW RATE < 1.01 mL/hr	0	2 (2.1)	0
FLOW RATE >= 1.01 mL/hr	0	2 (2.1)	0

Note: High and low columns only contain subjects whose high/low prescription is not 0.

Program Source Code: [redacted]

表9　レボドパの1日あたりの規定投与量（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__6.1.J

Daily Prescribed Dose
(Safety Analysis Set - Japan Subjects)

	N	Mean	SD	25% Quantile	Median	75% Quantile	Min / Max
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	11	61.3	17.37	47.8	56.3	80.3	37.6 / 87.1
Final prescription in study	11	62.9	20.30	47.8	51.2	87.1	37.6 / 93.9
Change from initial to final	11	1.6	4.98	0.0	0.0	3.4	-6.8 / 13.7
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	11	66.6	18.77	51.2	63.2	87.1	41.0 / 93.9
Final prescription in study	11	66.6	20.80	51.2	54.6	90.5	41.0 / 97.3
Change from initial to final	11	-0.0	5.24	0.0	0.0	1.7	-13.7 / 8.5
ABBV-951 continuous infusion rate ('low') & - LD mg/HR							
Initial CSCI prescription	11	50.0	15.27	34.2	47.8	61.5	29.0 / 80.3
Final prescription in study	11	52.6	20.56	34.2	46.1	78.5	29.0 / 85.4
Change from initial to final	11	2.6	8.62	0.0	0.0	1.7	-10.2 / 20.5
Extra dose $ - LD mg/use							
Initial prescription	11	32.29	11.364	25.61	32.44	40.98	18.78 / 51.23
Final prescription in study	11	30.89	11.130	25.61	25.61	32.44	18.78 / 51.23
Change from initial to final	11	-1.40	4.633	0.00	0.00	0.00	-15.37 / 0.00
Total daily dose # - LD mg/day							
Initial prescription	11	1471.6	416.89	1147.4	1352.3	1926.1	901.6 / 2090.0
Final prescription in study	11	1508.8	487.24	1147.4	1229.4	2090.0	901.6 / 2253.9
Change from initial to final	11	37.3	119.41	0.0	0.0	82.0	-163.9 / 327.8

& Only for subjects whose 'high' or 'low' flow rates are allowed, non-zero and different from 'base'.
$ Only for subjects whose extra dose function is allowed (volume > 0 mL).
# Calculated as 'base' (mL/HR) * 24 HR/day * 170.75 mg LD/mL.

Program Source Code: [redacted]

表10　ABBV-951及び併用薬のレボドパ換算1日投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__8.3

Daily Levodopa Equivalent Dose (mg) from ABBV-951 and All Concomitant Medications
(Safety Analysis Set)

Week		ABBV-951 (CSCI + Extra)	LED from Concomitant Medications	Total
WEEK 12	n	66	9	66
	Mean	1994.0	133.0	2012.2
	SD	808.67	86.84	813.12
	Median	1870.4	100.0	1897.0
	Min	664.7	25.0	664.7
	Max	4074.9	270.0	4074.9
WEEK 24	n	64	7	64
	Mean	2041.7	345.3	2079.5
	SD	693.84	540.71	731.66
	Median	1985.1	180.0	1985.1
	Min	949.4	25.0	949.4
	Max	3637.7	1552.0	3770.4
WEEK 36	n	62	6	62
	Mean	2071.0	702.5	2138.9
	SD	707.48	1053.92	826.82
	Median	2017.4	75.0	2017.4
	Min	954.2	25.0	954.2
	Max	3725.4	2500.0	5034.8
WEEK 48	n	43	4	43
	Mean	2141.7	846.9	2220.4
	SD	738.04	1436.30	873.87
	Median	2107.6	150.0	2158.4
	Min	953.1	87.5	953.1
	Max	4057.5	3000.0	5208.8

Program Source Code: [redacted]

TABLE 14.1 8.3

Daily Levodopa Equivalent Dose (mg) from ABBV-951 and All Concomitant Medications
(Safety Analysis Set)

Week		ABBV-951 (CSCI + Extra)	LED from Concomitant Medications	Total
WEEK 60	n	15	0	15
	Mean	1925.2		1925.2
	SD	761.30		761.30
	Median	1973.9		1973.9
	Min	876.6		876.6
	Max	3918.0		3918.0
WEEK 72	n	4	0	4
	Mean	2505.3		2505.3
	SD	1005.87		1005.87
	Median	2380.3		2380.3
	Min	1415.3		1415.3
	Max	3845.3		3845.3
WEEK 84	n	2	0	2
	Mean	1856.2		1856.2
	SD	667.44		667.44
	Median	1856.2		1856.2
	Min	1384.3		1384.3
	Max	2328.2		2328.2

Program Source Code: [redacted]

表11　レボドパの1日あたりの最頻投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Categories (mg LD)	CSCI + Extra (N=105) n (%)	CSCI + Extra + Rescue + Loading Oral (N=105) n (%)
< 500	0	0
500 - < 600	0	0
600 - < 700	0	0
700 - < 800	1 (1.0)	1 (1.0)
800 - < 900	3 (2.9)	3 (2.9)
900 - < 1000	4 (3.8)	4 (3.8)
1000 - < 1100	4 (3.8)	4 (3.8)
1100 - < 1200	6 (5.7)	6 (5.7)
1200 - < 1300	6 (5.7)	6 (5.7)
1300 - < 1400	8 (7.6)	8 (7.6)
1400 - < 1500	4 (3.8)	4 (3.8)
1500 - < 1600	3 (2.9)	3 (2.9)
1600 - < 1700	5 (4.8)	5 (4.8)
1700 - < 1800	1 (1.0)	1 (1.0)
1800 - < 1900	6 (5.7)	6 (5.7)
1900 - < 2000	6 (5.7)	6 (5.7)
2000 - < 2100	6 (5.7)	5 (4.8)
2100 - < 2200	4 (3.8)	5 (4.8)
2200 - < 2300	7 (6.7)	7 (6.7)
2300 - < 2400	5 (4.8)	5 (4.8)
2400 - < 2500	6 (5.7)	6 (5.7)
2500 - < 2600	2 (1.9)	2 (1.9)
2600 - < 2700	2 (1.9)	2 (1.9)
2700 - < 2800	3 (2.9)	3 (2.9)
2800 - < 2900	3 (2.9)	3 (2.9)
2900 - < 3000	0	0
3000 - < 3100	0	0
3100 - < 3200	2 (1.9)	2 (1.9)

Program Source Code: [redacted]

TABLE 14.1 8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Categories (mg LD)	CSCI + Extra (N=105) n (%)	CSCI + Extra + Rescue + Loading Oral (N=105) n (%)
3200 - < 3300	0	0
3300 - < 3400	1 (1.0)	1 (1.0)
3400 - < 3500	3 (2.9)	3 (2.9)
3500 - < 3600	1 (1.0)	1 (1.0)
3600 - < 3700	0	0
3700 - < 3800	0	0
3800 - < 3900	1 (1.0)	1 (1.0)
3900 - < 4000	0	0
4000 - < 4100	1 (1.0)	1 (1.0)
4100 - < 4200	0	0
4200 - < 4300	1 (1.0)	1 (1.0)
>= 4300	0	0

Program Source Code: [redacted]

表12　治験薬曝露期間（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__10

Duration of Study Drug Exposure
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Duration of ABBV-951 exposure (days) &			
n	45	60	105
Mean (SD)	222.3 (151.08)	251.8 (146.53)	239.1 (148.50)
Median	274.0	289.0	288.0
Min, Max	2, 509	1, 516	1, 516
By time intervals - n(%) &			
1 - 84 Days	14 (31.1)	16 (26.7)	30 (28.6)
85 - 168 Days	2 (4.4)	0	2 (1.9)
169 - 252 Days	6 (13.3)	5 (8.3)	11 (10.5)
253 - 336 Days	11 (24.4)	19 (31.7)	30 (28.6)
337 - 420 Days	11 (24.4)	16 (26.7)	27 (25.7)
421 - 504 Days	0	2 (3.3)	2 (1.9)
505 - 588 Days	1 (2.2)	2 (3.3)	3 (2.9)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure &	27.4	41.4	68.7

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10

Duration of Study Drug Exposure
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Duration of ABBV-951 exposure (days) without interruption *			
n	45	60	105
Mean (SD)	221.6 (151.64)	251.3 (146.23)	238.6 (148.58)
Median	274.0	289.0	288.0
Min, Max	2, 509	1, 516	1, 516
By time intervals - n(%) *			
1 - 84 Days	15 (33.3)	16 (26.7)	31 (29.5)
85 - 168 Days	1 (2.2)	0	1 (1.0)
169 - 252 Days	6 (13.3)	5 (8.3)	11 (10.5)
253 - 336 Days	11 (24.4)	19 (31.7)	30 (28.6)
337 - 420 Days	11 (24.4)	16 (26.7)	27 (25.7)
421 - 504 Days	0	2 (3.3)	2 (1.9)
505 - 588 Days	1 (2.2)	2 (3.3)	3 (2.9)
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure *	27.3	41.3	68.6

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表13　治験薬投与中断理由（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL
TABLE PAGE 1 OF 1

TABLE 14.1__12.1

All Reasons for Infusion Interruption
(Safety Analysis Set)

	Total
Total number of subjects with any interruptions	11
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	0
Pump malfunction	4
Adverse event (not COVID-19 infection)	2
Other	6

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表14　治験薬投与中断期間（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__12.2

Duration of Infusion Interruption
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=45)	High Dose (N=60)	All Subjects (N=105)
Duration of ABBV-951 interruption (days)			
n	3	8	11
Mean (SD)	9.25 (14.657)	2.17 (4.915)	4.10 (8.416)
Median	1.00	0.39	0.59
Min, Max	0.6, 26.2	0.1, 14.3	0.1, 26.2
By time intervals - n(%)			
< 1 day	1 (33.3)	7 (87.5)	8 (72.7)
1 - < 2 days	1 (33.3)	0	1 (9.1)
2 - < 3 days	0	0	0
3 - < 4 days	0	0	0
4 - < 5 days	0	0	0
5 - < 10 days	0	0	0
10 - < 20 days	0	1 (12.5)	1 (9.1)
20 - < 30 days	1 (33.3)	0	1 (9.1)
>= 30 days	0	0	0

Program Source Code: [redacted]

表15　レボドパの1日あたりの投与量（安全性解析対象集団）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 12	n	66	35	66	10	0	10	66
	Mean	1953.3	76.9	1994.0	110.0		110.0	2010.7
	SD	803.28	70.31	808.67	31.62		31.62	809.08
	Median	1829.8	48.7	1870.4	100.0		100.0	1870.4
	Min	664.7	18.8	664.7	100.0		100.0	664.7
	Max	4049.3	307.4	4074.9	200.0		200.0	4074.9
WEEK 24	n	64	37	64	8	3	11	64
	Mean	1996.2	78.8	2041.7	137.5	158.3	143.2	2066.3
	SD	684.62	75.38	693.84	74.40	80.36	72.54	706.36
	Median	1958.1	51.2	1985.1	100.0	125.0	100.0	2020.5
	Min	865.4	18.8	949.4	100.0	100.0	100.0	949.4
	Max	3613.8	333.0	3637.7	300.0	250.0	300.0	3737.7
WEEK 36	n	62	28	62	5	1	6	62
	Mean	2040.1	68.4	2071.0	110.0	250.0	133.3	2083.9
	SD	709.17	55.28	707.48	22.36	N/A	60.55	705.55
	Median	1978.4	51.2	2017.4	100.0	250.0	100.0	2017.4
	Min	857.5	18.8	954.2	100.0	250.0	100.0	954.2
	Max	3725.4	256.1	3725.4	150.0	250.0	250.0	3725.4
WEEK 48	n	43	24	43	1	1	2	43
	Mean	2098.4	77.5	2141.7	100.0	250.0	175.0	2149.8
	SD	734.09	77.37	738.04	N/A	N/A	106.07	736.56
	Median	2031.8	37.6	2107.6	100.0	250.0	175.0	2107.6
	Min	855.8	18.8	953.1	100.0	250.0	100.0	953.1
	Max	4031.9	281.7	4057.5	100.0	250.0	250.0	4057.5

Program Source Code: [redacted]

TABLE 14.1 8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Week		ABBV-951 CSCI			Oral			Overall Total
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	
WEEK 60	n	15	6	15	1	0	1	15
	Mean	1899.8	63.5	1925.2	100.0		100.0	1931.9
	SD	724.19	56.98	761.30	N/A		N/A	766.89
	Median	1973.9	41.0	1973.9	100.0		100.0	1973.9
	Min	876.6	32.4	876.6	100.0		100.0	876.6
	Max	3738.7	179.3	3918.0	100.0		100.0	3918.0
WEEK 72	n	4	4	4	0	0	0	4
	Mean	2457.7	47.6	2505.3				2505.3
	SD	1010.29	14.33	1005.87				1005.87
	Median	2343.5	46.1	2380.3				2380.3
	Min	1349.5	32.4	1415.3				1415.3
	Max	3794.1	65.7	3845.3				3845.3
WEEK 84	n	2	2	2	0	0	0	2
	Mean	1817.0	39.3	1856.2				1856.2
	SD	665.03	2.41	667.44				667.44
	Median	1817.0	39.3	1856.2				1856.2
	Min	1346.7	37.6	1384.3				1384.3
	Max	2287.2	41.0	2328.2				2328.2

Program Source Code: [redacted]

表16　治験薬曝露期間（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
Duration of ABBV-951 exposure (days) &			
n	7	4	11
Mean (SD)	114.7 (135.57)	309.3 (181.61)	185.5 (174.80)
Median	53.0	395.5	66.0
Min, Max	17, 366	37, 409	17, 409
By time intervals - n(%) &			
1 - 84 Days	5 (71.4)	1 (25.0)	6 (54.5)
85 - 168 Days	0	0	0
169 - 252 Days	1 (14.3)	0	1 (9.1)
253 - 336 Days	0	0	0
337 - 420 Days	1 (14.3)	3 (75.0)	4 (36.4)
421 - 504 Days	0	0	0
505 - 588 Days	0	0	0
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure &	2.2	3.4	5.6

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

TABLE 14.1 10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=7)	High Dose (N=4)	All Subjects (N=11)
Duration of ABBV-951 exposure (days) without interruption *			
n	7	4	11
Mean (SD)	114.7 (135.57)	309.0 (181.45)	185.4 (174.68)
Median	53.0	395.0	66.0
Min, Max	17, 366	37, 409	17, 409
By time intervals - n(%) *			
1 - 84 Days	5 (71.4)	1 (25.0)	6 (54.5)
85 - 168 Days	0	0	0
169 - 252 Days	1 (14.3)	0	1 (9.1)
253 - 336 Days	0	0	0
337 - 420 Days	1 (14.3)	3 (75.0)	4 (36.4)
421 - 504 Days	0	0	0
505 - 588 Days	0	0	0
589 - 672 Days	0	0	0
>= 673 Days	0	0	0
Patient-years of exposure *	2.2	3.4	5.6

Note: Percentages calculated on non-missing values.
&: Duration of ABBV-951 exposure (days) = Date of ABBV-951 stopped - Date of ABBV-951 started + 1.
*: Duration of ABBV-951 exposure (days) excluding study drug interruption = Duration of ABBV-951 exposure (days) - Duration of interruption (days).

Program Source Code: [redacted]

表17　治験薬投与中断理由（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__12.1.J

All Reasons for Infusion Interruption
(Safety Analysis Set - Japan Subjects)

	Total
Total number of subjects with any interruptions	1
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	0
Pump malfunction	0
Adverse event (not COVID-19 infection)	0
Other	1

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表18　レボドパの1日あたりの投与量（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
WEEK 12	n	7	6	7	2	0	2	7
	Mean	1536.0	71.6	1597.4	100.0		100.0	1625.9
	SD	491.47	25.42	468.45	0.00		0.00	452.35
	Median	1548.7	70.9	1595.7	100.0		100.0	1695.7
	Min	866.4	41.0	963.7	100.0		100.0	963.7
	Max	2178.8	102.5	2243.7	100.0		100.0	2243.7
WEEK 24	n	5	4	5	1	0	1	5
	Mean	1663.1	76.4	1724.3	100.0		100.0	1744.3
	SD	560.21	16.30	544.45	N/A		N/A	529.34
	Median	1949.2	73.4	1949.2	100.0		100.0	1949.2
	Min	865.4	61.5	962.7	100.0		100.0	962.7
	Max	2183.5	97.3	2264.6	100.0		100.0	2264.6
WEEK 36	n	5	3	5	0	0	0	5
	Mean	1605.6	77.4	1652.0				1652.0
	SD	583.12	34.50	570.13				570.13
	Median	1839.8	97.3	1839.8				1839.8
	Min	857.5	37.6	954.8				954.8
	Max	2183.5	97.3	2280.8				2280.8
WEEK 48	n	4	3	4	0	0	0	4
	Mean	1743.1	57.2	1786.0				1786.0
	SD	621.90	36.61	591.05				591.05
	Median	1919.5	48.7	1932.3				1932.3
	Min	855.8	25.6	953.1				953.1
	Max	2277.5	97.3	2326.1				2326.1

Program Source Code: [redacted]

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Week		ABBV-951 CSCI			Oral			Overall Total
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	
WEEK 60	n	3	1	3	0	0	0	3
	Mean	1728.2	32.4	1739.0				1739.0
	SD	759.59	N/A	772.68				772.68
	Median	1972.2	32.4	1972.2				1972.2
	Min	876.6	32.4	876.6				876.6
	Max	2335.9	32.4	2368.3				2368.3

Program Source Code: [redacted]

表19　パーキンソン病日誌に基づく，標準化した1日あたりの平均オフ時間及びオン時間の要約（FAS）：M15-737試験

TABLE 14.2__1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'Off' Time									
BASELINE	73		2.39 (2.68)	1.2	0.0, 10.1				
Low Dose	30		3.01 (2.66)	2.6	0.0, 10.1				
High Dose	43		1.96 (2.64)	0.5	0.0, 8.8				
WEEK 12	54	2.64	2.65 (2.51)	2.3	0.0, 7.6	0.01 (2.17)	0.0	-6.4, 6.8	0.9641
Low Dose	25	2.98	2.49 (2.27)	2.5	0.0, 7.3	-0.49 (1.80)	0.0	-4.2, 2.8	0.1884
High Dose	29	2.35	2.79 (2.72)	2.1	0.0, 7.6	0.44 (2.40)	0.0	-6.4, 6.8	0.3277
WEEK 24	62	2.12	2.96 (3.74)	1.8	0.0, 16.0	0.84 (2.78)	0.0	-5.7, 13.3	0.0208*
Low Dose	25	2.59	3.16 (4.23)	1.3	0.0, 16.0	0.57 (3.58)	0.0	-5.7, 13.3	0.4340
High Dose	37	1.81	2.83 (3.43)	2.3	0.0, 13.4	1.02 (2.11)	0.0	-3.3, 6.2	0.0058**
WEEK 36	34	2.54	2.63 (2.70)	2.0	0.0, 12.1	0.09 (2.04)	0.0	-5.5, 5.6	0.8007
Low Dose	17	2.93	3.14 (3.26)	2.3	0.0, 12.1	0.21 (2.09)	0.3	-5.5, 5.6	0.6847
High Dose	17	2.14	2.11 (1.96)	1.7	0.0, 6.1	-0.03 (2.06)	0.0	-3.9, 3.9	0.9517

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	25	1.80	2.76 (3.60)	1.1	0.0, 14.3	0.95 (2.29)	0.0	-3.0, 6.1	0.0477*
Low Dose	10	1.41	1.16 (1.49)	0.4	0.0, 4.2	-0.26 (1.21)	-0.0	-3.0, 1.6	0.5191
High Dose	15	2.06	3.82 (4.21)	2.8	0.0, 14.3	1.76 (2.51)	0.4	-1.0, 6.1	0.0166*
WEEK 60	4	0.26	1.57 (1.15)	1.9	0.0, 2.4	1.31 (1.07)	1.4	0.0, 2.4	0.0928
Low Dose	2	0.27	1.21 (1.71)	1.2	0.0, 2.4	0.95 (1.34)	0.9	0.0, 1.9	0.5000
High Dose	2	0.25	1.92 (0.72)	1.9	1.4, 2.4	1.67 (1.07)	1.7	0.9, 2.4	0.2710
WEEK 72	2	0.00	2.73 (3.85)	2.7	0.0, 5.5	2.73 (3.85)	2.7	0.0, 5.5	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	73		10.32 (4.99)	11.2	0.0, 16.0				
Low Dose	30		11.05 (4.22)	11.7	1.3, 16.0				
High Dose	43		9.80 (5.45)	10.0	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 12	54	10.32	11.08 (4.63)	11.9	0.0, 16.0	0.75 (3.51)	0.2	-9.6, 14.2	0.1205
Low Dose	25	11.31	12.05 (4.06)	13.3	1.0, 16.0	0.75 (3.93)	0.0	-6.6, 14.2	0.3513
High Dose	29	9.47	10.23 (4.99)	10.7	0.0, 16.0	0.76 (3.18)	0.3	-9.6, 9.0	0.2084
WEEK 24	62	10.84	11.09 (4.64)	11.9	0.0, 16.0	0.26 (4.45)	0.0	-13.3, 14.2	0.6529
Low Dose	25	11.46	11.58 (4.91)	13.6	0.0, 16.0	0.12 (4.91)	0.0	-13.3, 14.2	0.9026
High Dose	37	10.42	10.76 (4.48)	10.6	0.0, 16.0	0.35 (4.18)	0.0	-9.2, 13.7	0.6177
WEEK 36	34	10.89	10.88 (4.76)	11.9	0.0, 16.0	-0.00 (4.71)	0.0	-11.2, 14.2	0.9977
Low Dose	17	11.41	11.55 (4.61)	13.3	1.3, 16.0	0.14 (4.44)	-0.3	-5.9, 14.2	0.8972
High Dose	17	10.36	10.21 (4.95)	11.9	0.0, 16.0	-0.15 (5.09)	0.2	-11.2, 14.0	0.9073
WEEK 48	25	11.07	11.40 (4.61)	12.4	1.4, 16.0	0.34 (4.40)	0.0	-5.6, 13.7	0.7059
Low Dose	10	11.48	12.80 (4.75)	15.3	1.8, 16.0	1.32 (5.62)	0.0	-5.1, 13.7	0.4762
High Dose	15	10.79	10.47 (4.43)	10.7	1.4, 16.0	-0.32 (3.41)	0.0	-5.6, 7.9	0.7209

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 60	4	8.29	12.15 (4.14)	13.1	6.3, 16.0	3.86 (2.72)	4.6	0.0, 6.3	0.0655
Low Dose	2	12.32	14.79 (1.71)	14.8	13.6, 16.0	2.46 (3.48)	2.5	0.0, 4.9	0.5000
High Dose	2	4.25	9.50 (4.53)	9.5	6.3, 12.7	5.25 (1.48)	5.3	4.2, 6.3	0.1254
WEEK 72	2	13.65	8.71 (10.30)	8.7	1.4, 16.0	-4.93 (6.98)	-4.9	-9.9, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	73		2.86 (4.60)	0.5	0.0, 16.0				
Low Dose	30		1.66 (3.20)	0.0	0.0, 12.0				
High Dose	43		3.69 (5.24)	0.8	0.0, 16.0				
WEEK 12	54	2.61	1.88 (3.80)	0.0	0.0, 16.0	-0.73 (3.94)	0.0	-15.8, 7.4	0.1806
Low Dose	25	1.40	1.43 (3.22)	0.0	0.0, 12.4	0.03 (3.21)	0.0	-11.6, 7.4	0.9614
High Dose	29	3.65	2.27 (4.26)	0.0	0.0, 16.0	-1.38 (4.43)	0.0	-15.8, 6.7	0.1039

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 24	62	2.57	1.62 (3.16)	0.0	0.0, 16.0	-0.95 (4.06)	0.0	-16.0, 6.1	0.0702
Low Dose	25	1.70	1.18 (2.69)	0.0	0.0, 12.4	-0.52 (3.79)	0.0	-12.0, 5.7	0.5004
High Dose	37	3.15	1.91 (3.44)	0.0	0.0, 16.0	-1.24 (4.26)	0.0	-16.0, 6.1	0.0846
WEEK 36	34	2.27	2.29 (4.23)	0.1	0.0, 16.0	0.02 (4.10)	0.0	-12.9, 11.2	0.9767
Low Dose	17	1.48	1.21 (2.74)	0.0	0.0, 11.1	-0.28 (3.14)	0.0	-11.6, 4.4	0.7229
High Dose	17	3.05	3.37 (5.19)	0.2	0.0, 16.0	0.32 (4.96)	0.0	-12.9, 11.2	0.7959
WEEK 48	25	2.71	1.69 (2.95)	0.2	0.0, 11.9	-1.02 (4.31)	0.0	-12.8, 5.2	0.2477
Low Dose	10	2.51	1.95 (3.94)	0.0	0.0, 11.9	-0.56 (4.32)	0.0	-11.1, 5.2	0.6893
High Dose	15	2.85	1.52 (2.20)	0.3	0.0, 6.4	-1.33 (4.42)	0.0	-12.8, 4.9	0.2654
WEEK 60	4	5.06	1.93 (2.74)	0.9	0.0, 5.8	-3.14 (5.09)	-1.8	-10.2, 1.1	0.3056
Low Dose	2	1.75	0.00 (0.00)	0.0	0.0, 0.0	-1.75 (2.48)	-1.8	-3.5, 0.0	0.5000
High Dose	2	8.38	3.85 (2.78)	3.9	1.9, 5.8	-4.52 (8.00)	-4.5	-10.2, 1.1	0.5705

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 72	2	2.35	2.08 (2.94)	2.1	0.0, 4.2	-0.27 (0.39)	-0.3	-0.5, 0.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	73		0.43 (1.18)	0.0	0.0, 6.3				
Low Dose	30		0.27 (0.79)	0.0	0.0, 3.3				
High Dose	43		0.55 (1.38)	0.0	0.0, 6.3				
WEEK 12	54	0.43	0.39 (1.66)	0.0	0.0, 11.0	-0.04 (1.92)	0.0	-5.3, 11.0	0.8799
Low Dose	25	0.32	0.03 (0.13)	0.0	0.0, 0.7	-0.29 (0.88)	0.0	-3.3, 0.7	0.1107
High Dose	29	0.53	0.71 (2.24)	0.0	0.0, 11.0	0.18 (2.50)	0.0	-5.3, 11.0	0.7043
WEEK 24	62	0.47	0.33 (1.14)	0.0	0.0, 7.2	-0.14 (1.19)	0.0	-5.3, 4.3	0.3522
Low Dose	25	0.25	0.08 (0.24)	0.0	0.0, 0.9	-0.17 (0.89)	0.0	-3.3, 0.9	0.3423
High Dose	37	0.62	0.50 (1.45)	0.0	0.0, 7.2	-0.12 (1.37)	0.0	-5.3, 4.3	0.5934

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	34	0.31	0.20 (0.60)	0.0	0.0, 2.8	-0.11 (1.11)	0.0	-5.3, 1.8	0.5768
Low Dose	17	0.17	0.10 (0.31)	0.0	0.0, 1.2	-0.08 (0.74)	0.0	-2.7, 1.2	0.6799
High Dose	17	0.45	0.31 (0.79)	0.0	0.0, 2.8	-0.14 (1.42)	0.0	-5.3, 1.8	0.6895
WEEK 48	25	0.42	0.15 (0.35)	0.0	0.0, 1.6	-0.27 (0.98)	0.0	-3.3, 0.7	0.1821
Low Dose	10	0.60	0.10 (0.23)	0.0	0.0, 0.7	-0.50 (1.34)	0.0	-3.3, 0.7	0.2668
High Dose	15	0.31	0.19 (0.42)	0.0	0.0, 1.6	-0.12 (0.66)	0.0	-2.5, 0.4	0.5089
WEEK 60	4	2.39	0.36 (0.73)	0.0	0.0, 1.5	-2.03 (3.45)	-1.7	-6.3, 1.5	0.3247
Low Dose	2	1.66	0.00 (0.00)	0.0	0.0, 0.0	-1.66 (2.34)	-1.7	-3.3, 0.0	0.5000
High Dose	2	3.13	0.73 (1.03)	0.7	0.0, 1.5	-2.40 (5.45)	-2.4	-6.3, 1.5	0.6456
WEEK 72	2	0.00	2.48 (3.51)	2.5	0.0, 5.0	2.48 (3.51)	2.5	0.0, 5.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	73		13.17 (2.78)	13.7	5.9, 16.0				
Low Dose	30		12.72 (2.62)	13.3	5.9, 16.0				
High Dose	43		13.49 (2.88)	14.9	7.2, 16.0				
WEEK 12	54	12.93	12.96 (2.83)	13.5	5.0, 16.0	0.03 (2.87)	0.0	-11.0, 6.4	0.9464
Low Dose	25	12.70	13.48 (2.25)	13.5	8.8, 16.0	0.78 (1.96)	0.0	-2.8, 4.4	0.0586
High Dose	29	13.12	12.50 (3.23)	13.7	5.0, 16.0	-0.62 (3.37)	0.0	-11.0, 6.4	0.3284
WEEK 24	62	13.40	12.71 (3.87)	13.7	0.0, 16.0	-0.69 (2.98)	-0.0	-13.3, 5.7	0.0711
Low Dose	25	13.16	12.76 (4.27)	14.7	0.0, 16.0	-0.40 (3.78)	0.0	-13.3, 5.7	0.6038
High Dose	37	13.57	12.67 (3.64)	13.7	2.6, 16.0	-0.90 (2.32)	-0.6	-6.2, 3.3	0.0247*
WEEK 36	34	13.15	13.17 (2.70)	14.0	3.9, 16.0	0.02 (2.25)	0.0	-5.6, 5.5	0.9624
Low Dose	17	12.89	12.76 (3.31)	13.8	3.9, 16.0	-0.13 (2.26)	0.0	-5.6, 5.5	0.8106
High Dose	17	13.41	13.58 (1.93)	14.0	9.9, 16.0	0.17 (2.29)	0.0	-3.9, 4.3	0.7635

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.1

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	25	13.78	13.09 (3.61)	14.2	1.7, 16.0	-0.68 (2.48)	-0.2	-6.1, 3.8	0.1804
Low Dose	10	13.99	14.75 (1.67)	15.6	11.1, 16.0	0.76 (1.90)	0.0	-2.3, 3.8	0.2400
High Dose	15	13.64	11.99 (4.16)	13.2	1.7, 16.0	-1.65 (2.40)	-0.4	-6.1, 1.0	0.0187*
WEEK 60	4	13.35	14.07 (1.64)	14.1	12.1, 16.0	0.72 (3.81)	0.7	-3.9, 5.3	0.7302
Low Dose	2	14.08	14.79 (1.71)	14.8	13.6, 16.0	0.71 (1.01)	0.7	0.0, 1.4	0.5000
High Dose	2	12.63	13.35 (1.74)	13.4	12.1, 14.6	0.73 (6.52)	0.7	-3.9, 5.3	0.9000
WEEK 72	2	16.00	10.79 (7.36)	10.8	5.6, 16.0	-5.21 (7.36)	-5.2	-10.4, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表20　パーキンソン病日誌に基づく，標準化した1日あたりの平均オフ時間及びオン時間の要約（FAS，部分集団別）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Gender:Female									
Average Daily Normalized 'Off' Time									
BASELINE	24		2.09 (2.55)	1.0	0.0, 8.8				
Low Dose	15		2.29 (2.49)	1.2	0.0, 6.7				
High Dose	9		1.76 (2.78)	0.8	0.0, 8.8				
WEEK 12	20	2.35	2.27 (1.89)	2.3	0.0, 5.9	-0.08 (2.36)	0.0	-6.4, 4.2	0.8803
Low Dose	14	2.26	2.04 (1.86)	2.3	0.0, 5.9	-0.22 (1.67)	0.0	-4.2, 2.8	0.6332
High Dose	6	2.55	2.79 (2.01)	2.2	0.3, 5.7	0.24 (3.70)	0.9	-6.4, 4.2	0.8797
WEEK 24	21	1.89	3.80 (4.80)	1.7	0.0, 16.0	1.91 (3.53)	0.1	-2.3, 13.3	0.0223*
Low Dose	12	1.99	3.74 (5.34)	0.7	0.0, 16.0	1.74 (4.35)	0.0	-2.3, 13.3	0.1925
High Dose	9	1.76	3.88 (4.30)	2.7	0.0, 13.4	2.12 (2.24)	2.2	0.0, 6.2	0.0217*
WEEK 36	13	2.16	1.63 (2.01)	1.2	0.0, 6.5	-0.53 (2.01)	0.0	-5.5, 1.4	0.3625
Low Dose	8	1.87	1.33 (2.22)	0.4	0.0, 6.5	-0.54 (2.11)	0.0	-5.5, 1.4	0.4932
High Dose	5	2.62	2.11 (1.76)	2.0	0.0, 4.9	-0.51 (2.10)	0.0	-3.9, 1.2	0.6134

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	9	1.73	2.43 (4.57)	0.7	0.0, 14.3	0.70 (2.05)	0.0	-1.2, 5.5	0.3377
Low Dose	5	0.83	0.67 (1.15)	0.0	0.0, 2.7	-0.16 (0.62)	0.0	-1.2, 0.5	0.6037
High Dose	4	2.86	4.62 (6.52)	2.0	0.3, 14.3	1.76 (2.83)	1.2	-0.8, 5.5	0.3007
WEEK 60	2	0.25	0.71 (1.00)	0.7	0.0, 1.4	0.46 (0.64)	0.5	0.0, 0.9	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.50	1.41 (N/A)	1.4	1.4, 1.4	0.91 (N/A)	0.9	0.9, 0.9	
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	24		11.23 (5.19)	13.3	0.0, 16.0				
Low Dose	15		11.32 (5.30)	13.3	1.3, 16.0				
High Dose	9		11.07 (5.32)	13.3	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 12	20	11.38	12.25 (3.78)	13.4	4.2, 16.0	0.86 (4.08)	0.0	-6.6, 14.2	0.3554
Low Dose	14	12.04	12.64 (3.75)	13.7	4.5, 16.0	0.61 (4.57)	0.0	-6.6, 14.2	0.6281
High Dose	6	9.85	11.32 (4.04)	11.9	4.2, 15.8	1.46 (2.86)	0.9	-2.0, 5.4	0.2653
WEEK 24	21	11.39	11.70 (5.17)	14.3	0.0, 16.0	0.31 (5.31)	0.0	-13.3, 14.2	0.7935
Low Dose	12	11.63	12.20 (5.36)	15.3	0.0, 16.0	0.57 (6.08)	0.0	-13.3, 14.2	0.7524
High Dose	9	11.07	11.03 (5.14)	13.3	2.6, 16.0	-0.04 (4.40)	0.0	-4.5, 10.6	0.9789
WEEK 36	13	11.00	14.00 (2.72)	14.8	8.0, 16.0	3.00 (5.29)	0.7	-1.4, 14.2	0.0631
Low Dose	8	12.14	14.49 (2.58)	15.6	8.4, 16.0	2.35 (5.22)	0.0	-1.4, 14.2	0.2432
High Dose	5	9.17	13.22 (3.04)	14.0	8.0, 16.0	4.05 (5.83)	1.0	0.0, 14.0	0.1957
WEEK 48	9	12.33	13.37 (4.65)	15.3	1.4, 16.0	1.04 (5.19)	0.0	-5.6, 13.7	0.5646
Low Dose	5	12.28	15.18 (1.09)	15.3	13.3, 16.0	2.91 (6.09)	0.0	-0.5, 13.7	0.3464
High Dose	4	12.40	11.11 (6.62)	13.6	1.4, 15.7	-1.29 (3.04)	-0.4	-5.6, 1.3	0.4577
WEEK 60	2	12.25	14.35 (2.33)	14.4	12.7, 16.0	2.10 (2.97)	2.1	0.0, 4.2	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	8.50	12.71 (N/A)	12.7	12.7, 12.7	4.21 (N/A)	4.2	4.2, 4.2	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	24		2.24 (4.13)	0.1	0.0, 12.9				
Low Dose	15		2.10 (4.15)	0.0	0.0, 12.0				
High Dose	9		2.48 (4.33)	0.6	0.0, 12.9				
WEEK 12	20	2.05	1.45 (2.76)	0.0	0.0, 8.7	-0.60 (3.61)	0.0	-11.6, 7.4	0.4680
Low Dose	14	1.39	1.26 (2.90)	0.0	0.0, 8.7	-0.12 (3.91)	0.0	-11.6, 7.4	0.9075
High Dose	6	3.59	1.89 (2.58)	0.6	0.0, 6.1	-1.70 (2.78)	-1.1	-6.9, 1.0	0.1934
WEEK 24	21	2.29	0.15 (0.42)	0.0	0.0, 1.8	-2.14 (4.30)	0.0	-12.9, 0.1	0.0337*
Low Dose	12	2.15	0.04 (0.10)	0.0	0.0, 0.3	-2.11 (4.53)	0.0	-12.0, 0.0	0.1354
High Dose	9	2.48	0.29 (0.63)	0.0	0.0, 1.8	-2.19 (4.25)	-0.2	-12.9, 0.1	0.1613

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 36	13	2.64	0.33 (0.86)	0.0	0.0, 3.1	-2.31 (4.80)	0.0	-12.9, 2.9	0.1091
Low Dose	8	1.66	0.12 (0.25)	0.0	0.0, 0.7	-1.54 (4.05)	0.0	-11.6, 0.0	0.3187
High Dose	5	4.20	0.67 (1.37)	0.0	0.0, 3.1	-3.53 (6.12)	-2.0	-12.9, 2.9	0.2661
WEEK 48	9	1.64	0.20 (0.32)	0.0	0.0, 0.8	-1.44 (3.65)	0.0	-11.1, 0.1	0.2706
Low Dose	5	2.36	0.15 (0.33)	0.0	0.0, 0.7	-2.22 (4.96)	0.0	-11.1, 0.0	0.3739
High Dose	4	0.74	0.27 (0.36)	0.2	0.0, 0.8	-0.47 (0.73)	-0.3	-1.5, 0.1	0.2890
WEEK 60	2	0.38	0.94 (1.33)	0.9	0.0, 1.9	0.57 (0.80)	0.6	0.0, 1.1	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.75	1.88 (N/A)	1.9	1.9, 1.9	1.13 (N/A)	1.1	1.1, 1.1	
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	24		0.44 (1.38)	0.0	0.0, 6.3				
Low Dose	15		0.29 (0.76)	0.0	0.0, 2.7				
High Dose	9		0.69 (2.08)	0.0	0.0, 6.3				
WEEK 12	20	0.22	0.03 (0.15)	0.0	0.0, 0.7	-0.19 (0.69)	0.0	-2.7, 0.7	0.2449
Low Dose	14	0.31	0.05 (0.18)	0.0	0.0, 0.7	-0.26 (0.82)	0.0	-2.7, 0.7	0.2493
High Dose	6	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 24	21	0.42	0.35 (1.56)	0.0	0.0, 7.2	-0.07 (0.63)	0.0	-2.7, 0.9	0.6100
Low Dose	12	0.22	0.02 (0.07)	0.0	0.0, 0.3	-0.20 (0.78)	0.0	-2.7, 0.3	0.3901
High Dose	9	0.69	0.80 (2.39)	0.0	0.0, 7.2	0.10 (0.31)	0.0	0.0, 0.9	0.3466
WEEK 36	13	0.21	0.04 (0.13)	0.0	0.0, 0.5	-0.17 (0.76)	0.0	-2.7, 0.5	0.4362
Low Dose	8	0.33	0.06 (0.16)	0.0	0.0, 0.5	-0.28 (0.98)	0.0	-2.7, 0.5	0.4511
High Dose	5	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	9	0.30	0.00 (0.00)	0.0	0.0, 0.0	-0.30 (0.89)	0.0	-2.7, 0.0	0.3466
Low Dose	5	0.53	0.00 (0.00)	0.0	0.0, 0.0	-0.53 (1.19)	0.0	-2.7, 0.0	0.3739
High Dose	4	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 60	2	3.13	0.00 (0.00)	0.0	0.0, 0.0	-3.13 (4.42)	-3.1	-6.3, 0.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	6.25	0.00 (N/A)	0.0	0.0, 0.0	-6.25 (N/A)	-6.3	-6.3, -6.3	
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	24		13.47 (2.75)	14.8	7.2, 16.0				
Low Dose	15		13.42 (2.58)	13.3	8.7, 16.0				
High Dose	9		13.55 (3.18)	14.9	7.2, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 12	20	13.43	13.70 (1.85)	13.7	10.1, 16.0	0.27 (2.54)	-0.0	-4.2, 6.4	0.6457
Low Dose	14	13.43	13.91 (1.81)	13.7	10.1, 16.0	0.48 (2.00)	0.0	-2.8, 4.4	0.3842
High Dose	6	13.45	13.21 (2.01)	13.8	10.3, 15.8	-0.24 (3.70)	-0.9	-4.2, 6.4	0.8797
WEEK 24	21	13.68	11.85 (5.05)	14.3	0.0, 16.0	-1.83 (3.69)	-0.1	-13.3, 2.7	0.0337*
Low Dose	12	13.78	12.24 (5.37)	15.3	0.0, 16.0	-1.54 (4.54)	0.0	-13.3, 2.7	0.2646
High Dose	9	13.55	11.32 (4.86)	13.3	2.6, 16.0	-2.23 (2.31)	-2.2	-6.2, 0.0	0.0202*
WEEK 36	13	13.63	14.33 (2.11)	14.8	9.1, 16.0	0.70 (2.12)	0.0	-1.4, 5.5	0.2572
Low Dose	8	13.80	14.61 (2.37)	15.6	9.1, 16.0	0.81 (2.26)	0.0	-1.4, 5.5	0.3430
High Dose	5	13.38	13.89 (1.76)	14.0	11.1, 16.0	0.51 (2.10)	0.0	-1.2, 3.9	0.6134
WEEK 48	9	13.97	13.57 (4.57)	15.3	1.7, 16.0	-0.40 (2.34)	0.0	-5.5, 2.7	0.6207
Low Dose	5	14.64	15.33 (1.15)	16.0	13.3, 16.0	0.69 (1.26)	0.0	-0.5, 2.7	0.2898
High Dose	4	13.14	11.38 (6.52)	14.0	1.7, 15.7	-1.76 (2.83)	-1.2	-5.5, 0.8	0.3007
WEEK 60	2	12.63	15.29 (1.00)	15.3	14.6, 16.0	2.67 (3.77)	2.7	0.0, 5.3	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	9.25	14.59 (N/A)	14.6	14.6, 14.6	5.34 (N/A)	5.3	5.3, 5.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Female (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Gender:Male									
Average Daily Normalized 'Off' Time									
BASELINE	49		2.54 (2.75)	1.4	0.0, 10.1				
Low Dose	15		3.74 (2.72)	3.0	0.0, 10.1				
High Dose	34		2.01 (2.64)	0.5	0.0, 8.1				
WEEK 12	34	2.81	2.88 (2.81)	2.3	0.0, 7.6	0.07 (2.09)	0.0	-4.3, 6.8	0.8498
Low Dose	11	3.89	3.07 (2.69)	2.7	0.0, 7.3	-0.83 (1.97)	0.0	-4.1, 1.8	0.1942
High Dose	23	2.29	2.79 (2.92)	2.0	0.0, 7.6	0.50 (2.05)	0.0	-4.3, 6.8	0.2578
WEEK 24	41	2.24	2.53 (3.05)	1.9	0.0, 10.9	0.29 (2.15)	0.0	-5.7, 5.2	0.3953
Low Dose	13	3.14	2.62 (2.99)	1.9	0.0, 10.8	-0.51 (2.38)	-0.5	-5.7, 4.3	0.4528
High Dose	28	1.83	2.49 (3.12)	1.6	0.0, 10.9	0.66 (1.97)	0.0	-3.3, 5.2	0.0873

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 36	21	2.77	3.24 (2.92)	3.4	0.0, 12.1	0.47 (2.02)	0.3	-3.5, 5.6	0.2963
Low Dose	9	3.88	4.75 (3.28)	3.7	1.9, 12.1	0.87 (1.94)	0.4	-1.0, 5.6	0.2138
High Dose	12	1.94	2.11 (2.12)	1.3	0.0, 6.1	0.17 (2.10)	0.0	-3.5, 3.9	0.7840
WEEK 48	16	1.84	2.94 (3.07)	2.0	0.0, 8.6	1.10 (2.46)	0.2	-3.0, 6.1	0.0944
Low Dose	5	2.00	1.64 (1.76)	1.7	0.0, 4.2	-0.36 (1.70)	-0.0	-3.0, 1.6	0.6622
High Dose	11	1.77	3.53 (3.42)	4.0	0.0, 8.6	1.76 (2.53)	0.4	-1.0, 6.1	0.0436*
WEEK 60	2	0.27	2.42 (0.00)	2.4	2.4, 2.4	2.16 (0.38)	2.2	1.9, 2.4	0.0783
Low Dose	1	0.53	2.42 (N/A)	2.4	2.4, 2.4	1.89 (N/A)	1.9	1.9, 1.9	
High Dose	1	0.00	2.42 (N/A)	2.4	2.4, 2.4	2.42 (N/A)	2.4	2.4, 2.4	
WEEK 72	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Low Dose	0								
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	49		9.87 (4.88)	10.7	0.0, 16.0				
Low Dose	15		10.79 (2.94)	11.5	4.2, 14.6				
High Dose	34		9.46 (5.51)	9.8	0.0, 16.0				
WEEK 12	34	9.70	10.39 (4.99)	10.5	0.0, 16.0	0.69 (3.20)	0.4	-9.6, 9.0	0.2172
Low Dose	11	10.38	11.30 (4.49)	12.2	1.0, 16.0	0.93 (3.13)	0.6	-5.9, 6.1	0.3500
High Dose	23	9.37	9.95 (5.25)	10.1	0.0, 16.0	0.58 (3.30)	0.0	-9.6, 9.0	0.4095
WEEK 24	41	10.55	10.78 (4.38)	10.6	0.0, 16.0	0.23 (4.01)	0.0	-9.2, 13.7	0.7169
Low Dose	13	11.30	11.01 (4.60)	10.7	1.0, 16.0	-0.29 (3.73)	-0.1	-5.9, 7.4	0.7835
High Dose	28	10.21	10.68 (4.35)	10.4	0.0, 16.0	0.47 (4.18)	0.0	-9.2, 13.7	0.5569
WEEK 36	21	10.81	8.95 (4.76)	9.9	0.0, 15.8	-1.86 (3.20)	-0.6	-11.2, 2.4	0.0148*
Low Dose	9	10.76	8.94 (4.51)	10.9	1.3, 14.0	-1.82 (2.52)	-0.8	-5.9, 1.0	0.0616
High Dose	12	10.85	8.96 (5.14)	9.6	0.0, 15.8	-1.89 (3.75)	-0.4	-11.2, 2.4	0.1078

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	16	10.35	10.29 (4.34)	10.2	1.8, 16.0	-0.06 (4.01)	0.0	-5.1, 7.9	0.9532
Low Dose	5	10.68	10.42 (5.96)	10.2	1.8, 16.0	-0.26 (5.27)	-3.2	-5.1, 7.4	0.9167
High Dose	11	10.20	10.24 (3.76)	10.2	4.9, 16.0	0.03 (3.61)	0.1	-5.1, 7.9	0.9771
WEEK 60	2	4.32	9.94 (5.14)	9.9	6.3, 13.6	5.62 (0.97)	5.6	4.9, 6.3	0.0775
Low Dose	1	8.65	13.58 (N/A)	13.6	13.6, 13.6	4.93 (N/A)	4.9	4.9, 4.9	
High Dose	1	0.00	6.30 (N/A)	6.3	6.3, 6.3	6.30 (N/A)	6.3	6.3, 6.3	
WEEK 72	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Low Dose	0								
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	49		3.16 (4.82)	0.7	0.0, 16.0				
Low Dose	15		1.23 (1.91)	0.3	0.0, 6.7				
High Dose	34		4.01 (5.46)	0.8	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 12	34	2.94	2.13 (4.32)	0.0	0.0, 16.0	-0.81 (4.18)	0.0	-15.8, 6.7	0.2695
Low Dose	11	1.40	1.63 (3.72)	0.0	0.0, 12.4	0.23 (2.21)	0.0	-3.5, 5.7	0.7382
High Dose	23	3.67	2.37 (4.64)	0.0	0.0, 16.0	-1.30 (4.82)	0.0	-15.8, 6.7	0.2091
WEEK 24	41	2.71	2.37 (3.66)	0.0	0.0, 16.0	-0.34 (3.84)	0.0	-16.0, 6.1	0.5746
Low Dose	13	1.29	2.24 (3.46)	1.5	0.0, 12.4	0.95 (2.25)	0.1	-3.5, 5.7	0.1544
High Dose	28	3.37	2.43 (3.81)	0.0	0.0, 16.0	-0.94 (4.29)	0.0	-16.0, 6.1	0.2580
WEEK 36	21	2.04	3.50 (5.01)	0.5	0.0, 16.0	1.46 (2.86)	0.0	-1.0, 11.2	0.0299*
Low Dose	9	1.32	2.17 (3.56)	0.5	0.0, 11.1	0.85 (1.53)	0.2	-0.6, 4.4	0.1354
High Dose	12	2.57	4.49 (5.82)	2.4	0.0, 16.0	1.92 (3.56)	0.0	-1.0, 11.2	0.0884
WEEK 48	16	3.31	2.53 (3.43)	0.9	0.0, 11.9	-0.78 (4.73)	0.0	-12.8, 5.2	0.5174
Low Dose	5	2.66	3.75 (5.18)	0.9	0.0, 11.9	1.09 (3.25)	0.9	-3.5, 5.2	0.4949
High Dose	11	3.61	1.97 (2.43)	1.0	0.0, 6.4	-1.64 (5.18)	0.0	-12.8, 4.9	0.3195
WEEK 60	2	9.75	2.91 (4.11)	2.9	0.0, 5.8	-6.84 (4.72)	-6.8	-10.2, -3.5	0.2890
Low Dose	1	3.50	0.00 (N/A)	0.0	0.0, 0.0	-3.50 (N/A)	-3.5	-3.5, -3.5	
High Dose	1	16.00	5.82 (N/A)	5.8	5.8, 5.8	-10.18 (N/A)	-10.2	-10.2, -10.2	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 72	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Low Dose	0								
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	49		0.43 (1.08)	0.0	0.0, 5.3				
Low Dose	15		0.24 (0.85)	0.0	0.0, 3.3				
High Dose	34		0.51 (1.17)	0.0	0.0, 5.3				
WEEK 12	34	0.56	0.60 (2.08)	0.0	0.0, 11.0	0.05 (2.38)	0.0	-5.3, 11.0	0.9112
Low Dose	11	0.33	0.00 (0.00)	0.0	0.0, 0.0	-0.33 (0.99)	0.0	-3.3, 0.0	0.3006
High Dose	23	0.67	0.89 (2.49)	0.0	0.0, 11.0	0.22 (2.82)	0.0	-5.3, 11.0	0.7062
WEEK 24	41	0.50	0.32 (0.88)	0.0	0.0, 4.3	-0.18 (1.40)	0.0	-5.3, 4.3	0.4205
Low Dose	13	0.28	0.13 (0.32)	0.0	0.0, 0.9	-0.15 (1.01)	0.0	-3.3, 0.9	0.6135
High Dose	28	0.60	0.41 (1.04)	0.0	0.0, 4.3	-0.19 (1.57)	0.0	-5.3, 4.3	0.5193

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	21	0.38	0.31 (0.75)	0.0	0.0, 2.8	-0.07 (1.30)	0.0	-5.3, 1.8	0.8106
Low Dose	9	0.03	0.13 (0.40)	0.0	0.0, 1.2	0.10 (0.43)	0.0	-0.3, 1.2	0.4897
High Dose	12	0.63	0.44 (0.93)	0.0	0.0, 2.8	-0.20 (1.70)	0.0	-5.3, 1.8	0.6951
WEEK 48	16	0.49	0.24 (0.42)	0.0	0.0, 1.6	-0.26 (1.06)	0.0	-3.3, 0.7	0.3504
Low Dose	5	0.66	0.19 (0.31)	0.0	0.0, 0.7	-0.47 (1.62)	0.0	-3.3, 0.7	0.5513
High Dose	11	0.42	0.26 (0.48)	0.0	0.0, 1.6	-0.16 (0.78)	0.0	-2.5, 0.4	0.5162
WEEK 60	2	1.66	0.73 (1.03)	0.7	0.0, 1.5	-0.93 (3.37)	-0.9	-3.3, 1.5	0.7633
Low Dose	1	3.31	0.00 (N/A)	0.0	0.0, 0.0	-3.31 (N/A)	-3.3	-3.3, -3.3	
High Dose	1	0.00	1.45 (N/A)	1.5	1.5, 1.5	1.45 (N/A)	1.5	1.5, 1.5	
WEEK 72	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Low Dose	0								
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	49		13.03 (2.82)	13.6	5.9, 16.0				
Low Dose	15		12.02 (2.55)	12.4	5.9, 16.0				
High Dose	34		13.48 (2.85)	14.9	7.9, 16.0				
WEEK 12	34	12.63	12.52 (3.22)	12.9	5.0, 16.0	-0.11 (3.07)	0.0	-11.0, 5.3	0.8295
Low Dose	11	11.78	12.93 (2.69)	13.3	8.8, 16.0	1.16 (1.93)	0.5	-1.5, 4.1	0.0751
High Dose	23	13.04	12.32 (3.49)	12.2	5.0, 16.0	-0.72 (3.36)	0.0	-11.0, 5.3	0.3139
WEEK 24	41	13.26	13.15 (3.08)	13.7	5.1, 16.0	-0.11 (2.38)	0.0	-5.2, 5.7	0.7682
Low Dose	13	12.59	13.25 (3.08)	14.1	5.2, 16.0	0.66 (2.67)	0.9	-4.3, 5.7	0.3925
High Dose	28	13.57	13.11 (3.13)	13.7	5.1, 16.0	-0.47 (2.20)	-0.1	-5.2, 3.3	0.2707
WEEK 36	21	12.85	12.45 (2.82)	12.4	3.9, 16.0	-0.40 (2.27)	-0.2	-5.6, 4.3	0.4265
Low Dose	9	12.09	11.11 (3.25)	11.5	3.9, 14.1	-0.98 (2.01)	-0.4	-5.6, 1.0	0.1835
High Dose	12	13.42	13.45 (2.06)	13.4	9.9, 16.0	0.03 (2.45)	0.0	-3.9, 4.3	0.9697

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Gender:Male (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	16	13.67	12.82 (3.08)	13.9	7.3, 16.0	-0.84 (2.62)	-0.3	-6.1, 3.8	0.2169
Low Dose	5	13.34	14.16 (2.03)	14.1	11.1, 16.0	0.83 (2.56)	0.0	-2.3, 3.8	0.5101
High Dose	11	13.81	12.21 (3.36)	12.0	7.3, 16.0	-1.60 (2.38)	-0.4	-6.1, 1.0	0.0491*
WEEK 60	2	14.08	12.85 (1.03)	12.8	12.1, 13.6	-1.23 (3.75)	-1.2	-3.9, 1.4	0.7239
Low Dose	1	12.15	13.58 (N/A)	13.6	13.6, 13.6	1.42 (N/A)	1.4	1.4, 1.4	
High Dose	1	16.00	12.12 (N/A)	12.1	12.1, 12.1	-3.88 (N/A)	-3.9	-3.9, -3.9	
WEEK 72	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	
Low Dose	0								
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	
Race:WHITE									
Average Daily Normalized 'Off' Time									
BASELINE	64		1.98 (2.41)	0.9	0.0, 8.8				
Low Dose	25		2.41 (2.23)	2.3	0.0, 6.9				
High Dose	39		1.71 (2.51)	0.5	0.0, 8.8				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 12	45	2.10	2.29 (2.44)	1.7	0.0, 7.5	0.18 (2.13)	0.0	-6.4, 6.8	0.5669
Low Dose	20	2.21	2.08 (2.18)	1.9	0.0, 7.3	-0.13 (1.55)	0.0	-4.1, 2.8	0.7206
High Dose	25	2.02	2.45 (2.66)	1.7	0.0, 7.5	0.43 (2.51)	0.0	-6.4, 6.8	0.3987
WEEK 24	56	1.87	2.67 (3.67)	1.2	0.0, 16.0	0.80 (2.81)	0.0	-5.7, 13.3	0.0377*
Low Dose	23	2.42	2.94 (4.24)	1.2	0.0, 16.0	0.52 (3.72)	0.0	-5.7, 13.3	0.5076
High Dose	33	1.49	2.48 (3.28)	1.1	0.0, 13.4	0.99 (1.98)	0.0	-3.1, 6.2	0.0072**
WEEK 36	28	2.13	2.48 (2.86)	1.9	0.0, 12.1	0.35 (1.58)	0.1	-3.9, 5.6	0.2477
Low Dose	15	2.72	3.24 (3.44)	2.3	0.0, 12.1	0.52 (1.56)	0.3	-1.0, 5.6	0.2145
High Dose	13	1.44	1.60 (1.76)	1.0	0.0, 4.9	0.16 (1.65)	0.0	-3.9, 3.6	0.7368
WEEK 48	21	1.44	2.40 (3.76)	0.7	0.0, 14.3	0.96 (2.36)	0.0	-3.0, 6.1	0.0766
Low Dose	9	1.31	1.03 (1.52)	0.0	0.0, 4.2	-0.28 (1.28)	0.0	-3.0, 1.6	0.5297
High Dose	12	1.53	3.42 (4.61)	1.0	0.0, 14.3	1.89 (2.59)	0.3	-0.8, 6.1	0.0281*
WEEK 60	4	0.26	1.57 (1.15)	1.9	0.0, 2.4	1.31 (1.07)	1.4	0.0, 2.4	0.0928
Low Dose	2	0.27	1.21 (1.71)	1.2	0.0, 2.4	0.95 (1.34)	0.9	0.0, 1.9	0.5000
High Dose	2	0.25	1.92 (0.72)	1.9	1.4, 2.4	1.67 (1.07)	1.7	0.9, 2.4	0.2710

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 72	2	0.00	2.73 (3.85)	2.7	0.0, 5.5	2.73 (3.85)	2.7	0.0, 5.5	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	64		10.62 (5.07)	11.7	0.0, 16.0				
Low Dose	25		11.85 (4.02)	13.0	1.3, 16.0				
High Dose	39		9.84 (5.55)	11.2	0.0, 16.0				
WEEK 12	45	10.76	11.61 (4.53)	12.5	0.0, 16.0	0.85 (3.62)	0.0	-9.6, 14.2	0.1236
Low Dose	20	12.36	13.16 (3.12)	14.1	4.5, 16.0	0.80 (4.00)	0.0	-6.6, 14.2	0.3839
High Dose	25	9.48	10.37 (5.13)	10.7	0.0, 16.0	0.89 (3.37)	0.4	-9.6, 9.0	0.2004
WEEK 24	56	11.04	11.54 (4.48)	13.4	0.0, 16.0	0.51 (4.53)	0.0	-13.3, 14.2	0.4047
Low Dose	23	11.75	12.23 (4.47)	14.5	0.0, 16.0	0.48 (4.93)	0.0	-13.3, 14.2	0.6468
High Dose	33	10.54	11.07 (4.49)	11.8	0.0, 16.0	0.53 (4.30)	0.0	-9.2, 13.7	0.4851

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	28	11.29	11.33 (4.73)	12.6	0.0, 16.0	0.04 (4.90)	-0.1	-11.2, 14.2	0.9667
Low Dose	15	11.85	12.02 (3.97)	13.3	3.4, 16.0	0.17 (4.25)	-0.3	-5.9, 14.2	0.8819
High Dose	13	10.65	10.54 (5.54)	11.9	0.0, 16.0	-0.11 (5.73)	0.0	-11.2, 14.0	0.9471
WEEK 48	21	11.24	12.17 (4.26)	14.0	1.4, 16.0	0.93 (4.45)	0.0	-5.6, 13.7	0.3475
Low Dose	9	11.99	14.02 (2.94)	15.3	8.1, 16.0	2.04 (5.46)	0.0	-3.4, 13.7	0.2957
High Dose	12	10.68	10.79 (4.67)	11.3	1.4, 16.0	0.11 (3.54)	0.0	-5.6, 7.9	0.9189
WEEK 60	4	8.29	12.15 (4.14)	13.1	6.3, 16.0	3.86 (2.72)	4.6	0.0, 6.3	0.0655
Low Dose	2	12.32	14.79 (1.71)	14.8	13.6, 16.0	2.46 (3.48)	2.5	0.0, 4.9	0.5000
High Dose	2	4.25	9.50 (4.53)	9.5	6.3, 12.7	5.25 (1.48)	5.3	4.2, 6.3	0.1254
WEEK 72	2	13.65	8.71 (10.30)	8.7	1.4, 16.0	-4.93 (6.98)	-4.9	-9.9, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	64		2.96 (4.82)	0.5	0.0, 16.0				
Low Dose	25		1.49 (3.28)	0.0	0.0, 12.0				
High Dose	39		3.91 (5.42)	0.8	0.0, 16.0				
WEEK 12	45	2.70	1.74 (3.71)	0.0	0.0, 16.0	-0.97 (4.16)	0.0	-15.8, 7.4	0.1257
Low Dose	20	1.10	0.72 (2.01)	0.0	0.0, 8.7	-0.38 (3.27)	0.0	-11.6, 7.4	0.6102
High Dose	25	3.98	2.54 (4.52)	0.2	0.0, 16.0	-1.44 (4.76)	0.0	-15.8, 6.7	0.1444
WEEK 24	56	2.61	1.46 (2.95)	0.0	0.0, 16.0	-1.15 (4.15)	0.0	-16.0, 6.1	0.0432*
Low Dose	23	1.56	0.75 (1.37)	0.0	0.0, 4.6	-0.81 (3.71)	0.0	-12.0, 3.3	0.3054
High Dose	33	3.34	1.96 (3.61)	0.0	0.0, 16.0	-1.38 (4.47)	0.0	-16.0, 6.1	0.0854
WEEK 36	28	2.28	2.04 (4.23)	0.1	0.0, 16.0	-0.24 (4.42)	0.0	-12.9, 11.2	0.7744
Low Dose	15	1.23	0.63 (1.05)	0.0	0.0, 3.0	-0.60 (3.10)	0.0	-11.6, 1.8	0.4634
High Dose	13	3.50	3.67 (5.80)	0.2	0.0, 16.0	0.18 (5.69)	0.0	-12.9, 11.2	0.9131

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	21	2.82	1.25 (2.11)	0.2	0.0, 6.4	-1.57 (4.40)	0.0	-12.8, 4.9	0.1169
Low Dose	9	2.04	0.84 (1.95)	0.0	0.0, 6.0	-1.20 (4.05)	0.0	-11.1, 2.9	0.4008
High Dose	12	3.41	1.55 (2.26)	0.5	0.0, 6.4	-1.85 (4.80)	-0.3	-12.8, 4.9	0.2079
WEEK 60	4	5.06	1.93 (2.74)	0.9	0.0, 5.8	-3.14 (5.09)	-1.8	-10.2, 1.1	0.3056
Low Dose	2	1.75	0.00 (0.00)	0.0	0.0, 0.0	-1.75 (2.48)	-1.8	-3.5, 0.0	0.5000
High Dose	2	8.38	3.85 (2.78)	3.9	1.9, 5.8	-4.52 (8.00)	-4.5	-10.2, 1.1	0.5705
WEEK 72	2	2.35	2.08 (2.94)	2.1	0.0, 4.2	-0.27 (0.39)	-0.3	-0.5, 0.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	64		0.43 (1.22)	0.0	0.0, 6.3				
Low Dose	25		0.26 (0.83)	0.0	0.0, 3.3				
High Dose	39		0.55 (1.42)	0.0	0.0, 6.3				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 12	45	0.43	0.37 (1.71)	0.0	0.0, 11.0	-0.06 (2.07)	0.0	-5.3, 11.0	0.8387
Low Dose	20	0.33	0.03 (0.15)	0.0	0.0, 0.7	-0.29 (0.95)	0.0	-3.3, 0.7	0.1825
High Dose	25	0.52	0.64 (2.28)	0.0	0.0, 11.0	0.12 (2.67)	0.0	-5.3, 11.0	0.8239
WEEK 24	56	0.48	0.32 (1.17)	0.0	0.0, 7.2	-0.16 (1.25)	0.0	-5.3, 4.3	0.3453
Low Dose	23	0.27	0.09 (0.25)	0.0	0.0, 0.9	-0.19 (0.93)	0.0	-3.3, 0.9	0.3432
High Dose	33	0.63	0.49 (1.49)	0.0	0.0, 7.2	-0.14 (1.45)	0.0	-5.3, 4.3	0.5834
WEEK 36	28	0.30	0.15 (0.42)	0.0	0.0, 1.8	-0.15 (1.22)	0.0	-5.3, 1.8	0.5196
Low Dose	15	0.20	0.11 (0.33)	0.0	0.0, 1.2	-0.09 (0.79)	0.0	-2.7, 1.2	0.6817
High Dose	13	0.41	0.18 (0.51)	0.0	0.0, 1.8	-0.23 (1.62)	0.0	-5.3, 1.8	0.6240
WEEK 48	21	0.50	0.18 (0.38)	0.0	0.0, 1.6	-0.32 (1.07)	0.0	-3.3, 0.7	0.1831
Low Dose	9	0.66	0.11 (0.24)	0.0	0.0, 0.7	-0.56 (1.41)	0.0	-3.3, 0.7	0.2693
High Dose	12	0.38	0.24 (0.46)	0.0	0.0, 1.6	-0.14 (0.74)	0.0	-2.5, 0.4	0.5139
WEEK 60	4	2.39	0.36 (0.73)	0.0	0.0, 1.5	-2.03 (3.45)	-1.7	-6.3, 1.5	0.3247
Low Dose	2	1.66	0.00 (0.00)	0.0	0.0, 0.0	-1.66 (2.34)	-1.7	-3.3, 0.0	0.5000
High Dose	2	3.13	0.73 (1.03)	0.7	0.0, 1.5	-2.40 (5.45)	-2.4	-6.3, 1.5	0.6456

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 72	2	0.00	2.48 (3.51)	2.5	0.0, 5.0	2.48 (3.51)	2.5	0.0, 5.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	64		13.58 (2.52)	14.4	7.2, 16.0				
Low Dose	25		13.33 (2.15)	13.3	9.1, 16.0				
High Dose	39		13.75 (2.75)	15.2	7.2, 16.0				
WEEK 12	45	13.46	13.34 (2.70)	13.9	5.0, 16.0	-0.12 (2.90)	0.0	-11.0, 6.4	0.7818
Low Dose	20	13.46	13.88 (2.15)	14.1	8.8, 16.0	0.42 (1.72)	0.0	-2.8, 4.1	0.2892
High Dose	25	13.46	12.91 (3.04)	13.9	5.0, 16.0	-0.55 (3.55)	0.0	-11.0, 6.4	0.4450
WEEK 24	56	13.64	13.00 (3.79)	14.2	0.0, 16.0	-0.64 (3.03)	0.0	-13.3, 5.7	0.1193
Low Dose	23	13.31	12.98 (4.29)	14.8	0.0, 16.0	-0.34 (3.93)	0.0	-13.3, 5.7	0.6860
High Dose	33	13.88	13.02 (3.47)	13.8	2.6, 16.0	-0.85 (2.24)	-0.2	-6.2, 3.3	0.0362*

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:WHITE (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 36	28	13.58	13.38 (2.87)	14.1	3.9, 16.0	-0.20 (1.95)	0.0	-5.6, 4.3	0.5861
Low Dose	15	13.08	12.65 (3.50)	13.8	3.9, 16.0	-0.44 (1.83)	0.0	-5.6, 2.7	0.3709
High Dose	13	14.15	14.22 (1.67)	14.3	11.1, 16.0	0.07 (2.11)	0.0	-3.6, 4.3	0.9092
WEEK 48	21	14.06	13.42 (3.79)	15.1	1.7, 16.0	-0.64 (2.58)	-0.2	-6.1, 3.8	0.2694
Low Dose	9	14.03	14.86 (1.73)	16.0	11.1, 16.0	0.84 (2.00)	0.0	-2.3, 3.8	0.2452
High Dose	12	14.09	12.34 (4.58)	14.5	1.7, 16.0	-1.75 (2.46)	-0.3	-6.1, 0.8	0.0319*
WEEK 60	4	13.35	14.07 (1.64)	14.1	12.1, 16.0	0.72 (3.81)	0.7	-3.9, 5.3	0.7302
Low Dose	2	14.08	14.79 (1.71)	14.8	13.6, 16.0	0.71 (1.01)	0.7	0.0, 1.4	0.5000
High Dose	2	12.63	13.35 (1.74)	13.4	12.1, 14.6	0.73 (6.52)	0.7	-3.9, 5.3	0.9000
WEEK 72	2	16.00	10.79 (7.36)	10.8	5.6, 16.0	-5.21 (7.36)	-5.2	-10.4, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN									
Average Daily Normalized 'Off' Time									
BASELINE	9		5.33 (2.83)	5.8	0.0, 10.1				
Low Dose	5		6.05 (2.79)	5.8	2.4, 10.1				
High Dose	4		4.41 (2.99)	5.6	0.0, 6.4				
WEEK 12	9	5.33	4.49 (2.10)	4.3	2.1, 7.6	-0.84 (2.30)	0.2	-4.2, 2.1	0.3054
Low Dose	5	6.05	4.13 (2.09)	2.9	2.5, 6.9	-1.93 (2.16)	-3.0	-4.2, 0.6	0.1162
High Dose	4	4.41	4.94 (2.34)	5.0	2.1, 7.6	0.52 (1.84)	1.1	-2.1, 2.1	0.6096
WEEK 24	6	4.46	5.64 (3.60)	4.5	2.5, 10.9	1.18 (2.66)	1.5	-3.3, 4.5	0.3253
Low Dose	2	4.55	5.66 (4.41)	5.7	2.5, 8.8	1.11 (1.32)	1.1	0.2, 2.0	0.4455
High Dose	4	4.41	5.64 (3.89)	4.5	2.6, 10.9	1.22 (3.35)	1.8	-3.3, 4.5	0.5178
WEEK 36	6	4.46	3.32 (1.77)	3.5	1.2, 6.1	-1.14 (3.44)	-1.5	-5.5, 3.9	0.4526
Low Dose	2	4.55	2.41 (1.71)	2.4	1.2, 3.6	-2.15 (4.80)	-2.1	-5.5, 1.2	0.6410
High Dose	4	4.41	3.77 (1.85)	3.7	1.6, 6.1	-0.64 (3.32)	-1.5	-3.5, 3.9	0.7249

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	4	3.72	4.64 (1.95)	4.7	2.3, 6.9	0.92 (2.18)	0.4	-1.0, 4.0	0.4612
Low Dose	1	2.37	2.32 (N/A)	2.3	2.3, 2.3	-0.04 (N/A)	-0.0	-0.0, -0.0	
High Dose	3	4.17	5.41 (1.45)	5.3	4.0, 6.9	1.24 (2.56)	0.8	-1.0, 4.0	0.4888
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	9		8.12 (3.88)	8.1	4.0, 16.0				
Low Dose	5		7.09 (2.92)	6.9	4.2, 10.7				
High Dose	4		9.42 (4.99)	8.8	4.0, 16.0				
WEEK 12	9	8.12	8.42 (4.42)	8.4	1.0, 13.9	0.29 (3.09)	0.3	-5.9, 4.2	0.7819
Low Dose	5	7.09	7.64 (4.70)	7.8	1.0, 13.5	0.55 (4.08)	1.4	-5.9, 4.2	0.7791
High Dose	4	9.42	9.39 (4.51)	10.1	3.6, 13.9	-0.02 (1.73)	-0.1	-2.1, 2.1	0.9824
WEEK 24	6	8.97	6.87 (4.27)	6.1	1.0, 13.4	-2.10 (2.95)	-2.3	-5.9, 1.6	0.1411
Low Dose	2	8.09	4.12 (4.39)	4.1	1.0, 7.2	-3.97 (2.73)	-4.0	-5.9, -2.0	0.2883
High Dose	4	9.42	8.25 (4.04)	7.3	5.0, 13.4	-1.17 (2.91)	-0.8	-4.5, 1.6	0.4816

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	6	8.97	8.78 (4.70)	9.0	1.3, 14.8	-0.20 (4.07)	0.2	-5.6, 5.5	0.9110
Low Dose	2	8.09	8.05 (9.55)	8.0	1.3, 14.8	-0.04 (7.89)	-0.0	-5.6, 5.5	0.9950
High Dose	4	9.42	9.14 (2.43)	9.0	6.4, 12.1	-0.27 (2.62)	0.2	-3.9, 2.4	0.8494
WEEK 48	4	10.14	7.34 (4.81)	7.8	1.8, 12.0	-2.80 (2.69)	-3.6	-5.1, 1.0	0.1286
Low Dose	1	6.92	1.81 (N/A)	1.8	1.8, 1.8	-5.11 (N/A)	-5.1	-5.1, -5.1	
High Dose	3	11.22	9.19 (3.77)	10.7	4.9, 12.0	-2.03 (2.70)	-3.1	-4.0, 1.0	0.3225
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	9		2.13 (2.51)	1.7	0.0, 6.7				
Low Dose	5		2.56 (2.93)	1.7	0.0, 6.7				
High Dose	4		1.60 (2.16)	0.9	0.0, 4.6				
WEEK 12	9	2.13	2.60 (4.41)	0.0	0.0, 12.4	0.46 (2.48)	0.0	-2.3, 5.7	0.5894
Low Dose	5	2.56	4.23 (5.52)	1.3	0.0, 12.4	1.67 (2.66)	0.0	-0.4, 5.7	0.2333
High Dose	4	1.60	0.56 (1.11)	0.0	0.0, 2.2	-1.04 (1.22)	-0.9	-2.3, 0.0	0.1867

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 24	6	2.19	3.08 (4.83)	1.2	0.0, 12.4	0.89 (2.67)	0.0	-2.1, 5.7	0.4487
Low Dose	2	3.36	6.22 (8.80)	6.2	0.0, 12.4	2.86 (4.05)	2.9	0.0, 5.7	0.5000
High Dose	4	1.60	1.51 (1.80)	1.2	0.0, 3.6	-0.09 (1.59)	0.0	-2.1, 1.8	0.9172
WEEK 36	6	2.19	3.43 (4.42)	2.2	0.0, 11.1	1.25 (1.82)	0.3	0.0, 4.4	0.1551
Low Dose	2	3.36	5.55 (7.85)	5.5	0.0, 11.1	2.19 (3.10)	2.2	0.0, 4.4	0.5000
High Dose	4	1.60	2.37 (2.76)	2.2	0.0, 5.1	0.77 (1.20)	0.3	0.0, 2.5	0.2893
WEEK 48	4	2.14	4.02 (5.60)	2.1	0.0, 11.9	1.88 (2.45)	1.2	0.0, 5.2	0.2223
Low Dose	1	6.72	11.87 (N/A)	11.9	11.9, 11.9	5.15 (N/A)	5.2	5.2, 5.2	
High Dose	3	0.61	1.40 (2.42)	0.0	0.0, 4.2	0.79 (1.37)	0.0	0.0, 2.4	0.4226
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	9		0.42 (0.85)	0.0	0.0, 2.3				
Low Dose	5		0.29 (0.65)	0.0	0.0, 1.5				
High Dose	4		0.57 (1.14)	0.0	0.0, 2.3				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 12	9	0.42	0.49 (1.48)	0.0	0.0, 4.4	0.08 (0.92)	0.0	-1.5, 2.2	0.8043
Low Dose	5	0.29	0.00 (0.00)	0.0	0.0, 0.0	-0.29 (0.65)	0.0	-1.5, 0.0	0.3739
High Dose	4	0.57	1.11 (2.22)	0.0	0.0, 4.4	0.54 (1.08)	0.0	0.0, 2.2	0.3910
WEEK 24	6	0.38	0.40 (0.99)	0.0	0.0, 2.4	0.02 (0.05)	0.0	0.0, 0.1	0.3632
Low Dose	2	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	0.57	0.60 (1.21)	0.0	0.0, 2.4	0.03 (0.07)	0.0	0.0, 0.1	0.3910
WEEK 36	6	0.38	0.47 (1.16)	0.0	0.0, 2.8	0.09 (0.23)	0.0	0.0, 0.6	0.3632
Low Dose	2	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	4	0.57	0.71 (1.42)	0.0	0.0, 2.8	0.14 (0.28)	0.0	0.0, 0.6	0.3910
WEEK 48	4	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	3	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	9		10.26 (2.96)	9.6	5.9, 16.0				
Low Dose	5		9.65 (2.83)	9.3	5.9, 13.6				
High Dose	4		11.01 (3.37)	9.7	8.6, 16.0				
WEEK 12	9	10.26	11.02 (2.84)	11.7	5.8, 13.9	0.76 (2.77)	-0.2	-2.8, 4.4	0.4347
Low Dose	5	9.65	11.87 (2.09)	13.1	9.1, 13.5	2.22 (2.41)	3.2	-0.6, 4.4	0.1090
High Dose	4	11.01	9.95 (3.59)	10.1	5.8, 13.9	-1.06 (2.17)	-1.8	-2.8, 2.1	0.4000
WEEK 24	6	11.16	9.95 (3.80)	10.3	5.1, 13.5	-1.21 (2.66)	-1.6	-4.5, 3.3	0.3171
Low Dose	2	11.45	10.34 (4.41)	10.3	7.2, 13.5	-1.11 (1.32)	-1.1	-2.0, -0.2	0.4455
High Dose	4	11.01	9.76 (4.18)	10.3	5.1, 13.4	-1.26 (3.35)	-1.9	-4.5, 3.3	0.5073
WEEK 36	6	11.16	12.21 (1.60)	12.2	9.9, 14.8	1.05 (3.37)	1.5	-3.9, 5.5	0.4798
Low Dose	2	11.45	13.59 (1.71)	13.6	12.4, 14.8	2.15 (4.80)	2.1	-1.2, 5.5	0.6410
High Dose	4	11.01	11.52 (1.18)	11.8	9.9, 12.6	0.50 (3.17)	1.5	-3.9, 2.9	0.7722

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Race:ASIAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	4	12.28	11.36 (1.95)	11.3	9.1, 13.7	-0.92 (2.18)	-0.4	-4.0, 1.0	0.4612
Low Dose	1	13.63	13.68 (N/A)	13.7	13.7, 13.7	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	3	11.83	10.59 (1.45)	10.7	9.1, 12.0	-1.24 (2.56)	-0.8	-4.0, 1.0	0.4888
Age category:< 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	41		2.46 (2.73)	1.3	0.0, 10.1				
Low Dose	18		2.92 (2.92)	2.0	0.0, 10.1				
High Dose	23		2.10 (2.59)	0.5	0.0, 8.8				
WEEK 12	29	2.73	2.95 (2.68)	2.5	0.0, 7.6	0.22 (2.43)	0.0	-6.4, 6.8	0.6347
Low Dose	14	2.80	2.55 (2.17)	2.6	0.0, 6.9	-0.26 (1.92)	0.0	-4.1, 2.8	0.6249
High Dose	15	2.67	3.33 (3.12)	2.3	0.0, 7.6	0.66 (2.83)	0.0	-6.4, 6.8	0.3809
WEEK 24	34	2.27	2.43 (3.02)	1.6	0.0, 13.4	0.16 (2.12)	0.0	-5.7, 5.2	0.6706
Low Dose	14	2.16	1.68 (1.79)	1.2	0.0, 5.9	-0.48 (1.79)	0.0	-5.7, 2.3	0.3346
High Dose	20	2.35	2.95 (3.59)	2.3	0.0, 13.4	0.60 (2.26)	0.0	-3.3, 5.2	0.2497

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 36	21	2.41	2.20 (2.08)	2.0	0.0, 7.7	-0.21 (1.67)	0.0	-3.9, 3.6	0.5661
Low Dose	12	2.22	2.43 (2.28)	2.1	0.0, 7.7	0.22 (0.81)	0.1	-1.0, 1.4	0.3722
High Dose	9	2.68	1.89 (1.86)	1.6	0.0, 4.9	-0.79 (2.32)	0.0	-3.9, 3.6	0.3389
WEEK 48	17	1.81	3.11 (4.14)	0.9	0.0, 14.3	1.31 (2.34)	0.3	-1.2, 6.1	0.0349*
Low Dose	7	1.12	1.27 (1.58)	0.7	0.0, 4.2	0.15 (0.82)	0.0	-1.2, 1.6	0.6444
High Dose	10	2.29	4.40 (4.94)	2.7	0.0, 14.3	2.11 (2.74)	0.6	-0.8, 6.1	0.0372*
WEEK 60	2	0.00	1.21 (1.71)	1.2	0.0, 2.4	1.21 (1.71)	1.2	0.0, 2.4	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	2.42 (N/A)	2.4	2.4, 2.4	2.42 (N/A)	2.4	2.4, 2.4	
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	41		9.61 (5.40)	10.7	0.0, 16.0				
Low Dose	18		11.09 (4.46)	11.9	1.5, 16.0				
High Dose	23		8.46 (5.87)	8.1	0.0, 16.0				
WEEK 12	29	9.35	10.79 (4.62)	11.4	0.0, 16.0	1.44 (3.75)	0.4	-5.9, 14.2	0.0477*
Low Dose	14	10.85	11.56 (4.32)	12.7	1.0, 15.8	0.71 (4.51)	-0.2	-5.9, 14.2	0.5677
High Dose	15	7.96	10.08 (4.93)	9.0	0.0, 16.0	2.13 (2.86)	0.5	-0.4, 9.0	0.0121*
WEEK 24	34	10.47	11.46 (4.24)	11.9	1.0, 16.0	1.00 (4.59)	0.0	-6.3, 14.2	0.2147
Low Dose	14	11.82	12.10 (4.38)	14.0	1.0, 16.0	0.28 (4.75)	-0.1	-5.9, 14.2	0.8271
High Dose	20	9.52	11.02 (4.20)	11.2	2.6, 16.0	1.50 (4.53)	0.7	-6.3, 13.7	0.1564
WEEK 36	21	10.82	11.65 (4.29)	13.3	1.3, 16.0	0.83 (4.76)	0.0	-5.6, 14.2	0.4337
Low Dose	12	11.58	11.86 (4.59)	13.5	1.3, 16.0	0.28 (4.76)	-0.2	-5.6, 14.2	0.8443
High Dose	9	9.81	11.38 (4.10)	11.9	6.4, 16.0	1.57 (4.93)	0.2	-3.6, 14.0	0.3686

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 48	17	10.39	10.56 (5.23)	10.2	1.4, 16.0	0.17 (4.90)	0.0	-5.6, 13.7	0.8884
Low Dose	7	11.41	11.81 (5.41)	15.3	1.8, 16.0	0.40 (6.29)	-0.5	-5.1, 13.7	0.8729
High Dose	10	9.68	9.69 (5.20)	8.6	1.4, 16.0	0.01 (4.02)	0.3	-5.6, 7.9	0.9940
WEEK 60	2	8.00	11.15 (6.86)	11.2	6.3, 16.0	3.15 (4.46)	3.2	0.0, 6.3	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	6.30 (N/A)	6.3	6.3, 6.3	6.30 (N/A)	6.3	6.3, 6.3	
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	41		3.55 (5.04)	0.8	0.0, 16.0				
Low Dose	18		1.75 (3.12)	0.3	0.0, 11.8				
High Dose	23		4.95 (5.82)	1.8	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 12	29	3.44	2.01 (3.89)	0.2	0.0, 16.0	-1.43 (4.29)	0.0	-15.8, 5.7	0.0828
Low Dose	14	2.03	1.85 (3.67)	0.2	0.0, 12.4	-0.18 (3.72)	0.0	-11.6, 5.7	0.8581
High Dose	15	4.76	2.16 (4.21)	0.2	0.0, 16.0	-2.60 (4.58)	-0.6	-15.8, 1.0	0.0449*
WEEK 24	34	2.86	1.85 (3.00)	0.0	0.0, 12.4	-1.01 (4.92)	0.0	-16.0, 6.1	0.2404
Low Dose	14	1.81	2.10 (3.36)	0.9	0.0, 12.4	0.29 (3.85)	0.1	-11.6, 5.7	0.7858
High Dose	20	3.59	1.67 (2.79)	0.0	0.0, 10.2	-1.92 (5.46)	-0.1	-16.0, 6.1	0.1334
WEEK 36	21	2.51	1.92 (3.05)	0.2	0.0, 11.1	-0.59 (4.09)	0.0	-12.9, 4.4	0.5168
Low Dose	12	1.96	1.61 (3.20)	0.1	0.0, 11.1	-0.35 (3.78)	0.0	-11.6, 4.4	0.7544
High Dose	9	3.26	2.35 (2.97)	0.5	0.0, 8.1	-0.91 (4.70)	0.0	-12.9, 2.9	0.5775
WEEK 48	17	3.37	2.12 (3.29)	0.7	0.0, 11.9	-1.26 (5.18)	0.0	-12.8, 5.2	0.3326
Low Dose	7	3.08	2.78 (4.54)	0.7	0.0, 11.9	-0.30 (5.13)	0.0	-11.1, 5.2	0.8804
High Dose	10	3.58	1.65 (2.22)	0.7	0.0, 6.4	-1.92 (5.38)	-0.3	-12.8, 4.9	0.2882
WEEK 60	2	8.00	2.91 (4.11)	2.9	0.0, 5.8	-5.09 (7.20)	-5.1	-10.2, 0.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	16.00	5.82 (N/A)	5.8	5.8, 5.8	-10.18 (N/A)	-10.2	-10.2, -10.2	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	41		0.38 (0.85)	0.0	0.0, 3.0				
Low Dose	18		0.24 (0.70)	0.0	0.0, 2.7				
High Dose	23		0.49 (0.95)	0.0	0.0, 3.0				
WEEK 12	29	0.47	0.25 (0.90)	0.0	0.0, 4.4	-0.22 (0.93)	0.0	-3.0, 2.2	0.2067
Low Dose	14	0.31	0.05 (0.18)	0.0	0.0, 0.7	-0.27 (0.82)	0.0	-2.7, 0.7	0.2450
High Dose	15	0.61	0.43 (1.23)	0.0	0.0, 4.4	-0.18 (1.05)	0.0	-3.0, 2.2	0.5119
WEEK 24	34	0.40	0.26 (0.66)	0.0	0.0, 2.4	-0.14 (0.91)	0.0	-3.0, 1.9	0.3677
Low Dose	14	0.21	0.12 (0.31)	0.0	0.0, 0.9	-0.09 (0.81)	0.0	-2.7, 0.9	0.6890
High Dose	20	0.54	0.36 (0.81)	0.0	0.0, 2.4	-0.18 (1.00)	0.0	-3.0, 1.9	0.4269

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	21	0.25	0.22 (0.67)	0.0	0.0, 2.8	-0.03 (0.68)	0.0	-2.7, 1.2	0.8529
Low Dose	12	0.25	0.10 (0.35)	0.0	0.0, 1.2	-0.15 (0.87)	0.0	-2.7, 1.2	0.5772
High Dose	9	0.25	0.38 (0.94)	0.0	0.0, 2.8	0.13 (0.25)	0.0	0.0, 0.6	0.1692
WEEK 48	17	0.43	0.21 (0.42)	0.0	0.0, 1.6	-0.22 (0.90)	0.0	-2.7, 0.7	0.3319
Low Dose	7	0.38	0.14 (0.27)	0.0	0.0, 0.7	-0.24 (1.10)	0.0	-2.7, 0.7	0.5804
High Dose	10	0.46	0.25 (0.50)	0.0	0.0, 1.6	-0.20 (0.80)	0.0	-2.5, 0.4	0.4448
WEEK 60	2	0.00	0.73 (1.03)	0.7	0.0, 1.5	0.73 (1.03)	0.7	0.0, 1.5	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	1.45 (N/A)	1.5	1.5, 1.5	1.45 (N/A)	1.5	1.5, 1.5	
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	41		13.16 (2.88)	13.9	5.9, 16.0				
Low Dose	18		12.84 (2.92)	13.5	5.9, 16.0				
High Dose	23		13.41 (2.88)	14.2	7.2, 16.0				
WEEK 12	29	12.80	12.80 (2.89)	13.5	5.8, 16.0	0.01 (2.55)	0.0	-6.8, 6.4	0.9899
Low Dose	14	12.88	13.40 (2.11)	13.4	9.1, 16.0	0.52 (2.19)	-0.1	-2.8, 4.4	0.3870
High Dose	15	12.72	12.24 (3.44)	13.7	5.8, 16.0	-0.48 (2.82)	0.0	-6.8, 6.4	0.5230
WEEK 24	34	13.33	13.31 (3.09)	13.9	2.6, 16.0	-0.01 (2.21)	0.0	-5.2, 5.7	0.9724
Low Dose	14	13.63	14.20 (1.99)	14.8	9.3, 16.0	0.57 (2.02)	0.0	-3.1, 5.7	0.3111
High Dose	20	13.11	12.69 (3.59)	13.7	2.6, 16.0	-0.42 (2.29)	-0.1	-5.2, 3.3	0.4218
WEEK 36	21	13.34	13.58 (2.17)	14.0	8.3, 16.0	0.24 (1.78)	0.0	-3.6, 3.9	0.5435
Low Dose	12	13.54	13.47 (2.36)	13.9	8.3, 16.0	-0.07 (1.31)	0.0	-2.3, 2.7	0.8494
High Dose	9	13.07	13.73 (2.00)	14.0	11.1, 16.0	0.66 (2.29)	0.0	-3.6, 3.9	0.4126

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:< 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	17	13.76	12.68 (4.16)	14.2	1.7, 16.0	-1.09 (2.41)	-0.4	-6.1, 2.7	0.0814
Low Dose	7	14.50	14.59 (1.82)	15.3	11.1, 16.0	0.09 (1.54)	0.0	-2.3, 2.7	0.8791
High Dose	10	13.25	11.34 (4.87)	12.7	1.7, 16.0	-1.91 (2.62)	-0.6	-6.1, 0.8	0.0468*
WEEK 60	2	16.00	14.06 (2.74)	14.1	12.1, 16.0	-1.94 (2.74)	-1.9	-3.9, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	16.00	12.12 (N/A)	12.1	12.1, 12.1	-3.88 (N/A)	-3.9	-3.9, -3.9	
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Age category:>= 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	32		2.31 (2.65)	1.0	0.0, 8.1				
Low Dose	12		3.16 (2.35)	2.9	0.0, 6.7				
High Dose	20		1.80 (2.75)	0.4	0.0, 8.1				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 12	25	2.53	2.31 (2.29)	2.1	0.0, 7.3	-0.22 (1.85)	0.0	-4.3, 4.2	0.5520
Low Dose	11	3.20	2.42 (2.51)	2.5	0.0, 7.3	-0.78 (1.66)	0.0	-4.2, 0.8	0.1521
High Dose	14	2.00	2.22 (2.20)	1.9	0.0, 6.1	0.21 (1.93)	0.0	-4.3, 4.2	0.6859
WEEK 24	28	1.94	3.61 (4.45)	2.0	0.0, 16.0	1.66 (3.26)	0.3	-3.0, 13.3	0.0118*
Low Dose	11	3.14	5.04 (5.64)	2.4	0.0, 16.0	1.90 (4.80)	0.0	-3.0, 13.3	0.2178
High Dose	17	1.17	2.68 (3.34)	1.7	0.0, 10.9	1.51 (1.85)	0.9	-0.2, 6.2	0.0040**
WEEK 36	13	2.74	3.31 (3.47)	2.0	0.0, 12.1	0.58 (2.54)	0.3	-5.5, 5.6	0.4292
Low Dose	5	4.66	4.85 (4.80)	4.5	0.0, 12.1	0.19 (3.95)	0.3	-5.5, 5.6	0.9209
High Dose	8	1.54	2.36 (2.18)	1.8	0.0, 6.1	0.82 (1.41)	0.5	-0.3, 3.9	0.1430
WEEK 48	8	1.78	1.99 (2.03)	1.9	0.0, 5.3	0.21 (2.13)	-0.0	-3.0, 4.0	0.7890
Low Dose	3	2.09	0.89 (1.53)	0.0	0.0, 2.7	-1.21 (1.61)	-0.5	-3.0, -0.0	0.3251
High Dose	5	1.60	2.66 (2.14)	2.8	0.0, 5.3	1.06 (2.06)	0.0	-1.0, 4.0	0.3145
WEEK 60	2	0.52	1.92 (0.72)	1.9	1.4, 2.4	1.40 (0.69)	1.4	0.9, 1.9	0.2140
Low Dose	1	0.53	2.42 (N/A)	2.4	2.4, 2.4	1.89 (N/A)	1.9	1.9, 1.9	
High Dose	1	0.50	1.41 (N/A)	1.4	1.4, 1.4	0.91 (N/A)	0.9	0.9, 0.9	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 72	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Low Dose	0								
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	32		11.22 (4.32)	11.5	0.0, 16.0				
Low Dose	12		11.01 (4.02)	11.5	1.3, 16.0				
High Dose	20		11.35 (4.58)	11.5	0.0, 16.0				
WEEK 12	25	11.44	11.40 (4.71)	12.3	0.0, 16.0	-0.04 (3.11)	0.0	-9.6, 6.1	0.9479
Low Dose	11	11.88	12.68 (3.81)	13.5	4.5, 16.0	0.80 (3.27)	0.3	-6.6, 6.1	0.4358
High Dose	14	11.10	10.39 (5.23)	11.0	0.0, 16.0	-0.70 (2.93)	-0.3	-9.6, 2.8	0.3865
WEEK 24	28	11.28	10.64 (5.12)	11.6	0.0, 16.0	-0.64 (4.17)	0.0	-13.3, 7.4	0.4207
Low Dose	11	11.00	10.91 (5.66)	13.6	0.0, 16.0	-0.08 (5.32)	1.0	-13.3, 7.4	0.9592
High Dose	17	11.47	10.46 (4.91)	9.7	0.0, 16.0	-1.01 (3.36)	-0.6	-9.2, 6.5	0.2341

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	13	10.99	9.64 (5.38)	11.5	0.0, 16.0	-1.35 (4.47)	-0.3	-11.2, 5.5	0.2991
Low Dose	5	11.00	10.82 (5.12)	11.5	3.4, 16.0	-0.18 (4.04)	-0.3	-5.9, 5.5	0.9242
High Dose	8	10.98	8.90 (5.75)	10.9	0.0, 14.1	-2.07 (4.84)	-0.5	-11.2, 4.5	0.2647
WEEK 48	8	12.50	13.19 (2.27)	12.9	10.2, 16.0	0.69 (3.35)	0.0	-4.0, 7.4	0.5788
Low Dose	3	11.64	15.11 (1.53)	16.0	13.3, 16.0	3.48 (3.68)	3.0	0.0, 7.4	0.2430
High Dose	5	13.01	12.03 (1.83)	12.0	10.2, 14.9	-0.98 (1.89)	-0.9	-4.0, 1.0	0.3081
WEEK 60	2	8.57	13.14 (0.62)	13.1	12.7, 13.6	4.57 (0.51)	4.6	4.2, 4.9	0.0502
Low Dose	1	8.65	13.58 (N/A)	13.6	13.6, 13.6	4.93 (N/A)	4.9	4.9, 4.9	
High Dose	1	8.50	12.71 (N/A)	12.7	12.7, 12.7	4.21 (N/A)	4.2	4.2, 4.2	
WEEK 72	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Low Dose	0								
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	32		1.98 (3.86)	0.0	0.0, 16.0				
Low Dose	12		1.54 (3.46)	0.0	0.0, 12.0				
High Dose	20		2.24 (4.15)	0.0	0.0, 16.0				
WEEK 12	25	1.64	1.73 (3.77)	0.0	0.0, 16.0	0.09 (3.40)	0.0	-11.0, 7.4	0.8946
Low Dose	11	0.59	0.89 (2.60)	0.0	0.0, 8.7	0.30 (2.57)	0.0	-3.5, 7.4	0.7046
High Dose	14	2.46	2.39 (4.46)	0.0	0.0, 16.0	-0.08 (4.02)	0.0	-11.0, 6.7	0.9453
WEEK 24	28	2.21	1.34 (3.38)	0.0	0.0, 16.0	-0.88 (2.75)	0.0	-12.0, 5.1	0.1034
Low Dose	11	1.56	0.02 (0.07)	0.0	0.0, 0.2	-1.54 (3.63)	0.0	-12.0, 0.0	0.1890
High Dose	17	2.63	2.19 (4.16)	0.0	0.0, 16.0	-0.45 (2.02)	0.0	-3.9, 5.1	0.3744
WEEK 36	13	1.87	2.87 (5.76)	0.0	0.0, 16.0	1.01 (4.07)	0.0	-5.7, 11.2	0.3906
Low Dose	5	0.34	0.24 (0.34)	0.0	0.0, 0.7	-0.10 (0.39)	0.0	-0.8, 0.3	0.6153
High Dose	8	2.82	4.51 (6.98)	0.1	0.0, 16.0	1.69 (5.19)	0.0	-5.7, 11.2	0.3866

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	8	1.30	0.78 (1.93)	0.0	0.0, 5.5	-0.52 (1.36)	0.0	-3.5, 0.8	0.3131
Low Dose	3	1.17	0.00 (0.00)	0.0	0.0, 0.0	-1.17 (2.02)	0.0	-3.5, 0.0	0.4226
High Dose	5	1.39	1.25 (2.40)	0.0	0.0, 5.5	-0.13 (0.82)	0.0	-1.5, 0.8	0.7345
WEEK 60	2	2.13	0.94 (1.33)	0.9	0.0, 1.9	-1.19 (3.28)	-1.2	-3.5, 1.1	0.6989
Low Dose	1	3.50	0.00 (N/A)	0.0	0.0, 0.0	-3.50 (N/A)	-3.5	-3.5, -3.5	
High Dose	1	0.75	1.88 (N/A)	1.9	1.9, 1.9	1.13 (N/A)	1.1	1.1, 1.1	
WEEK 72	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Low Dose	0								
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	32		0.50 (1.52)	0.0	0.0, 6.3				
Low Dose	12		0.30 (0.95)	0.0	0.0, 3.3				
High Dose	20		0.62 (1.78)	0.0	0.0, 6.3				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 12	25	0.39	0.56 (2.26)	0.0	0.0, 11.0	0.17 (2.66)	0.0	-5.3, 11.0	0.7479
Low Dose	11	0.32	0.00 (0.00)	0.0	0.0, 0.0	-0.32 (0.99)	0.0	-3.3, 0.0	0.3053
High Dose	14	0.44	1.00 (2.99)	0.0	0.0, 11.0	0.56 (3.46)	0.0	-5.3, 11.0	0.5521
WEEK 24	28	0.56	0.42 (1.55)	0.0	0.0, 7.2	-0.14 (1.48)	0.0	-5.3, 4.3	0.6194
Low Dose	11	0.30	0.02 (0.08)	0.0	0.0, 0.3	-0.28 (1.01)	0.0	-3.3, 0.3	0.3817
High Dose	17	0.73	0.68 (1.97)	0.0	0.0, 7.2	-0.05 (1.74)	0.0	-5.3, 4.3	0.9052
WEEK 36	13	0.41	0.17 (0.51)	0.0	0.0, 1.8	-0.24 (1.61)	0.0	-5.3, 1.8	0.6071
Low Dose	5	0.00	0.09 (0.20)	0.0	0.0, 0.5	0.09 (0.20)	0.0	0.0, 0.5	0.3739
High Dose	8	0.67	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669
WEEK 48	8	0.41	0.04 (0.10)	0.0	0.0, 0.3	-0.38 (1.19)	0.0	-3.3, 0.3	0.4002
Low Dose	3	1.10	0.00 (0.00)	0.0	0.0, 0.0	-1.10 (1.91)	0.0	-3.3, 0.0	0.4226
High Dose	5	0.00	0.06 (0.13)	0.0	0.0, 0.3	0.06 (0.13)	0.0	0.0, 0.3	0.3739
WEEK 60	2	4.78	0.00 (0.00)	0.0	0.0, 0.0	-4.78 (2.08)	-4.8	-6.3, -3.3	0.1896
Low Dose	1	3.31	0.00 (N/A)	0.0	0.0, 0.0	-3.31 (N/A)	-3.3	-3.3, -3.3	
High Dose	1	6.25	0.00 (N/A)	0.0	0.0, 0.0	-6.25 (N/A)	-6.3	-6.3, -6.3	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 72	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Low Dose	0								
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	32		13.20 (2.71)	13.5	7.9, 16.0				
Low Dose	12		12.55 (2.20)	12.7	9.3, 16.0				
High Dose	20		13.59 (2.96)	15.2	7.9, 16.0				
WEEK 12	25	13.08	13.13 (2.82)	13.5	5.0, 16.0	0.05 (3.26)	0.0	-11.0, 5.3	0.9396
Low Dose	11	12.47	13.58 (2.51)	13.5	8.8, 16.0	1.10 (1.66)	0.5	-0.8, 4.2	0.0529
High Dose	14	13.56	12.78 (3.09)	13.1	5.0, 16.0	-0.78 (3.97)	-0.3	-11.0, 5.3	0.4775
WEEK 24	28	13.50	11.98 (4.60)	13.6	0.0, 16.0	-1.52 (3.58)	-0.3	-13.3, 3.8	0.0326*
Low Dose	11	12.56	10.94 (5.66)	13.6	0.0, 16.0	-1.63 (5.10)	0.0	-13.3, 3.8	0.3149
High Dose	17	14.10	12.65 (3.80)	13.7	5.1, 16.0	-1.45 (2.30)	-0.9	-6.2, 3.0	0.0193*

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Age category:>= 65 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 36	13	12.85	12.51 (3.40)	14.0	3.9, 16.0	-0.34 (2.90)	-0.3	-5.6, 5.5	0.6797
Low Dose	5	11.34	11.06 (4.84)	11.5	3.9, 16.0	-0.28 (3.96)	-0.3	-5.6, 5.5	0.8830
High Dose	8	13.80	13.42 (1.98)	14.1	9.9, 16.0	-0.38 (2.33)	-0.6	-3.9, 4.3	0.6592
WEEK 48	8	13.80	13.97 (2.00)	14.1	10.7, 16.0	0.17 (2.58)	0.0	-4.0, 3.8	0.8592
Low Dose	3	12.80	15.11 (1.53)	16.0	13.3, 16.0	2.31 (2.01)	3.0	0.0, 3.8	0.1847
High Dose	5	14.40	13.28 (2.05)	13.2	10.7, 15.7	-1.12 (2.03)	-0.3	-4.0, 1.0	0.2848
WEEK 60	2	10.70	14.08 (0.72)	14.1	13.6, 14.6	3.38 (2.77)	3.4	1.4, 5.3	0.3341
Low Dose	1	12.15	13.58 (N/A)	13.6	13.6, 13.6	1.42 (N/A)	1.4	1.4, 1.4	
High Dose	1	9.25	14.59 (N/A)	14.6	14.6, 14.6	5.34 (N/A)	5.3	5.3, 5.3	
WEEK 72	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	
Low Dose	0								
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA									
Average Daily Normalized 'Off' Time									
BASELINE	32		1.71 (2.30)	0.5	0.0, 8.1				
Low Dose	10		2.35 (1.91)	2.6	0.0, 5.9				
High Dose	22		1.41 (2.44)	0.1	0.0, 8.1				
WEEK 12	22	1.86	2.32 (2.32)	2.1	0.0, 6.8	0.46 (2.28)	0.0	-4.3, 6.8	0.3596
Low Dose	8	2.27	2.35 (1.93)	2.5	0.0, 5.9	0.07 (1.67)	-0.0	-3.0, 2.8	0.9044
High Dose	14	1.63	2.30 (2.59)	1.6	0.0, 6.8	0.67 (2.60)	0.0	-4.3, 6.8	0.3501
WEEK 24	27	1.30	2.16 (2.86)	0.9	0.0, 10.3	0.86 (2.18)	0.0	-3.0, 7.6	0.0506
Low Dose	9	2.23	2.51 (3.50)	1.1	0.0, 10.3	0.28 (2.95)	-0.0	-3.0, 7.6	0.7844
High Dose	18	0.84	1.99 (2.57)	0.4	0.0, 7.4	1.15 (1.70)	0.3	-0.5, 6.2	0.0107*
WEEK 36	14	1.32	1.72 (1.98)	1.4	0.0, 6.5	0.40 (0.69)	0.3	-1.1, 1.4	0.0496*
Low Dose	6	2.30	2.85 (2.52)	3.0	0.0, 6.5	0.55 (0.57)	0.4	-0.0, 1.4	0.0639
High Dose	8	0.57	0.86 (0.92)	0.6	0.0, 2.0	0.29 (0.79)	0.1	-1.1, 1.2	0.3349

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	9	0.83	1.46 (1.87)	0.7	0.0, 4.5	0.63 (2.07)	0.4	-3.0, 4.5	0.3904
Low Dose	5	1.29	0.98 (1.82)	0.0	0.0, 4.2	-0.31 (1.72)	0.0	-3.0, 1.6	0.7077
High Dose	4	0.25	2.05 (2.00)	1.9	0.0, 4.5	1.80 (2.06)	1.4	0.0, 4.5	0.1794
WEEK 60	4	0.26	1.57 (1.15)	1.9	0.0, 2.4	1.31 (1.07)	1.4	0.0, 2.4	0.0928
Low Dose	2	0.27	1.21 (1.71)	1.2	0.0, 2.4	0.95 (1.34)	0.9	0.0, 1.9	0.5000
High Dose	2	0.25	1.92 (0.72)	1.9	1.4, 2.4	1.67 (1.07)	1.7	0.9, 2.4	0.2710
WEEK 72	2	0.00	2.73 (3.85)	2.7	0.0, 5.5	2.73 (3.85)	2.7	0.0, 5.5	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	32		10.40 (5.28)	11.2	0.0, 16.0				
Low Dose	10		11.47 (4.43)	12.4	1.3, 16.0				
High Dose	22		9.91 (5.66)	10.6	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 12	22	10.31	10.53 (4.97)	11.0	0.0, 16.0	0.22 (3.82)	0.2	-9.6, 9.0	0.7939
Low Dose	8	12.50	12.43 (3.90)	13.5	4.5, 16.0	-0.08 (3.76)	0.2	-6.6, 6.1	0.9565
High Dose	14	9.06	9.44 (5.31)	10.0	0.0, 16.0	0.38 (3.98)	0.2	-9.6, 9.0	0.7255
WEEK 24	27	11.14	12.31 (3.82)	13.6	4.4, 16.0	1.17 (4.48)	0.0	-9.2, 13.7	0.1869
Low Dose	9	11.52	13.14 (3.71)	14.9	5.5, 16.0	1.62 (2.92)	1.1	-2.6, 7.4	0.1343
High Dose	18	10.95	11.89 (3.92)	12.6	4.4, 16.0	0.94 (5.15)	0.0	-9.2, 13.7	0.4487
WEEK 36	14	11.66	11.39 (5.41)	13.9	0.0, 16.0	-0.28 (5.45)	-0.3	-11.2, 14.0	0.8530
Low Dose	6	13.46	12.72 (2.99)	12.6	8.4, 16.0	-0.74 (1.01)	-0.3	-2.5, 0.0	0.1319
High Dose	8	10.32	10.40 (6.73)	14.0	0.0, 16.0	0.07 (7.36)	-0.1	-11.2, 14.0	0.9784
WEEK 48	9	11.78	13.23 (3.13)	15.1	7.9, 16.0	1.46 (3.86)	0.0	-3.2, 7.9	0.2896
Low Dose	5	13.35	14.70 (2.54)	16.0	10.2, 16.0	1.35 (4.02)	0.0	-3.2, 7.4	0.4941
High Dose	4	9.81	11.40 (3.08)	11.3	7.9, 15.1	1.59 (4.25)	-0.2	-1.1, 7.9	0.5085
WEEK 60	4	8.29	12.15 (4.14)	13.1	6.3, 16.0	3.86 (2.72)	4.6	0.0, 6.3	0.0655
Low Dose	2	12.32	14.79 (1.71)	14.8	13.6, 16.0	2.46 (3.48)	2.5	0.0, 4.9	0.5000
High Dose	2	4.25	9.50 (4.53)	9.5	6.3, 12.7	5.25 (1.48)	5.3	4.2, 6.3	0.1254

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 72	2	13.65	8.71 (10.30)	8.7	1.4, 16.0	-4.93 (6.98)	-4.9	-9.9, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	32		3.33 (5.03)	0.6	0.0, 16.0				
Low Dose	10		1.82 (3.75)	0.0	0.0, 12.0				
High Dose	22		4.01 (5.45)	0.8	0.0, 16.0				
WEEK 12	22	3.31	2.93 (4.93)	0.1	0.0, 16.0	-0.38 (4.62)	0.0	-15.8, 7.4	0.7050
Low Dose	8	0.78	1.23 (3.04)	0.0	0.0, 8.7	0.45 (3.06)	0.0	-3.5, 7.4	0.6916
High Dose	14	4.75	3.90 (5.61)	1.1	0.0, 16.0	-0.85 (5.36)	0.0	-15.8, 6.7	0.5636
WEEK 24	27	2.91	1.04 (1.96)	0.0	0.0, 5.8	-1.87 (4.64)	0.0	-16.0, 5.1	0.0462*
Low Dose	9	1.88	0.22 (0.57)	0.0	0.0, 1.7	-1.67 (4.12)	0.0	-12.0, 1.7	0.2599
High Dose	18	3.42	1.45 (2.28)	0.0	0.0, 5.8	-1.97 (4.99)	0.0	-16.0, 5.1	0.1121

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 36	14	2.64	2.65 (5.59)	0.0	0.0, 16.0	0.01 (5.41)	0.0	-12.9, 11.2	0.9961
Low Dose	6	0.24	0.15 (0.28)	0.0	0.0, 0.7	-0.09 (0.34)	0.0	-0.8, 0.2	0.5663
High Dose	8	4.44	4.51 (6.98)	0.1	0.0, 16.0	0.08 (7.36)	0.0	-12.9, 11.2	0.9771
WEEK 48	9	3.03	1.15 (1.94)	0.0	0.0, 5.5	-1.88 (4.31)	0.0	-12.8, 0.9	0.2274
Low Dose	5	0.70	0.18 (0.40)	0.0	0.0, 0.9	-0.52 (1.71)	0.0	-3.5, 0.9	0.5316
High Dose	4	5.94	2.37 (2.50)	2.0	0.0, 5.5	-3.57 (6.22)	-1.1	-12.8, 0.8	0.3344
WEEK 60	4	5.06	1.93 (2.74)	0.9	0.0, 5.8	-3.14 (5.09)	-1.8	-10.2, 1.1	0.3056
Low Dose	2	1.75	0.00 (0.00)	0.0	0.0, 0.0	-1.75 (2.48)	-1.8	-3.5, 0.0	0.5000
High Dose	2	8.38	3.85 (2.78)	3.9	1.9, 5.8	-4.52 (8.00)	-4.5	-10.2, 1.1	0.5705
WEEK 72	2	2.35	2.08 (2.94)	2.1	0.0, 4.2	-0.27 (0.39)	-0.3	-0.5, 0.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	32		0.57 (1.56)	0.0	0.0, 6.3				
Low Dose	10		0.36 (1.04)	0.0	0.0, 3.3				
High Dose	22		0.66 (1.75)	0.0	0.0, 6.3				
WEEK 12	22	0.52	0.23 (0.75)	0.0	0.0, 3.0	-0.29 (1.49)	0.0	-5.3, 3.0	0.3665
Low Dose	8	0.45	0.00 (0.00)	0.0	0.0, 0.0	-0.45 (1.16)	0.0	-3.3, 0.0	0.3143
High Dose	14	0.56	0.36 (0.93)	0.0	0.0, 3.0	-0.21 (1.69)	0.0	-5.3, 3.0	0.6542
WEEK 24	27	0.65	0.49 (1.58)	0.0	0.0, 7.2	-0.16 (1.56)	0.0	-5.3, 4.3	0.6024
Low Dose	9	0.37	0.13 (0.31)	0.0	0.0, 0.9	-0.24 (1.19)	0.0	-3.3, 0.9	0.5690
High Dose	18	0.79	0.67 (1.92)	0.0	0.0, 7.2	-0.12 (1.75)	0.0	-5.3, 4.3	0.7751
WEEK 36	14	0.38	0.25 (0.56)	0.0	0.0, 1.8	-0.13 (1.60)	0.0	-5.3, 1.8	0.7608
Low Dose	6	0.00	0.28 (0.49)	0.0	0.0, 1.2	0.28 (0.49)	0.0	0.0, 1.2	0.2252
High Dose	8	0.67	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	9	0.37	0.16 (0.26)	0.0	0.0, 0.7	-0.21 (1.19)	0.0	-3.3, 0.7	0.6145
Low Dose	5	0.66	0.14 (0.32)	0.0	0.0, 0.7	-0.52 (1.59)	0.0	-3.3, 0.7	0.5073
High Dose	4	0.00	0.18 (0.21)	0.1	0.0, 0.4	0.18 (0.21)	0.1	0.0, 0.4	0.1912
WEEK 60	4	2.39	0.36 (0.73)	0.0	0.0, 1.5	-2.03 (3.45)	-1.7	-6.3, 1.5	0.3247
Low Dose	2	1.66	0.00 (0.00)	0.0	0.0, 0.0	-1.66 (2.34)	-1.7	-3.3, 0.0	0.5000
High Dose	2	3.13	0.73 (1.03)	0.7	0.0, 1.5	-2.40 (5.45)	-2.4	-6.3, 1.5	0.6456
WEEK 72	2	0.00	2.48 (3.51)	2.5	0.0, 5.0	2.48 (3.51)	2.5	0.0, 5.0	0.5000
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	32		13.73 (2.47)	14.7	7.9, 16.0				
Low Dose	10		13.30 (1.86)	13.1	10.1, 16.0				
High Dose	22		13.92 (2.72)	15.5	7.9, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 12	22	13.62	13.46 (2.27)	13.9	9.2, 16.0	-0.16 (2.78)	0.0	-6.8, 5.3	0.7869
Low Dose	8	13.28	13.65 (1.93)	13.5	10.1, 16.0	0.37 (1.90)	0.3	-2.8, 3.0	0.5967
High Dose	14	13.81	13.34 (2.51)	13.9	9.2, 16.0	-0.47 (3.21)	0.0	-6.8, 5.3	0.5947
WEEK 24	27	14.05	13.35 (3.29)	14.9	5.2, 16.0	-0.70 (2.64)	0.0	-7.8, 3.8	0.1789
Low Dose	9	13.40	13.36 (3.59)	14.9	5.5, 16.0	-0.04 (3.34)	0.0	-7.8, 3.8	0.9712
High Dose	18	14.37	13.34 (3.24)	14.4	5.2, 16.0	-1.03 (2.24)	-0.3	-6.2, 3.0	0.0678
WEEK 36	14	14.30	14.04 (2.11)	14.3	9.1, 16.0	-0.27 (1.57)	-0.3	-2.3, 4.3	0.5345
Low Dose	6	13.70	12.87 (2.77)	12.6	9.1, 16.0	-0.83 (0.91)	-0.7	-2.3, 0.0	0.0758
High Dose	8	14.76	14.91 (0.90)	14.6	14.0, 16.0	0.15 (1.88)	-0.1	-1.6, 4.3	0.8278
WEEK 48	9	14.80	14.38 (2.06)	15.3	11.1, 16.0	-0.42 (2.69)	-0.4	-4.9, 3.8	0.6518
Low Dose	5	14.05	14.88 (2.14)	16.0	11.1, 16.0	0.83 (2.56)	0.0	-2.3, 3.8	0.5094
High Dose	4	15.75	13.77 (2.08)	14.1	11.1, 15.7	-1.98 (2.17)	-1.4	-4.9, -0.3	0.1653
WEEK 60	4	13.35	14.07 (1.64)	14.1	12.1, 16.0	0.72 (3.81)	0.7	-3.9, 5.3	0.7302
Low Dose	2	14.08	14.79 (1.71)	14.8	13.6, 16.0	0.71 (1.01)	0.7	0.0, 1.4	0.5000
High Dose	2	12.63	13.35 (1.74)	13.4	12.1, 14.6	0.73 (6.52)	0.7	-3.9, 5.3	0.9000

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 72	2	16.00	10.79 (7.36)	10.8	5.6, 16.0	-5.21 (7.36)	-5.2	-10.4, 0.0	0.5000
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	
Geographic region:EUROPE AND AUSTRALIA									
Average Daily Normalized 'Off' Time									
BASELINE	34		2.45 (2.56)	1.4	0.0, 8.8				
Low Dose	16		2.66 (2.54)	2.0	0.0, 6.9				
High Dose	18		2.26 (2.63)	1.1	0.0, 8.8				
WEEK 12	25	2.59	2.42 (2.58)	1.7	0.0, 7.5	-0.16 (2.00)	0.0	-6.4, 2.9	0.6862
Low Dose	13	2.45	1.98 (2.30)	1.5	0.0, 7.3	-0.47 (1.65)	0.0	-4.1, 1.8	0.3263
High Dose	12	2.73	2.90 (2.88)	2.0	0.0, 7.5	0.16 (2.36)	0.3	-6.4, 2.9	0.8138
WEEK 24	30	2.49	3.25 (4.26)	1.5	0.0, 16.0	0.75 (3.27)	0.0	-5.7, 13.3	0.2177
Low Dose	14	2.54	3.22 (4.77)	1.2	0.0, 16.0	0.68 (4.25)	0.0	-5.7, 13.3	0.5593
High Dose	16	2.45	3.27 (3.92)	2.0	0.0, 13.4	0.82 (2.24)	0.0	-3.1, 5.2	0.1666

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 36	15	3.08	3.14 (3.34)	2.0	0.0, 12.1	0.05 (2.31)	0.0	-3.9, 5.6	0.9317
Low Dose	9	3.00	3.50 (4.07)	2.0	0.0, 12.1	0.51 (2.01)	0.0	-1.0, 5.6	0.4715
High Dose	6	3.22	2.59 (2.05)	2.9	0.0, 4.9	-0.63 (2.75)	-0.1	-3.9, 3.6	0.5990
WEEK 48	12	1.89	3.10 (4.68)	0.7	0.0, 14.3	1.21 (2.61)	0.0	-1.2, 6.1	0.1366
Low Dose	4	1.33	1.09 (1.32)	0.8	0.0, 2.7	-0.24 (0.65)	-0.0	-1.2, 0.3	0.5086
High Dose	8	2.17	4.11 (5.49)	0.7	0.0, 14.3	1.94 (2.96)	0.1	-0.8, 6.1	0.1060
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	34		10.45 (5.03)	12.0	0.0, 16.0				
Low Dose	16		11.61 (4.20)	12.8	1.5, 16.0				
High Dose	18		9.42 (5.59)	9.9	0.0, 16.0				
WEEK 12	25	10.63	12.00 (4.36)	12.7	0.0, 16.0	1.37 (3.27)	0.0	-1.3, 14.2	0.0467*
Low Dose	13	11.66	13.03 (3.29)	14.5	5.7, 16.0	1.38 (4.03)	0.0	-1.3, 14.2	0.2413
High Dose	12	9.51	10.88 (5.20)	11.6	0.0, 16.0	1.36 (2.37)	0.2	-0.9, 6.2	0.0716

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 24	30	10.71	10.64 (5.00)	11.1	0.0, 16.0	-0.07 (4.48)	0.0	-13.3, 14.2	0.9305
Low Dose	14	11.90	11.64 (4.93)	14.0	0.0, 16.0	-0.26 (5.86)	0.0	-13.3, 14.2	0.8707
High Dose	16	9.66	9.76 (5.05)	9.9	0.0, 16.0	0.09 (3.01)	0.0	-6.3, 5.5	0.9040
WEEK 36	15	10.46	10.95 (4.19)	11.9	3.4, 16.0	0.49 (4.33)	0.2	-5.9, 14.2	0.6687
Low Dose	9	10.79	11.56 (4.63)	13.3	3.4, 16.0	0.77 (5.48)	0.0	-5.9, 14.2	0.6843
High Dose	6	9.98	10.04 (3.64)	9.9	6.4, 15.5	0.07 (2.04)	0.6	-3.6, 2.4	0.9390
WEEK 48	12	10.84	11.38 (4.93)	13.7	1.4, 16.0	0.54 (4.97)	0.1	-5.6, 13.7	0.7140
Low Dose	4	10.28	13.18 (3.57)	14.3	8.1, 16.0	2.89 (7.50)	0.6	-3.4, 13.7	0.4965
High Dose	8	11.12	10.48 (5.47)	11.7	1.4, 16.0	-0.64 (3.16)	0.0	-5.6, 3.6	0.5870
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	34		2.71 (4.54)	0.5	0.0, 16.0				
Low Dose	16		1.45 (3.04)	0.1	0.0, 11.8				
High Dose	18		3.82 (5.39)	0.7	0.0, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 12	25	2.31	0.93 (1.82)	0.0	0.0, 7.4	-1.38 (3.64)	0.0	-11.6, 3.1	0.0704
Low Dose	13	1.55	0.93 (2.14)	0.0	0.0, 7.4	-0.62 (3.45)	0.0	-11.6, 3.1	0.5281
High Dose	12	3.14	0.94 (1.51)	0.0	0.0, 5.0	-2.20 (3.81)	-0.6	-11.0, 1.0	0.0709
WEEK 24	30	2.40	1.87 (3.57)	0.0	0.0, 16.0	-0.53 (3.53)	0.0	-11.6, 6.1	0.4181
Low Dose	14	1.35	1.08 (1.63)	0.0	0.0, 4.6	-0.26 (3.48)	0.0	-11.6, 3.3	0.7800
High Dose	16	3.32	2.56 (4.60)	0.0	0.0, 16.0	-0.76 (3.68)	-0.1	-10.7, 6.1	0.4207
WEEK 36	15	2.10	1.68 (2.39)	0.5	0.0, 8.1	-0.42 (3.24)	0.0	-11.6, 2.9	0.6224
Low Dose	9	1.89	0.94 (1.27)	0.3	0.0, 3.0	-0.95 (4.05)	0.0	-11.6, 1.8	0.5024
High Dose	6	2.43	2.80 (3.30)	1.8	0.0, 8.1	0.37 (1.35)	0.0	-1.0, 2.9	0.5307
WEEK 48	12	2.67	1.32 (2.32)	0.3	0.0, 6.4	-1.34 (4.64)	0.0	-11.1, 4.9	0.3372
Low Dose	4	3.72	1.67 (2.88)	0.4	0.0, 6.0	-2.04 (6.18)	0.0	-11.1, 2.9	0.5557
High Dose	8	2.14	1.14 (2.18)	0.3	0.0, 6.4	-1.00 (4.13)	0.0	-9.7, 4.9	0.5175

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	34		0.39 (0.84)	0.0	0.0, 3.0				
Low Dose	16		0.28 (0.73)	0.0	0.0, 2.7				
High Dose	18		0.50 (0.93)	0.0	0.0, 3.0				
WEEK 12	25	0.47	0.65 (2.34)	0.0	0.0, 11.0	0.17 (2.47)	0.0	-3.0, 11.0	0.7307
Low Dose	13	0.34	0.05 (0.19)	0.0	0.0, 0.7	-0.29 (0.85)	0.0	-2.7, 0.7	0.2461
High Dose	12	0.62	1.29 (3.32)	0.0	0.0, 11.0	0.67 (3.47)	0.0	-3.0, 11.0	0.5171
WEEK 24	30	0.40	0.25 (0.68)	0.0	0.0, 2.4	-0.15 (0.89)	0.0	-3.0, 1.9	0.3625
Low Dose	14	0.21	0.06 (0.21)	0.0	0.0, 0.8	-0.16 (0.76)	0.0	-2.7, 0.8	0.4557
High Dose	16	0.56	0.42 (0.90)	0.0	0.0, 2.4	-0.15 (1.02)	0.0	-3.0, 1.9	0.5748
WEEK 36	15	0.35	0.23 (0.74)	0.0	0.0, 2.8	-0.12 (0.74)	0.0	-2.7, 0.6	0.5396
Low Dose	9	0.33	0.00 (0.00)	0.0	0.0, 0.0	-0.33 (0.88)	0.0	-2.7, 0.0	0.2969
High Dose	6	0.38	0.57 (1.14)	0.0	0.0, 2.8	0.19 (0.30)	0.0	0.0, 0.6	0.1749

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 48	12	0.60	0.20 (0.46)	0.0	0.0, 1.6	-0.41 (1.01)	0.0	-2.7, 0.2	0.1912
Low Dose	4	0.67	0.06 (0.12)	0.0	0.0, 0.2	-0.61 (1.38)	0.0	-2.7, 0.2	0.4440
High Dose	8	0.57	0.27 (0.56)	0.0	0.0, 1.6	-0.31 (0.87)	0.0	-2.5, 0.0	0.3521
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	34		13.16 (2.77)	14.0	7.2, 16.0				
Low Dose	16		13.07 (2.57)	13.5	8.7, 16.0				
High Dose	18		13.24 (3.00)	14.7	7.2, 16.0				
WEEK 12	25	12.94	12.93 (3.32)	13.7	5.0, 16.0	-0.01 (3.12)	0.0	-11.0, 6.4	0.9892
Low Dose	13	13.21	13.97 (2.26)	14.5	8.8, 16.0	0.75 (1.94)	0.0	-1.5, 4.4	0.1865
High Dose	12	12.65	11.81 (3.98)	12.2	5.0, 16.0	-0.84 (3.96)	-0.2	-11.0, 6.4	0.4800
WEEK 24	30	13.11	12.51 (4.28)	14.1	0.0, 16.0	-0.60 (3.34)	0.0	-13.3, 5.7	0.3311
Low Dose	14	13.25	12.73 (4.80)	14.8	0.0, 16.0	-0.52 (4.38)	0.0	-13.3, 5.7	0.6610
High Dose	16	12.98	12.32 (3.91)	13.7	2.6, 16.0	-0.67 (2.22)	-0.4	-5.2, 3.3	0.2457

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:EUROPE AND AUSTRALIA (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 36	15	12.57	12.64 (3.30)	13.3	3.9, 16.0	0.07 (2.37)	0.0	-5.6, 3.9	0.9134
Low Dose	9	12.68	12.50 (4.07)	14.0	3.9, 16.0	-0.18 (2.28)	0.0	-5.6, 2.7	0.8196
High Dose	6	12.40	12.84 (2.00)	11.9	11.1, 16.0	0.44 (2.69)	0.1	-3.6, 3.9	0.7063
WEEK 48	12	13.50	12.70 (4.66)	14.5	1.7, 16.0	-0.81 (2.61)	-0.0	-6.1, 2.7	0.3076
Low Dose	4	14.00	14.85 (1.36)	15.0	13.3, 16.0	0.85 (1.40)	0.6	-0.5, 2.7	0.3131
High Dose	8	13.26	11.62 (5.42)	14.5	1.7, 16.0	-1.63 (2.74)	-0.1	-6.1, 0.8	0.1354
Geographic region:JAPAN									
Average Daily Normalized 'Off' Time									
BASELINE	7		5.28 (3.26)	6.1	0.0, 10.1				
Low Dose	4		6.11 (3.22)	6.0	2.4, 10.1				
High Dose	3		4.17 (3.62)	6.1	0.0, 6.4				
WEEK 12	7	5.28	4.54 (2.27)	4.3	2.1, 7.6	-0.74 (2.43)	0.2	-4.2, 2.1	0.4483
Low Dose	4	6.11	4.44 (2.27)	4.2	2.5, 6.9	-1.67 (2.40)	-1.5	-4.2, 0.6	0.2582
High Dose	3	4.17	4.66 (2.78)	4.3	2.1, 7.6	0.49 (2.26)	1.5	-2.1, 2.1	0.7445

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 24	5	4.32	5.54 (4.01)	2.8	2.5, 10.9	1.21 (2.97)	2.0	-3.3, 4.5	0.4127
Low Dose	2	4.55	5.66 (4.41)	5.7	2.5, 8.8	1.11 (1.32)	1.1	0.2, 2.0	0.4455
High Dose	3	4.17	5.46 (4.74)	2.8	2.6, 10.9	1.29 (4.10)	2.6	-3.3, 4.5	0.6410
WEEK 36	5	4.32	3.65 (1.75)	3.6	1.2, 6.1	-0.67 (3.62)	-0.3	-5.5, 3.9	0.6997
Low Dose	2	4.55	2.41 (1.71)	2.4	1.2, 3.6	-2.15 (4.80)	-2.1	-5.5, 1.2	0.6410
High Dose	3	4.17	4.48 (1.45)	3.9	3.4, 6.1	0.31 (3.34)	-0.3	-2.7, 3.9	0.8866
WEEK 48	4	3.72	4.64 (1.95)	4.7	2.3, 6.9	0.92 (2.18)	0.4	-1.0, 4.0	0.4612
Low Dose	1	2.37	2.32 (N/A)	2.3	2.3, 2.3	-0.04 (N/A)	-0.0	-0.0, -0.0	
High Dose	3	4.17	5.41 (1.45)	5.3	4.0, 6.9	1.24 (2.56)	0.8	-1.0, 4.0	0.4888
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	7		9.25 (3.66)	9.3	4.2, 16.0				
Low Dose	4		7.77 (2.87)	8.1	4.2, 10.7				
High Dose	3		11.22 (4.21)	9.6	8.1, 16.0				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 12	7	9.25	9.50 (4.42)	10.2	1.0, 13.9	0.25 (3.52)	0.3	-5.9, 4.2	0.8578
Low Dose	4	7.77	8.12 (5.28)	9.0	1.0, 13.5	0.35 (4.68)	1.5	-5.9, 4.2	0.8918
High Dose	3	11.22	11.34 (2.78)	11.7	8.4, 13.9	0.12 (2.10)	0.3	-2.1, 2.1	0.9298
WEEK 24	5	9.97	7.26 (4.65)	7.2	1.0, 13.4	-2.71 (2.84)	-2.6	-5.9, 1.6	0.0994
Low Dose	2	8.09	4.12 (4.39)	4.1	1.0, 7.2	-3.97 (2.73)	-4.0	-5.9, -2.0	0.2883
High Dose	3	11.22	9.35 (4.16)	9.6	5.1, 13.4	-1.87 (3.12)	-2.6	-4.5, 1.6	0.4076
WEEK 36	5	9.97	9.26 (5.09)	9.9	1.3, 14.8	-0.71 (4.33)	0.2	-5.6, 5.5	0.7320
Low Dose	2	8.09	8.05 (9.55)	8.0	1.3, 14.8	-0.04 (7.89)	-0.0	-5.6, 5.5	0.9950
High Dose	3	11.22	10.06 (1.95)	9.9	8.2, 12.1	-1.16 (2.37)	0.2	-3.9, 0.3	0.4870
WEEK 48	4	10.14	7.34 (4.81)	7.8	1.8, 12.0	-2.80 (2.69)	-3.6	-5.1, 1.0	0.1286
Low Dose	1	6.92	1.81 (N/A)	1.8	1.8, 1.8	-5.11 (N/A)	-5.1	-5.1, -5.1	
High Dose	3	11.22	9.19 (3.77)	10.7	4.9, 12.0	-2.03 (2.70)	-3.1	-4.0, 1.0	0.3225

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	7		1.47 (2.46)	0.0	0.0, 6.7				
Low Dose	4		2.11 (3.18)	0.9	0.0, 6.7				
High Dose	3		0.61 (1.05)	0.0	0.0, 1.8				
WEEK 12	7	1.47	1.96 (4.65)	0.0	0.0, 12.4	0.50 (2.40)	0.0	-1.8, 5.7	0.6046
Low Dose	4	2.11	3.44 (6.04)	0.6	0.0, 12.4	1.32 (2.94)	0.0	-0.4, 5.7	0.4347
High Dose	3	0.61	0.00 (0.00)	0.0	0.0, 0.0	-0.61 (1.05)	0.0	-1.8, 0.0	0.4226
WEEK 24	5	1.71	3.21 (5.39)	0.0	0.0, 12.4	1.50 (2.48)	0.0	0.0, 5.7	0.2490
Low Dose	2	3.36	6.22 (8.80)	6.2	0.0, 12.4	2.86 (4.05)	2.9	0.0, 5.7	0.5000
High Dose	3	0.61	1.19 (2.07)	0.0	0.0, 3.6	0.59 (1.02)	0.0	0.0, 1.8	0.4226
WEEK 36	5	1.71	3.09 (4.86)	0.0	0.0, 11.1	1.38 (2.00)	0.0	0.0, 4.4	0.1974
Low Dose	2	3.36	5.55 (7.85)	5.5	0.0, 11.1	2.19 (3.10)	2.2	0.0, 4.4	0.5000
High Dose	3	0.61	1.45 (2.52)	0.0	0.0, 4.4	0.85 (1.46)	0.0	0.0, 2.5	0.4226

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	4	2.14	4.02 (5.60)	2.1	0.0, 11.9	1.88 (2.45)	1.2	0.0, 5.2	0.2223
Low Dose	1	6.72	11.87 (N/A)	11.9	11.9, 11.9	5.15 (N/A)	5.2	5.2, 5.2	
High Dose	3	0.61	1.40 (2.42)	0.0	0.0, 4.2	0.79 (1.37)	0.0	0.0, 2.4	0.4226
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	7		0.00 (0.00)	0.0	0.0, 0.0				
Low Dose	4		0.00 (0.00)	0.0	0.0, 0.0				
High Dose	3		0.00 (0.00)	0.0	0.0, 0.0				
WEEK 12	7	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	4	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 24	5	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	2	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 36	5	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	2	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
High Dose	3	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 48	4	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	3	0.00	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	7		10.72 (3.26)	9.9	5.9, 16.0				
Low Dose	4		9.89 (3.22)	10.0	5.9, 13.6				
High Dose	3		11.83 (3.62)	9.9	9.6, 16.0				
WEEK 12	7	10.72	11.46 (2.27)	11.7	8.4, 13.9	0.74 (2.43)	-0.2	-2.1, 4.2	0.4483
Low Dose	4	9.89	11.56 (2.27)	11.8	9.1, 13.5	1.67 (2.40)	1.5	-0.6, 4.2	0.2582
High Dose	3	11.83	11.34 (2.78)	11.7	8.4, 13.9	-0.49 (2.26)	-1.5	-2.1, 2.1	0.7445

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 24	5	11.68	10.46 (4.01)	13.2	5.1, 13.5	-1.21 (2.97)	-2.0	-4.5, 3.3	0.4127
Low Dose	2	11.45	10.34 (4.41)	10.3	7.2, 13.5	-1.11 (1.32)	-1.1	-2.0, -0.2	0.4455
High Dose	3	11.83	10.54 (4.74)	13.2	5.1, 13.4	-1.29 (4.10)	-2.6	-4.5, 3.3	0.6410
WEEK 36	5	11.68	12.35 (1.75)	12.4	9.9, 14.8	0.67 (3.62)	0.3	-3.9, 5.5	0.6997
Low Dose	2	11.45	13.59 (1.71)	13.6	12.4, 14.8	2.15 (4.80)	2.1	-1.2, 5.5	0.6410
High Dose	3	11.83	11.52 (1.45)	12.1	9.9, 12.6	-0.31 (3.34)	0.3	-3.9, 2.7	0.8866
WEEK 48	4	12.28	11.36 (1.95)	11.3	9.1, 13.7	-0.92 (2.18)	-0.4	-4.0, 1.0	0.4612
Low Dose	1	13.63	13.68 (N/A)	13.7	13.7, 13.7	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	3	11.83	10.59 (1.45)	10.7	9.1, 12.0	-1.24 (2.56)	-0.8	-4.0, 1.0	0.4888
PD duration (time since diagnosis) category:<10 years									
Average Daily Normalized 'Off' Time									
BASELINE	42		2.63 (2.83)	1.3	0.0, 10.1				
Low Dose	18		3.19 (2.89)	2.5	0.0, 10.1				
High Dose	24		2.22 (2.78)	0.7	0.0, 8.8				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 12	33	2.86	2.61 (2.55)	2.1	0.0, 7.5	-0.26 (2.27)	0.0	-6.4, 6.8	0.5197
Low Dose	15	3.18	2.41 (2.34)	2.5	0.0, 6.9	-0.77 (1.89)	0.0	-4.1, 2.8	0.1373
High Dose	18	2.59	2.76 (2.77)	2.1	0.0, 7.5	0.17 (2.51)	0.0	-6.4, 6.8	0.7768
WEEK 24	35	2.33	2.60 (3.26)	1.7	0.0, 13.4	0.27 (2.21)	0.0	-5.7, 6.2	0.4776
Low Dose	14	2.50	1.61 (1.85)	1.2	0.0, 6.0	-0.90 (1.67)	-0.0	-5.7, 0.5	0.0663
High Dose	21	2.22	3.27 (3.84)	2.3	0.0, 13.4	1.04 (2.21)	0.0	-3.1, 6.2	0.0430*
WEEK 36	21	2.83	2.62 (2.45)	2.0	0.0, 7.7	-0.21 (1.31)	0.0	-3.9, 1.2	0.4654
Low Dose	12	2.53	2.77 (2.73)	2.7	0.0, 7.7	0.24 (0.66)	0.1	-0.9, 1.2	0.2410
High Dose	9	3.23	2.41 (2.16)	2.0	0.0, 6.1	-0.81 (1.73)	-0.2	-3.9, 1.2	0.1979
WEEK 48	16	1.80	2.16 (3.70)	0.5	0.0, 14.3	0.36 (2.06)	0.0	-3.0, 5.5	0.4913
Low Dose	9	1.27	0.99 (1.48)	0.0	0.0, 4.2	-0.28 (1.28)	0.0	-3.0, 1.6	0.5285
High Dose	7	2.48	3.67 (5.15)	1.1	0.0, 14.3	1.19 (2.65)	0.0	-1.0, 5.5	0.2792
WEEK 60	4	0.26	1.57 (1.15)	1.9	0.0, 2.4	1.31 (1.07)	1.4	0.0, 2.4	0.0928
Low Dose	2	0.27	1.21 (1.71)	1.2	0.0, 2.4	0.95 (1.34)	0.9	0.0, 1.9	0.5000
High Dose	2	0.25	1.92 (0.72)	1.9	1.4, 2.4	1.67 (1.07)	1.7	0.9, 2.4	0.2710

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	42		9.89 (5.07)	10.0	0.0, 16.0				
Low Dose	18		10.51 (4.33)	11.1	1.5, 16.0				
High Dose	24		9.42 (5.60)	9.6	0.0, 16.0				
WEEK 12	33	9.96	11.38 (4.56)	12.3	0.0, 16.0	1.42 (3.49)	0.4	-5.9, 14.2	0.0259*
Low Dose	15	10.26	11.87 (4.52)	13.3	1.0, 16.0	1.61 (4.46)	0.5	-5.9, 14.2	0.1841
High Dose	18	9.71	10.97 (4.69)	11.2	0.0, 16.0	1.26 (2.55)	0.4	-0.9, 9.0	0.0507
WEEK 24	35	10.61	11.55 (4.51)	12.1	1.0, 16.0	0.94 (4.49)	0.0	-5.9, 14.2	0.2253
Low Dose	14	11.08	12.50 (4.30)	14.2	1.0, 16.0	1.42 (4.75)	0.5	-5.9, 14.2	0.2846
High Dose	21	10.30	10.92 (4.64)	11.8	2.6, 16.0	0.62 (4.40)	0.0	-4.5, 13.7	0.5270

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 36	21	10.19	11.39 (4.25)	11.5	1.3, 16.0	1.19 (4.70)	0.0	-5.6, 14.2	0.2580
Low Dose	12	11.21	11.43 (4.75)	11.3	1.3, 16.0	0.21 (4.74)	-0.3	-5.6, 14.2	0.8789
High Dose	9	8.83	11.34 (3.74)	11.9	6.4, 15.8	2.50 (4.58)	1.0	-0.6, 14.0	0.1400
WEEK 48	16	11.12	11.91 (5.06)	15.1	1.4, 16.0	0.79 (5.26)	0.0	-5.6, 13.7	0.5558
Low Dose	9	11.28	12.74 (5.04)	15.3	1.8, 16.0	1.46 (5.94)	0.0	-5.1, 13.7	0.4810
High Dose	7	10.92	10.85 (5.27)	10.7	1.4, 16.0	-0.07 (4.54)	0.0	-5.6, 7.9	0.9683
WEEK 60	4	8.29	12.15 (4.14)	13.1	6.3, 16.0	3.86 (2.72)	4.6	0.0, 6.3	0.0655
Low Dose	2	12.32	14.79 (1.71)	14.8	13.6, 16.0	2.46 (3.48)	2.5	0.0, 4.9	0.5000
High Dose	2	4.25	9.50 (4.53)	9.5	6.3, 12.7	5.25 (1.48)	5.3	4.2, 6.3	0.1254
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	42		3.00 (4.81)	0.4	0.0, 16.0				
Low Dose	18		1.89 (3.14)	0.0	0.0, 11.8				
High Dose	24		3.84 (5.67)	0.6	0.0, 16.0				
WEEK 12	33	2.77	1.82 (3.73)	0.0	0.0, 16.0	-0.95 (3.83)	0.0	-15.8, 5.7	0.1650
Low Dose	15	2.06	1.72 (3.58)	0.0	0.0, 12.4	-0.34 (3.69)	0.0	-11.6, 5.7	0.7232
High Dose	18	3.36	1.91 (3.95)	0.0	0.0, 16.0	-1.45 (3.98)	0.0	-15.8, 1.0	0.1403
WEEK 24	35	2.53	1.48 (2.88)	0.0	0.0, 12.4	-1.05 (4.36)	0.0	-16.0, 5.7	0.1633
Low Dose	14	1.99	1.83 (3.44)	0.1	0.0, 12.4	-0.16 (3.92)	0.0	-11.6, 5.7	0.8805
High Dose	21	2.89	1.25 (2.50)	0.0	0.0, 10.2	-1.64 (4.63)	0.0	-16.0, 4.5	0.1193
WEEK 36	21	2.74	1.75 (3.01)	0.2	0.0, 11.1	-0.99 (4.17)	0.0	-12.9, 4.4	0.2901
Low Dose	12	2.03	1.66 (3.18)	0.3	0.0, 11.1	-0.37 (3.78)	0.0	-11.6, 4.4	0.7439
High Dose	9	3.68	1.86 (2.96)	0.0	0.0, 8.1	-1.82 (4.74)	0.0	-12.9, 2.9	0.2825

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	16	2.71	1.84 (3.42)	0.0	0.0, 11.9	-0.87 (4.81)	0.0	-12.8, 5.2	0.4810
Low Dose	9	2.79	2.16 (4.12)	0.0	0.0, 11.9	-0.63 (4.57)	0.0	-11.1, 5.2	0.6920
High Dose	7	2.60	1.42 (2.50)	0.0	0.0, 6.4	-1.18 (5.46)	0.0	-12.8, 4.9	0.5875
WEEK 60	4	5.06	1.93 (2.74)	0.9	0.0, 5.8	-3.14 (5.09)	-1.8	-10.2, 1.1	0.3056
Low Dose	2	1.75	0.00 (0.00)	0.0	0.0, 0.0	-1.75 (2.48)	-1.8	-3.5, 0.0	0.5000
High Dose	2	8.38	3.85 (2.78)	3.9	1.9, 5.8	-4.52 (8.00)	-4.5	-10.2, 1.1	0.5705
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	42		0.47 (1.24)	0.0	0.0, 6.3				
Low Dose	18		0.41 (1.00)	0.0	0.0, 3.3				
High Dose	24		0.52 (1.42)	0.0	0.0, 6.3				

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 12	33	0.41	0.20 (0.84)	0.0	0.0, 4.4	-0.22 (0.89)	0.0	-3.3, 2.2	0.1725
Low Dose	15	0.50	0.00 (0.00)	0.0	0.0, 0.0	-0.50 (1.09)	0.0	-3.3, 0.0	0.0990
High Dose	18	0.34	0.36 (1.13)	0.0	0.0, 4.4	0.02 (0.63)	0.0	-1.3, 2.2	0.9127
WEEK 24	35	0.53	0.37 (1.30)	0.0	0.0, 7.2	-0.16 (0.92)	0.0	-3.3, 1.9	0.3238
Low Dose	14	0.43	0.07 (0.25)	0.0	0.0, 0.9	-0.36 (1.15)	0.0	-3.3, 0.9	0.2615
High Dose	21	0.59	0.57 (1.65)	0.0	0.0, 7.2	-0.02 (0.73)	0.0	-2.1, 1.9	0.9048
WEEK 36	21	0.24	0.24 (0.67)	0.0	0.0, 2.8	0.01 (0.69)	0.0	-2.7, 1.2	0.9611
Low Dose	12	0.22	0.14 (0.36)	0.0	0.0, 1.2	-0.08 (0.89)	0.0	-2.7, 1.2	0.7523
High Dose	9	0.25	0.38 (0.94)	0.0	0.0, 2.8	0.13 (0.25)	0.0	0.0, 0.6	0.1692
WEEK 48	16	0.37	0.09 (0.21)	0.0	0.0, 0.7	-0.29 (1.08)	0.0	-3.3, 0.7	0.3048
Low Dose	9	0.66	0.11 (0.24)	0.0	0.0, 0.7	-0.56 (1.41)	0.0	-3.3, 0.7	0.2693
High Dose	7	0.00	0.06 (0.16)	0.0	0.0, 0.4	0.06 (0.16)	0.0	0.0, 0.4	0.3559
WEEK 60	4	2.39	0.36 (0.73)	0.0	0.0, 1.5	-2.03 (3.45)	-1.7	-6.3, 1.5	0.3247
Low Dose	2	1.66	0.00 (0.00)	0.0	0.0, 0.0	-1.66 (2.34)	-1.7	-3.3, 0.0	0.5000
High Dose	2	3.13	0.73 (1.03)	0.7	0.0, 1.5	-2.40 (5.45)	-2.4	-6.3, 1.5	0.6456

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 72	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	42		12.89 (2.94)	13.4	5.9, 16.0				
Low Dose	18		12.40 (2.78)	13.1	5.9, 16.0				
High Dose	24		13.27 (3.05)	14.9	7.2, 16.0				
WEEK 12	33	12.73	13.20 (2.78)	13.9	5.8, 16.0	0.47 (2.43)	0.0	-6.8, 6.4	0.2713
Low Dose	15	12.32	13.59 (2.34)	13.5	9.1, 16.0	1.27 (2.06)	0.5	-2.8, 4.4	0.0318*
High Dose	18	13.06	12.88 (3.14)	13.9	5.8, 16.0	-0.19 (2.57)	0.0	-6.8, 6.4	0.7612
WEEK 24	35	13.14	13.03 (3.59)	14.1	2.6, 16.0	-0.11 (2.49)	0.0	-6.2, 5.7	0.7907
Low Dose	14	13.07	14.33 (1.90)	14.8	10.0, 16.0	1.26 (1.92)	0.5	-0.9, 5.7	0.0294*
High Dose	21	13.19	12.16 (4.19)	13.7	2.6, 16.0	-1.02 (2.44)	-0.6	-6.2, 3.3	0.0683

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:<10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 36	21	12.93	13.14 (2.52)	14.0	8.3, 16.0	0.21 (1.47)	0.0	-2.3, 3.9	0.5298
Low Dose	12	13.24	13.09 (2.84)	13.3	8.3, 16.0	-0.15 (1.25)	-0.1	-2.3, 2.7	0.6798
High Dose	9	12.52	13.20 (2.18)	14.0	9.9, 16.0	0.68 (1.69)	0.2	-1.2, 3.9	0.2594
WEEK 48	16	13.83	13.75 (3.74)	15.5	1.7, 16.0	-0.08 (2.51)	0.0	-5.5, 3.8	0.9044
Low Dose	9	14.06	14.90 (1.69)	16.0	11.1, 16.0	0.84 (2.00)	0.0	-2.3, 3.8	0.2447
High Dose	7	13.52	12.27 (5.17)	14.9	1.7, 16.0	-1.25 (2.74)	-0.0	-5.5, 1.0	0.2724
WEEK 60	4	13.35	14.07 (1.64)	14.1	12.1, 16.0	0.72 (3.81)	0.7	-3.9, 5.3	0.7302
Low Dose	2	14.08	14.79 (1.71)	14.8	13.6, 16.0	0.71 (1.01)	0.7	0.0, 1.4	0.5000
High Dose	2	12.63	13.35 (1.74)	13.4	12.1, 14.6	0.73 (6.52)	0.7	-3.9, 5.3	0.9000
WEEK 72	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
Low Dose	1	16.00	16.00 (N/A)	16.0	16.0, 16.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	0								

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years									
Average Daily Normalized 'Off' Time									
BASELINE	31		2.07 (2.46)	0.9	0.0, 8.1				
Low Dose	12		2.75 (2.38)	2.7	0.0, 6.7				
High Dose	19		1.64 (2.48)	0.5	0.0, 8.1				
WEEK 12	21	2.29	2.73 (2.50)	2.5	0.0, 7.6	0.44 (1.99)	0.0	-4.3, 4.2	0.3254
Low Dose	10	2.67	2.61 (2.29)	2.6	0.0, 7.3	-0.06 (1.64)	0.0	-4.2, 1.8	0.9104
High Dose	11	1.94	2.83 (2.79)	2.1	0.0, 7.6	0.89 (2.25)	0.8	-4.3, 4.2	0.2176
WEEK 24	27	1.85	3.42 (4.31)	2.3	0.0, 16.0	1.57 (3.27)	0.2	-3.3, 13.3	0.0191*
Low Dose	11	2.69	5.13 (5.55)	2.5	0.0, 16.0	2.43 (4.50)	0.2	-2.3, 13.3	0.1032
High Dose	16	1.27	2.25 (2.83)	1.6	0.0, 7.7	0.98 (2.03)	0.4	-3.3, 5.2	0.0720
WEEK 36	13	2.06	2.64 (3.17)	2.0	0.0, 12.1	0.58 (2.86)	0.3	-5.5, 5.6	0.4811
Low Dose	5	3.90	4.04 (4.54)	2.3	1.2, 12.1	0.15 (4.02)	0.3	-5.5, 5.6	0.9393
High Dose	8	0.92	1.77 (1.80)	1.4	0.0, 4.1	0.85 (2.14)	0.5	-2.7, 3.9	0.3002

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 48	9	1.80	3.81 (3.35)	2.8	0.0, 8.6	2.01 (2.40)	0.8	-0.3, 6.1	0.0368*
Low Dose	1	2.69	2.66 (N/A)	2.7	2.7, 2.7	-0.04 (N/A)	-0.0	-0.0, -0.0	
High Dose	8	1.69	3.95 (3.55)	3.4	0.0, 8.6	2.26 (2.44)	1.6	-0.3, 6.1	0.0342*
WEEK 72	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Low Dose	0								
High Dose	1	0.00	5.45 (N/A)	5.5	5.5, 5.5	5.45 (N/A)	5.5	5.5, 5.5	
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	31		10.89 (4.90)	12.4	0.0, 16.0				
Low Dose	12		11.87 (4.09)	12.8	1.3, 16.0				
High Dose	19		10.28 (5.36)	11.3	0.0, 16.0				
WEEK 12	21	10.89	10.60 (4.81)	11.4	0.0, 16.0	-0.29 (3.36)	0.0	-9.6, 6.2	0.6946
Low Dose	10	12.88	12.33 (3.46)	13.1	4.5, 16.0	-0.55 (2.66)	-0.6	-6.6, 4.2	0.5306
High Dose	11	9.09	9.03 (5.45)	8.9	0.0, 16.0	-0.06 (4.02)	0.0	-9.6, 6.2	0.9616

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 24	27	11.13	10.50 (4.82)	9.7	0.0, 16.0	-0.63 (4.31)	0.0	-13.3, 6.5	0.4542
Low Dose	11	11.94	10.42 (5.59)	13.5	0.0, 16.0	-1.53 (4.80)	-0.1	-13.3, 4.2	0.3164
High Dose	16	10.57	10.56 (4.41)	9.7	0.0, 16.0	-0.01 (3.97)	0.0	-9.2, 6.5	0.9900
WEEK 36	13	12.00	10.06 (5.57)	12.1	0.0, 16.0	-1.94 (4.19)	-1.3	-11.2, 5.5	0.1213
Low Dose	5	11.88	11.85 (4.77)	13.8	3.4, 14.8	-0.03 (4.13)	0.6	-5.9, 5.5	0.9874
High Dose	8	12.07	8.95 (6.04)	10.6	0.0, 16.0	-3.13 (4.01)	-2.5	-11.2, 0.8	0.0631
WEEK 48	9	10.97	10.49 (3.80)	12.0	4.9, 15.1	-0.48 (2.22)	0.0	-4.0, 3.6	0.5368
Low Dose	1	13.31	13.34 (N/A)	13.3	13.3, 13.3	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	8	10.68	10.14 (3.89)	11.1	4.9, 15.1	-0.54 (2.36)	-0.4	-4.0, 3.6	0.5377
WEEK 72	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	
Low Dose	0								
High Dose	1	11.29	1.43 (N/A)	1.4	1.4, 1.4	-9.87 (N/A)	-9.9	-9.9, -9.9	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	31		2.66 (4.36)	0.5	0.0, 16.0				
Low Dose	12		1.33 (3.40)	0.1	0.0, 12.0				
High Dose	19		3.50 (4.77)	0.8	0.0, 16.0				
WEEK 12	21	2.36	1.97 (4.00)	0.0	0.0, 16.0	-0.38 (4.19)	0.0	-11.0, 7.4	0.6790
Low Dose	10	0.40	0.99 (2.71)	0.0	0.0, 8.7	0.59 (2.40)	0.0	-0.6, 7.4	0.4541
High Dose	11	4.14	2.87 (4.86)	1.0	0.0, 16.0	-1.27 (5.30)	-0.8	-11.0, 6.7	0.4437
WEEK 24	27	2.62	1.80 (3.54)	0.0	0.0, 16.0	-0.82 (3.71)	0.0	-12.0, 6.1	0.2611
Low Dose	11	1.34	0.36 (0.84)	0.0	0.0, 2.5	-0.97 (3.75)	0.0	-12.0, 2.5	0.4091
High Dose	16	3.49	2.78 (4.32)	0.1	0.0, 16.0	-0.71 (3.79)	0.0	-10.7, 6.1	0.4641
WEEK 36	13	1.50	3.15 (5.73)	0.0	0.0, 16.0	1.65 (3.55)	0.0	-2.0, 11.2	0.1190
Low Dose	5	0.16	0.11 (0.24)	0.0	0.0, 0.5	-0.06 (0.31)	0.0	-0.6, 0.3	0.7011
High Dose	8	2.34	5.06 (6.74)	2.3	0.0, 16.0	2.72 (4.26)	1.3	-2.0, 11.2	0.1137

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 48	9	2.72	1.43 (2.02)	0.8	0.0, 5.5	-1.29 (3.48)	0.0	-9.7, 2.4	0.2987
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	8	3.06	1.61 (2.08)	0.9	0.0, 5.5	-1.45 (3.69)	-0.4	-9.7, 2.4	0.3023
WEEK 72	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Low Dose	0								
High Dose	1	4.71	4.16 (N/A)	4.2	4.2, 4.2	-0.55 (N/A)	-0.5	-0.5, -0.5	
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	31		0.38 (1.10)	0.0	0.0, 5.3				
Low Dose	12		0.04 (0.10)	0.0	0.0, 0.3				
High Dose	19		0.59 (1.38)	0.0	0.0, 5.3				
WEEK 12	21	0.46	0.70 (2.46)	0.0	0.0, 11.0	0.24 (2.90)	0.0	-5.3, 11.0	0.7111
Low Dose	10	0.05	0.07 (0.21)	0.0	0.0, 0.7	0.01 (0.26)	0.0	-0.3, 0.7	0.8739
High Dose	11	0.83	1.27 (3.36)	0.0	0.0, 11.0	0.44 (4.08)	0.0	-5.3, 11.0	0.7271

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 24	27	0.41	0.28 (0.93)	0.0	0.0, 4.3	-0.12 (1.49)	0.0	-5.3, 4.3	0.6694
Low Dose	11	0.03	0.09 (0.24)	0.0	0.0, 0.8	0.07 (0.26)	0.0	-0.3, 0.8	0.4177
High Dose	16	0.67	0.41 (1.19)	0.0	0.0, 4.3	-0.26 (1.94)	0.0	-5.3, 4.3	0.6063
WEEK 36	13	0.43	0.14 (0.50)	0.0	0.0, 1.8	-0.29 (1.60)	0.0	-5.3, 1.8	0.5208
Low Dose	5	0.06	0.00 (0.00)	0.0	0.0, 0.0	-0.06 (0.13)	0.0	-0.3, 0.0	0.3739
High Dose	8	0.67	0.23 (0.64)	0.0	0.0, 1.8	-0.44 (2.08)	0.0	-5.3, 1.8	0.5669
WEEK 48	9	0.51	0.27 (0.52)	0.0	0.0, 1.6	-0.24 (0.84)	0.0	-2.5, 0.3	0.4162
Low Dose	1	0.00	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
High Dose	8	0.57	0.30 (0.55)	0.0	0.0, 1.6	-0.27 (0.89)	0.0	-2.5, 0.3	0.4205
WEEK 72	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	
Low Dose	0								
High Dose	1	0.00	4.96 (N/A)	5.0	5.0, 5.0	4.96 (N/A)	5.0	5.0, 5.0	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	Change from Baseline: P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	31		13.55 (2.56)	14.2	7.9, 16.0				
Low Dose	12		13.20 (2.38)	13.3	9.3, 16.0				
High Dose	19		13.78 (2.70)	15.2	7.9, 16.0				
WEEK 12	21	13.25	12.57 (2.94)	12.7	5.0, 16.0	-0.68 (3.39)	-0.6	-11.0, 5.3	0.3718
Low Dose	10	13.27	13.32 (2.22)	13.4	8.8, 16.0	0.05 (1.63)	-0.3	-1.5, 4.2	0.9298
High Dose	11	13.23	11.89 (3.43)	11.9	5.0, 16.0	-1.33 (4.43)	-1.5	-11.0, 5.3	0.3415
WEEK 24	27	13.74	12.30 (4.24)	13.7	0.0, 16.0	-1.45 (3.41)	-0.2	-13.3, 3.3	0.0364*
Low Dose	11	13.28	10.78 (5.59)	13.5	0.0, 16.0	-2.50 (4.56)	-0.2	-13.3, 2.3	0.0986
High Dose	16	14.06	13.34 (2.73)	13.7	8.3, 16.0	-0.73 (2.23)	-0.5	-5.2, 3.3	0.2134
WEEK 36	13	13.50	13.22 (3.09)	14.0	3.9, 16.0	-0.28 (3.18)	0.0	-5.6, 5.5	0.7529
Low Dose	5	12.05	11.96 (4.54)	13.8	3.9, 14.8	-0.09 (4.02)	0.0	-5.6, 5.5	0.9631
High Dose	8	14.41	14.01 (1.65)	14.3	11.9, 16.0	-0.41 (2.84)	-0.6	-3.9, 4.3	0.6975

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 1.3

Change from Baseline to Each Planned Visit in Average Daily Normalized Time in Hours
Based on Parkinson's Disease Diary by Subgroups
(FAS)

Variable / Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PD duration (time since diagnosis) category:>=10 years (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 48	9	13.69	11.92 (3.23)	13.2	7.3, 15.7	-1.77 (2.15)	-0.8	-6.1, 0.3	0.0390*
Low Dose	1	13.31	13.34 (N/A)	13.3	13.3, 13.3	0.04 (N/A)	0.0	0.0, 0.0	
High Dose	8	13.73	11.74 (3.41)	12.6	7.3, 15.7	-1.99 (2.18)	-1.6	-6.1, 0.3	0.0364*
WEEK 72	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	
Low Dose	0								
High Dose	1	16.00	5.59 (N/A)	5.6	5.6, 5.6	-10.41 (N/A)	-10.4	-10.4, -10.4	

Note: A PD diary recording day with no more than 2 hours of missing data (4 or less missing entries) or at least 12 awake hours (i.e., at least 24 'Off' or 'On' time entries) for the entire 24-hour diary is considered as a valid PD diary day.
&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表21　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__1.4

Distribution of Early Morning First Non-Sleep Symptom in PD Diary
(FAS)

	N	Off n (%)	On without Dyskinesia n (%)	On with Non-Troublesome Dyskinesia n (%)	On with Troublesome Dyskinesia n (%)	Total n (%)
BASELINE	73	15 (33.3)	26 (57.8)	3 (6.7)	1 (2.2)	45 (100)
Low Dose	30	10 (52.6)	8 (42.1)	0	1 (5.3)	19 (100)
High Dose	43	5 (19.2)	18 (69.2)	3 (11.5)	0	26 (100)
WEEK 12	56	13 (30.2)	24 (55.8)	4 (9.3)	2 (4.7)	43 (100)
Low Dose	27	9 (42.9)	10 (47.6)	1 (4.8)	1 (4.8)	21 (100)
High Dose	29	4 (18.2)	14 (63.6)	3 (13.6)	1 (4.5)	22 (100)
WEEK 24	68	11 (22.4)	36 (73.5)	2 (4.1)	0	49 (100)
Low Dose	26	5 (26.3)	14 (73.7)	0	0	19 (100)
High Dose	42	6 (20.0)	22 (73.3)	2 (6.7)	0	30 (100)
WEEK 36	38	4 (16.7)	17 (70.8)	2 (8.3)	1 (4.2)	24 (100)
Low Dose	19	2 (22.2)	7 (77.8)	0	0	9 (100)
High Dose	19	2 (13.3)	10 (66.7)	2 (13.3)	1 (6.7)	15 (100)
WEEK 48	28	6 (31.6)	12 (63.2)	1 (5.3)	0	19 (100)
Low Dose	11	1 (16.7)	4 (66.7)	1 (16.7)	0	6 (100)
High Dose	17	5 (38.5)	8 (61.5)	0	0	13 (100)
WEEK 60	7	1 (33.3)	2 (66.7)	0	0	3 (100)
Low Dose	2	0	1 (100)	0	0	1 (100)
High Dose	5	1 (50.0)	1 (50.0)	0	0	2 (100)
WEEK 72	3	1 (50.0)	1 (50.0)	0	0	2 (100)
Low Dose	1	0	1 (100)	0	0	1 (100)
High Dose	2	1 (100)	0	0	0	1 (100)

Program Source Code: [redacted]

表22　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__1.4.J

Distribution of Early Morning First Non-Sleep Symptom in PD Diary
(FAS - Japan Subjects)

	N	Off n (%)	On without Dyskinesia n (%)	On with Non-Troublesome Dyskinesia n (%)	On with Troublesome Dyskinesia n (%)	Total n (%)
BASELINE	7	5 (100)	0	0	0	5 (100)
Low Dose	4	3 (100)	0	0	0	3 (100)
High Dose	3	2 (100)	0	0	0	2 (100)
WEEK 12	7	4 (80.0)	1 (20.0)	0	0	5 (100)
Low Dose	4	3 (100)	0	0	0	3 (100)
High Dose	3	1 (50.0)	1 (50.0)	0	0	2 (100)
WEEK 24	5	3 (75.0)	1 (25.0)	0	0	4 (100)
Low Dose	2	1 (100)	0	0	0	1 (100)
High Dose	3	2 (66.7)	1 (33.3)	0	0	3 (100)
WEEK 36	5	1 (33.3)	2 (66.7)	0	0	3 (100)
Low Dose	2	1 (100)	0	0	0	1 (100)
High Dose	3	0	2 (100)	0	0	2 (100)
WEEK 48	4	0	1 (100)	0	0	1 (100)
Low Dose	1	0	0	0	0	0
High Dose	3	0	1 (100)	0	0	1 (100)
WEEK 60	1	1 (100)	0	0	0	1 (100)
Low Dose	0	0	0	0	0	0
High Dose	1	1 (100)	0	0	0	1 (100)

Program Source Code: [redacted]

表23　MDS-UPDRSスコア（FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part I Score									
BASELINE	81		11.1 (6.25)	11.0	2, 27				
Low dose	33		11.2 (6.28)	11.0	2, 27				
High dose	48		11.1 (6.31)	11.0	2, 25				
WEEK 24	73	10.5	10.8 (6.17)	10.0	0, 26	0.4 (4.33)	1.0	-11, 12	0.4680
Low dose	28	10.5	10.7 (6.52)	11.5	0, 26	0.2 (4.36)	0.5	-8, 8	0.8299
High dose	45	10.5	11.0 (6.01)	10.0	1, 23	0.5 (4.36)	1.0	-11, 12	0.4562
WEEK 48	29	10.3	10.8 (5.08)	10.0	4, 23	0.5 (3.85)	1.0	-9, 8	0.5052
Low dose	11	9.5	9.9 (5.80)	8.0	4, 23	0.4 (3.41)	1.0	-6, 8	0.7312
High dose	18	10.7	11.3 (4.68)	10.5	4, 20	0.6 (4.19)	1.0	-9, 8	0.5811
WEEK 72	3	6.7	9.7 (9.07)	6.0	3, 20	3.0 (5.20)	0.0	0, 9	0.4226
Low dose	1	6.0	6.0 (N/A)	6.0	6, 6	0.0 (N/A)	0.0	0, 0	
High dose	2	7.0	11.5 (12.02)	11.5	3, 20	4.5 (6.36)	4.5	0, 9	0.5000
MDS-UPDRS Part II Score									
BASELINE	81		11.9 (7.18)	12.0	1, 29				
Low dose	33		11.4 (8.02)	10.0	1, 26				
High dose	48		12.3 (6.60)	12.0	1, 29				
WEEK 24	73	11.9	12.8 (8.17)	12.0	0, 38	0.9 (4.41)	0.0	-9, 15	0.0889
Low dose	28	11.1	11.6 (8.44)	10.0	0, 32	0.5 (4.95)	0.5	-9, 11	0.5972
High dose	45	12.3	13.4 (8.02)	13.0	2, 38	1.1 (4.08)	0.0	-7, 15	0.0692

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total (FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part II Score									
WEEK 48	29	9.4	11.1 (6.39)	11.0	1, 25	1.8 (4.43)	1.0	-4, 14	0.0414*
Low dose	11	5.5	7.0 (4.10)	6.0	1, 15	1.5 (3.93)	2.0	-4, 9	0.2218
High dose	18	11.8	13.7 (6.29)	13.5	3, 25	1.9 (4.81)	1.0	-4, 14	0.1142
WEEK 72	3	8.3	9.7 (9.81)	4.0	4, 21	1.3 (1.53)	1.0	0, 3	0.2697
Low dose	1	4.0	4.0 (N/A)	4.0	4, 4	0.0 (N/A)	0.0	0, 0	
High dose	2	10.5	12.5 (12.02)	12.5	4, 21	2.0 (1.41)	2.0	1, 3	0.2952
MDS-UPDRS Part III Score									
BASELINE	81		23.2 (13.89)	21.0	1, 62				
Low dose	33		20.5 (13.51)	19.0	1, 58				
High dose	48		25.1 (13.99)	23.0	2, 62				
WEEK 24	69	23.5	25.0 (16.31)	24.0	0, 92	1.5 (9.73)	1.0	-21, 40	0.2048
Low dose	27	19.0	23.3 (14.65)	23.0	0, 58	4.2 (7.35)	3.0	-6, 22	0.0061**
High dose	42	26.3	26.1 (17.37)	24.5	0, 92	-0.3 (10.71)	-0.5	-21, 40	0.8798
WEEK 48	24	21.1	21.2 (13.92)	22.0	0, 45	0.1 (8.48)	0.0	-16, 16	0.9620
Low dose	9	16.0	20.2 (14.32)	17.0	0, 40	4.2 (8.61)	3.0	-9, 16	0.1796
High dose	15	24.2	21.8 (14.14)	23.0	2, 45	-2.4 (7.63)	-1.0	-16, 13	0.2434
WEEK 72	3	7.7	10.0 (13.05)	4.1	1, 25	2.4 (4.51)	2.1	-2, 7	0.4576
Low dose	1	3.0	1.0 (N/A)	1.0	1, 1	-2.0 (N/A)	-2.0	-2, -2	
High dose	2	10.0	14.6 (14.76)	14.6	4, 25	4.6 (3.45)	4.6	2, 7	0.3124

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total (FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part IV Score									
BASELINE	81		5.1 (3.91)	5.0	0, 17				
Low dose	33		5.3 (4.03)	5.0	0, 16				
High dose	48		5.0 (3.86)	4.5	0, 17				
WEEK 24	73	4.6	5.4 (3.95)	6.0	0, 18	0.8 (3.26)	0.0	-10, 14	0.0410*
Low dose	28	4.4	4.7 (3.45)	5.0	0, 13	0.3 (1.60)	0.0	-3, 4	0.4160
High dose	45	4.8	5.9 (4.20)	6.0	0, 18	1.1 (3.94)	0.0	-10, 14	0.0601
WEEK 48	29	4.6	5.2 (3.96)	5.0	0, 13	0.6 (3.66)	0.0	-11, 8	0.3957
Low dose	11	4.1	4.8 (4.35)	5.0	0, 12	0.7 (3.32)	0.0	-3, 8	0.4841
High dose	18	4.9	5.4 (3.82)	5.5	0, 13	0.5 (3.94)	1.0	-11, 6	0.5977
WEEK 72	3	2.7	4.0 (1.00)	4.0	3, 5	1.3 (0.58)	1.0	1, 2	0.0572
Low dose	1	2.0	3.0 (N/A)	3.0	3, 3	1.0 (N/A)	1.0	1, 1	
High dose	2	3.0	4.5 (0.71)	4.5	4, 5	1.5 (0.71)	1.5	1, 2	0.2048
MDS-UPDRS Total Score of Parts I-III									
BASELINE	81		46.2 (22.33)	45.0	6, 105				
Low dose	33		43.1 (22.55)	38.0	8, 94				
High dose	48		48.4 (22.15)	47.0	6, 105				
WEEK 24	69	45.7	48.4 (26.98)	46.0	1, 148	2.7 (13.68)	2.0	-24, 64	0.1098
Low dose	27	40.1	45.2 (25.09)	39.0	1, 105	5.0 (11.23)	6.0	-12, 39	0.0283*
High dose	42	49.3	50.5 (28.23)	46.5	7, 148	1.2 (14.98)	0.5	-24, 64	0.6197

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Total Score of Parts I-III									
WEEK 48	24	41.1	43.0 (20.51)	42.5	11, 77	1.9 (11.40)	3.0	-23, 21	0.4187
Low dose	9	31.4	37.3 (20.61)	40.0	11, 72	5.9 (11.20)	4.0	-12, 20	0.1532
High dose	15	46.9	46.5 (20.37)	49.0	13, 77	-0.5 (11.21)	1.0	-23, 21	0.8742
WEEK 72	3	22.7	29.4 (31.70)	11.2	11, 66	6.7 (9.59)	5.2	-2, 17	0.3483
Low dose	1	13.0	11.0 (N/A)	11.0	11, 11	-2.0 (N/A)	-2.0	-2, -2	
High dose	2	27.5	38.6 (38.76)	38.6	11, 66	11.1 (8.35)	11.1	5, 17	0.3114

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表24　MDS-UPDRSスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part I Score									
BASELINE	7		7.4 (3.64)	6.0	3, 14				
Low dose	4		8.8 (4.11)	8.0	5, 14				
High dose	3		5.7 (2.52)	6.0	3, 8				
WEEK 24	5	7.4	10.0 (6.40)	7.0	5, 21	2.6 (2.51)	2.0	1, 7	0.0815
Low dose	2	10.0	14.0 (9.90)	14.0	7, 21	4.0 (4.24)	4.0	1, 7	0.4097
High dose	3	5.7	7.3 (2.52)	7.0	5, 10	1.7 (0.58)	2.0	1, 2	0.0377*
WEEK 48	4	5.8	7.3 (2.75)	7.5	4, 10	1.5 (1.29)	1.5	0, 3	0.1027
Low dose	1	6.0	6.0 (N/A)	6.0	6, 6	0.0 (N/A)	0.0	0, 0	
High dose	3	5.7	7.7 (3.21)	9.0	4, 10	2.0 (1.00)	2.0	1, 3	0.0742
MDS-UPDRS Part II Score									
BASELINE	7		12.4 (7.14)	9.0	5, 22				
Low dose	4		14.0 (8.76)	14.5	5, 22				
High dose	3		10.3 (5.13)	9.0	6, 16				
WEEK 24	5	11.6	15.4 (10.36)	11.0	5, 32	3.8 (4.27)	2.0	-1, 10	0.1172
Low dose	2	13.5	21.5 (14.85)	21.5	11, 32	8.0 (2.83)	8.0	6, 10	0.1560
High dose	3	10.3	11.3 (6.51)	11.0	5, 18	1.0 (1.73)	2.0	-1, 2	0.4226
WEEK 48	4	9.0	11.5 (6.14)	11.5	4, 19	2.5 (3.70)	2.5	-2, 7	0.2691
Low dose	1	5.0	12.0 (N/A)	12.0	12, 12	7.0 (N/A)	7.0	7, 7	
High dose	3	10.3	11.3 (7.51)	11.0	4, 19	1.0 (2.65)	2.0	-2, 3	0.5799

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Part III Score									
BASELINE	7		22.0 (17.56)	30.0	1, 47				
Low dose	4		17.8 (16.66)	18.0	1, 34				
High dose	3		27.7 (20.60)	30.0	6, 47				
WEEK 24	5	23.8	28.0 (20.74)	30.0	6, 52	4.2 (10.11)	0.0	-3, 22	0.4055
Low dose	2	18.0	30.0 (31.11)	30.0	8, 52	12.0 (14.14)	12.0	2, 22	0.4423
High dose	3	27.7	26.7 (19.22)	30.0	6, 44	-1.0 (1.73)	0.0	-3, 0	0.4226
WEEK 48	4	22.3	22.3 (18.71)	19.5	5, 45	0.0 (2.16)	-0.5	-2, 3	>0.999
Low dose	1	6.0	9.0 (N/A)	9.0	9, 9	3.0 (N/A)	3.0	3, 3	
High dose	3	27.7	26.7 (20.21)	30.0	5, 45	-1.0 (1.00)	-1.0	-2, 0	0.2254
MDS-UPDRS Part IV Score									
BASELINE	7		5.9 (2.19)	6.0	2, 8				
Low dose	4		6.8 (0.96)	6.5	6, 8				
High dose	3		4.7 (3.06)	4.0	2, 8				
WEEK 24	5	5.6	5.6 (2.61)	6.0	2, 8	0.0 (0.00)	0.0	0, 0	
Low dose	2	7.0	7.0 (1.41)	7.0	6, 8	0.0 (0.00)	0.0	0, 0	
High dose	3	4.7	4.7 (3.06)	4.0	2, 8	0.0 (0.00)	0.0	0, 0	
WEEK 48	4	5.5	6.0 (2.94)	6.0	3, 9	0.5 (0.58)	0.5	0, 1	0.1817
Low dose	1	8.0	8.0 (N/A)	8.0	8, 8	0.0 (N/A)	0.0	0, 0	
High dose	3	4.7	5.3 (3.21)	4.0	3, 9	0.7 (0.58)	1.0	0, 1	0.1835

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 2.1.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed
by The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score by Part and Total
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Total Score of Parts I-III									
BASELINE	7		41.9 (22.00)	45.0	15, 71				
Low dose	4		40.5 (20.95)	39.5	17, 66				
High dose	3		43.7 (28.02)	45.0	15, 71				
WEEK 24	5	42.8	53.4 (36.01)	48.0	16, 105	10.6 (16.21)	3.0	1, 39	0.2175
Low dose	2	41.5	65.5 (55.86)	65.5	26, 105	24.0 (21.21)	24.0	9, 39	0.3556
High dose	3	43.7	45.3 (28.10)	48.0	16, 72	1.7 (1.15)	1.0	1, 3	0.1296
WEEK 48	4	37.0	41.0 (26.77)	38.5	13, 74	4.0 (4.97)	4.0	-2, 10	0.2056
Low dose	1	17.0	27.0 (N/A)	27.0	27, 27	10.0 (N/A)	10.0	10, 10	
High dose	3	43.7	45.7 (30.73)	50.0	13, 74	2.0 (3.61)	3.0	-2, 5	0.4380

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表25　MDS-UPDRSスコア（Hoehn-Yahr 重症度分類，FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__2.2

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by
The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score Hoehn and Yahr Stage
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Hoehn and Yahr Stage									
BASELINE	81		2.0 (0.53)	2.0	0, 3				
Low dose	33		2.0 (0.50)	2.0	0, 3				
High dose	48		2.1 (0.56)	2.0	0, 3				
WEEK 24	70	2.0	2.0 (0.85)	2.0	0, 5	0.0 (0.67)	0.0	-2, 2	0.8590
Low dose	27	1.9	2.1 (0.80)	2.0	0, 4	0.2 (0.62)	0.0	-1, 2	0.1342
High dose	43	2.1	2.0 (0.89)	2.0	0, 5	-0.1 (0.68)	0.0	-2, 2	0.3773
WEEK 48	24	1.9	2.0 (0.69)	2.0	0, 3	0.0 (0.36)	0.0	-1, 1	0.5748
Low dose	9	1.8	1.9 (0.78)	2.0	0, 3	0.1 (0.33)	0.0	0, 1	0.3466
High dose	15	2.0	2.0 (0.65)	2.0	0, 3	0.0 (0.38)	0.0	-1, 1	>0.999
WEEK 72	3	0.7	1.0 (1.00)	1.0	0, 2	0.3 (0.58)	0.0	0, 1	0.4226
Low dose	1	0.0	0.0 (N/A)	0.0	0, 0	0.0 (N/A)	0.0	0, 0	
High dose	2	1.0	1.5 (0.71)	1.5	1, 2	0.5 (0.71)	0.5	0, 1	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.

Program Source Code: [redacted]

表26　MDS-UPDRSスコア（Hoehn-Yahr 重症度分類，FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__2.2.J

Change from Baseline to Each Planned Visit in Parkinson's Disease Symptoms as Assessed by
The Movement Disorder Society-Unified Parkinson's Disease Rating Scale Score Hoehn and Yahr Stage
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
MDS-UPDRS Hoehn and Yahr Stage									
BASELINE	7		2.4 (0.53)	2.0	2, 3				
Low dose	4		2.5 (0.58)	2.5	2, 3				
High dose	3		2.3 (0.58)	2.0	2, 3				
WEEK 24	5	2.4	2.6 (0.89)	2.0	2, 4	0.2 (0.45)	0.0	0, 1	0.3739
Low dose	2	2.5	3.0 (1.41)	3.0	2, 4	0.5 (0.71)	0.5	0, 1	0.5000
High dose	3	2.3	2.3 (0.58)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	
WEEK 48	4	2.3	2.3 (0.50)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	
Low dose	1	2.0	2.0 (N/A)	2.0	2, 2	0.0 (N/A)	0.0	0, 0	
High dose	3	2.3	2.3 (0.58)	2.0	2, 3	0.0 (0.00)	0.0	0, 0	

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

表27　PDQ-39スコア（FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Bodily Discomfort Domain Score									
BASELINE	81		29.5 (24.12)	25.0	0.0, 91.7				
Low dose	33		27.8 (23.91)	25.0	0.0, 75.0				
High dose	48		30.7 (24.44)	25.0	0.0, 91.7				
WEEK 24	73	27.7	29.5 (23.90)	25.0	0.0, 91.7	1.7 (17.68)	0.0	-41.7, 41.7	0.4106
Low dose	28	25.0	25.0 (21.99)	25.0	0.0, 75.0	-0.0 (20.91)	0.0	-41.7, 41.7	>0.999
High dose	45	29.4	32.2 (24.85)	25.0	0.0, 91.7	2.8 (15.49)	0.0	-41.7, 41.7	0.2354
WEEK 48	29	27.0	35.3 (22.57)	33.3	0.0, 83.3	8.3 (19.92)	8.3	-25.0, 41.7	0.0323*
Low dose	11	17.4	28.0 (16.78)	33.3	8.3, 58.3	10.6 (21.44)	8.3	-16.7, 41.7	0.1319
High dose	18	32.9	39.8 (24.85)	37.5	0.0, 83.3	6.9 (19.44)	8.3	-25.0, 41.7	0.1480
WEEK 72	3	19.4	22.2 (12.73)	25.0	8.3, 33.3	2.8 (4.81)	0.0	0.0, 8.3	0.4226
Low dose	1	25.0	25.0 (N/A)	25.0	25.0, 25.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	16.7	20.8 (17.68)	20.8	8.3, 33.3	4.2 (5.89)	4.2	0.0, 8.3	0.5000
PDQ-Communication Domain Score									
BASELINE	81		27.4 (21.82)	25.0	0.0, 83.3				
Low dose	33		23.0 (21.85)	16.7	0.0, 75.0				
High dose	48		30.4 (21.50)	25.0	0.0, 83.3				
WEEK 24	73	26.3	25.6 (23.91)	16.7	0.0, 83.3	-0.7 (17.83)	0.0	-41.7, 50.0	0.7437
Low dose	28	21.4	18.2 (19.25)	12.5	0.0, 66.7	-3.3 (11.42)	0.0	-41.7, 16.7	0.1408
High dose	45	29.3	30.2 (25.52)	16.7	0.0, 83.3	0.9 (20.81)	0.0	-41.7, 50.0	0.7668

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Communication Domain Score									
WEEK 48	29	23.9	26.7 (26.85)	16.7	0.0, 100.0	2.9 (16.71)	0.0	-33.3, 41.7	0.3623
Low dose	11	9.8	12.9 (19.49)	8.3	0.0, 58.3	3.0 (13.06)	0.0	-8.3, 33.3	0.4592
High dose	18	32.4	35.2 (27.65)	33.3	0.0, 100.0	2.8 (18.96)	0.0	-33.3, 41.7	0.5425
WEEK 72	3	27.8	25.0 (30.05)	16.7	0.0, 58.3	-2.8 (4.81)	0.0	-8.3, 0.0	0.4226
Low dose	1	16.7	16.7 (N/A)	16.7	16.7, 16.7	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	33.3	29.2 (41.25)	29.2	0.0, 58.3	-4.2 (5.89)	-4.2	-8.3, 0.0	0.5000
PDQ-Social Support Domain Score									
BASELINE	73		12.6 (18.59)	0.0	0.0, 75.0				
Low dose	29		13.8 (20.93)	0.0	0.0, 75.0				
High dose	44		11.7 (17.08)	0.0	0.0, 66.7				
WEEK 24	66	12.1	13.4 (19.00)	4.2	0.0, 75.0	1.3 (19.07)	0.0	-58.3, 50.0	0.5925
Low dose	25	13.7	14.3 (19.91)	0.0	0.0, 58.3	0.7 (18.15)	0.0	-41.7, 50.0	0.8558
High dose	41	11.2	12.8 (18.64)	8.3	0.0, 75.0	1.6 (19.83)	0.0	-58.3, 50.0	0.6024
WEEK 48	25	7.3	7.7 (11.52)	0.0	0.0, 33.3	0.3 (8.83)	0.0	-16.7, 25.0	0.8519
Low dose	9	3.7	1.9 (5.56)	0.0	0.0, 16.7	-1.9 (9.11)	0.0	-16.7, 16.7	0.5588
High dose	16	9.4	10.9 (12.81)	8.3	0.0, 33.3	1.6 (8.72)	0.0	-16.7, 25.0	0.4847
WEEK 72	3	0.0	2.8 (4.81)	0.0	0.0, 8.3	2.8 (4.81)	0.0	0.0, 8.3	0.4226
Low dose	1	0.0	0.0 (N/A)	0.0	0.0, 0.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	0.0	4.2 (5.89)	4.2	0.0, 8.3	4.2 (5.89)	4.2	0.0, 8.3	0.5000

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Cognition Domain Score									
BASELINE	81		26.9 (19.22)	25.0	0.0, 81.3				
Low dose	33		24.2 (18.47)	18.8	0.0, 62.5				
High dose	48		28.6 (19.72)	25.0	0.0, 81.3				
WEEK 24	73	25.3	27.1 (22.44)	25.0	0.0, 87.5	1.8 (17.88)	0.0	-43.8, 68.8	0.3930
Low dose	28	22.1	25.4 (18.00)	25.0	0.0, 56.3	3.3 (11.72)	6.3	-25.0, 18.8	0.1423
High dose	45	27.4	28.2 (24.95)	18.8	0.0, 87.5	0.8 (20.88)	0.0	-43.8, 68.8	0.7902
WEEK 48	29	25.4	27.4 (16.65)	25.0	6.3, 75.0	1.9 (17.29)	6.3	-31.3, 31.3	0.5506
Low dose	11	19.3	26.7 (14.00)	25.0	12.5, 62.5	7.4 (18.71)	12.5	-25.0, 31.3	0.2198
High dose	18	29.2	27.8 (18.47)	25.0	6.3, 75.0	-1.4 (15.98)	0.0	-31.3, 31.3	0.7168
WEEK 72	3	29.2	31.3 (32.48)	12.5	12.5, 68.8	2.1 (9.55)	0.0	-6.3, 12.5	0.7418
Low dose	1	18.8	12.5 (N/A)	12.5	12.5, 12.5	-6.3 (N/A)	-6.3	-6.3, -6.3	
High dose	2	34.4	40.6 (39.77)	40.6	12.5, 68.8	6.3 (8.84)	6.3	0.0, 12.5	0.5000
PDQ-Stigma Domain Score									
BASELINE	81		14.1 (18.46)	6.3	0.0, 75.0				
Low dose	33		17.6 (18.65)	18.8	0.0, 56.3				
High dose	48		11.7 (18.12)	0.0	0.0, 75.0				
WEEK 24	73	12.3	13.5 (18.10)	6.3	0.0, 100.0	1.2 (14.12)	0.0	-43.8, 43.8	0.4705
Low dose	28	15.8	13.6 (15.78)	6.3	0.0, 50.0	-2.2 (14.15)	0.0	-43.8, 25.0	0.4113
High dose	45	10.1	13.5 (19.58)	0.0	0.0, 100.0	3.3 (13.82)	0.0	-25.0, 43.8	0.1129

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Stigma Domain Score									
WEEK 48	29	11.2	12.9 (19.97)	6.3	0.0, 87.5	1.7 (15.93)	0.0	-31.3, 43.8	0.5645
Low dose	11	7.4	8.0 (10.86)	0.0	0.0, 31.3	0.6 (16.17)	0.0	-31.3, 18.8	0.9095
High dose	18	13.5	16.0 (23.70)	6.3	0.0, 87.5	2.4 (16.20)	0.0	-25.0, 43.8	0.5330
WEEK 72	3	10.4	0.0 (0.00)	0.0	0.0, 0.0	-10.4 (18.04)	0.0	-31.3, 0.0	0.4226
Low dose	1	31.3	0.0 (N/A)	0.0	0.0, 0.0	-31.3 (N/A)	-31.3	-31.3, -31.3	
High dose	2	0.0	0.0 (0.00)	0.0	0.0, 0.0	0.0 (0.00)	0.0	0.0, 0.0	
PDQ-Activities of Daily Living Domain Score									
BASELINE	81		30.1 (22.30)	25.0	0.0, 87.5				
Low dose	33		30.3 (24.03)	20.8	0.0, 87.5				
High dose	48		30.0 (21.28)	25.0	0.0, 87.5				
WEEK 24	73	29.5	31.2 (23.53)	25.0	0.0, 100.0	1.7 (16.69)	0.0	-29.2, 62.5	0.3997
Low dose	28	27.7	27.4 (21.80)	20.8	0.0, 75.0	-0.3 (15.13)	0.0	-29.2, 45.8	0.9179
High dose	45	30.6	33.5 (24.49)	29.2	0.0, 100.0	2.9 (17.65)	0.0	-29.2, 62.5	0.2813
WEEK 48	29	23.7	28.4 (23.86)	20.8	0.0, 100.0	4.7 (13.26)	4.2	-25.0, 29.2	0.0643
Low dose	11	12.1	15.5 (14.68)	12.5	0.0, 41.7	3.4 (13.54)	0.0	-20.8, 29.2	0.4233
High dose	18	30.8	36.3 (25.24)	31.3	4.2, 100.0	5.6 (13.41)	4.2	-25.0, 29.2	0.0967
WEEK 72	3	15.3	29.2 (36.08)	8.3	8.3, 70.8	13.9 (13.39)	8.3	4.2, 29.2	0.2143
Low dose	1	0.0	8.3 (N/A)	8.3	8.3, 8.3	8.3 (N/A)	8.3	8.3, 8.3	
High dose	2	22.9	39.6 (44.19)	39.6	8.3, 70.8	16.7 (17.68)	16.7	4.2, 29.2	0.4097

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
PDQ-Emotional Well-being Domain Score									
BASELINE	81		25.1 (19.68)	20.8	0.0, 79.2				
Low dose	33		25.3 (19.09)	20.8	0.0, 62.5				
High dose	48		25.0 (20.27)	20.8	0.0, 79.2				
WEEK 24	73	23.6	26.4 (19.64)	20.8	0.0, 75.0	2.8 (15.90)	4.2	-37.5, 45.8	0.1372
Low dose	28	23.7	25.7 (21.84)	20.8	0.0, 70.8	2.1 (13.63)	0.0	-20.8, 33.3	0.4258
High dose	45	23.5	26.8 (18.39)	25.0	0.0, 75.0	3.2 (17.29)	4.2	-37.5, 45.8	0.2153
WEEK 48	29	23.6	26.3 (21.62)	20.8	0.0, 79.2	2.7 (10.52)	4.2	-16.7, 20.8	0.1733
Low dose	11	13.6	14.8 (17.12)	12.5	0.0, 58.3	1.1 (10.05)	0.0	-12.5, 20.8	0.7155
High dose	18	29.6	33.3 (21.44)	29.2	0.0, 79.2	3.7 (10.97)	6.3	-16.7, 16.7	0.1701
WEEK 72	3	22.2	19.4 (15.77)	12.5	8.3, 37.5	-2.8 (6.36)	-4.2	-8.3, 4.2	0.5286
Low dose	1	20.8	12.5 (N/A)	12.5	12.5, 12.5	-8.3 (N/A)	-8.3	-8.3, -8.3	
High dose	2	22.9	22.9 (20.62)	22.9	8.3, 37.5	0.0 (5.89)	0.0	-4.2, 4.2	>0.999
PDQ-Mobility Domain Score									
BASELINE	81		32.6 (25.39)	27.5	0.0, 100.0				
Low dose	33		34.5 (28.01)	35.0	0.0, 92.5				
High dose	48		31.4 (23.64)	26.3	0.0, 100.0				
WEEK 24	73	30.7	35.8 (27.78)	32.5	0.0, 100.0	5.1 (19.77)	0.0	-30.0, 70.0	0.0318*
Low dose	28	29.9	32.4 (28.12)	23.8	0.0, 90.0	2.5 (19.38)	0.0	-27.5, 50.0	0.5006
High dose	45	31.2	37.9 (27.67)	32.5	0.0, 100.0	6.7 (20.06)	2.5	-30.0, 70.0	0.0310*

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Mobility Domain Score									
WEEK 48	29	23.8	31.9 (24.19)	22.5	0.0, 100.0	8.1 (13.41)	7.5	-17.5, 35.0	0.0030**
Low dose	11	9.3	19.5 (13.36)	17.5	0.0, 42.5	10.2 (10.92)	7.5	0.0, 35.0	0.0111*
High dose	18	32.6	39.4 (26.45)	32.5	5.0, 100.0	6.8 (14.87)	6.3	-17.5, 32.5	0.0690
WEEK 72	3	22.5	25.0 (33.07)	12.5	0.0, 62.5	2.5 (11.46)	0.0	-7.5, 15.0	0.7418
Low dose	1	12.5	12.5 (N/A)	12.5	12.5, 12.5	0.0 (N/A)	0.0	0.0, 0.0	
High dose	2	27.5	31.3 (44.19)	31.3	0.0, 62.5	3.8 (15.91)	3.8	-7.5, 15.0	0.7952
PDQ-Summary Index Total Score									
BASELINE	81		26.4 (17.15)	23.7	3.2, 76.9				
Low dose	33		26.6 (18.30)	21.8	3.2, 64.1				
High dose	48		26.2 (16.50)	24.0	3.2, 76.9				
WEEK 24	73	25.0	27.4 (17.15)	25.6	0.0, 76.3	2.5 (11.34)	0.6	-21.2, 35.9	0.0670
Low dose	28	24.0	24.9 (16.86)	20.8	0.0, 64.7	0.8 (10.04)	-1.9	-17.9, 22.4	0.6622
High dose	45	25.5	29.0 (17.33)	27.6	4.5, 76.3	3.5 (12.08)	1.9	-21.2, 35.9	0.0595
WEEK 48	29	21.6	26.1 (16.75)	23.0	3.8, 77.6	4.5 (8.95)	4.5	-14.7, 23.0	0.0110*
Low dose	11	11.5	16.7 (9.44)	14.1	3.8, 32.1	5.1 (9.62)	5.1	-7.1, 23.0	0.1066
High dose	18	27.8	31.9 (17.78)	31.1	9.6, 77.6	4.1 (8.78)	4.2	-14.7, 18.6	0.0613
WEEK 72	3	19.2	20.9 (23.17)	10.9	4.5, 47.4	1.7 (7.03)	-0.6	-3.8, 9.6	0.7146
Low dose	1	14.7	10.9 (N/A)	10.9	10.9, 10.9	-3.8 (N/A)	-3.8	-3.8, -3.8	
High dose	2	21.5	26.0 (30.37)	26.0	4.5, 47.4	4.5 (7.25)	4.5	-0.6, 9.6	0.5424

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表28　EQ-5D-5Lスコア（FAS）：M15-737試験

[redacted]20[redacted] 07:19 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed
by EQ-5D-5L
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	Change from Baseline P-Value &
EQ-5D-5L Mobility									
BASELINE	81		2.0 (0.97)	2.0	1.0, 5.0				
Low dose	33		2.0 (1.02)	2.0	1.0, 4.0				
High dose	48		1.9 (0.94)	2.0	1.0, 5.0				
WEEK 24	70	2.0	2.1 (1.08)	2.0	1.0, 5.0	0.1 (1.08)	0.0	-3.0, 3.0	0.5822
Low dose	27	2.0	2.1 (1.19)	2.0	1.0, 5.0	0.1 (1.05)	0.0	-2.0, 3.0	0.5871
High dose	43	2.0	2.0 (1.02)	2.0	1.0, 4.0	0.0 (1.11)	0.0	-3.0, 2.0	0.7852
WEEK 48	24	1.7	2.1 (1.06)	2.0	1.0, 5.0	0.4 (0.77)	0.0	-1.0, 2.0	0.0256*
Low dose	9	1.4	2.0 (1.00)	2.0	1.0, 4.0	0.6 (0.88)	1.0	-1.0, 2.0	0.0955
High dose	15	1.9	2.1 (1.13)	2.0	1.0, 5.0	0.3 (0.70)	0.0	-1.0, 2.0	0.1643
WEEK 72	2	2.0	2.5 (0.71)	2.5	2.0, 3.0	0.5 (0.71)	0.5	0.0, 1.0	0.5000
Low dose	1	2.0	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	1	2.0	3.0 (N/A)	3.0	3.0, 3.0	1.0 (N/A)	1.0	1.0, 1.0	
EQ-5D-5L Self-care									
BASELINE	81		1.7 (0.81)	1.0	1.0, 4.0				
Low dose	33		1.7 (0.69)	2.0	1.0, 3.0				
High dose	48		1.7 (0.88)	1.0	1.0, 4.0				
WEEK 24	70	1.7	1.8 (0.80)	2.0	1.0, 4.0	0.1 (0.74)	0.0	-2.0, 2.0	0.1509
Low dose	27	1.7	1.7 (0.76)	2.0	1.0, 3.0	0.1 (0.62)	0.0	-1.0, 1.0	0.5372
High dose	43	1.7	1.9 (0.83)	2.0	1.0, 4.0	0.2 (0.81)	0.0	-2.0, 2.0	0.1971

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Self-care									
WEEK 48	24	1.6	1.9 (1.08)	2.0	1.0, 5.0	0.3 (0.79)	0.0	-1.0, 2.0	0.1366
Low dose	9	1.4	1.8 (0.83)	2.0	1.0, 3.0	0.3 (0.87)	0.0	-1.0, 2.0	0.2815
High dose	15	1.7	1.9 (1.22)	2.0	1.0, 5.0	0.2 (0.77)	0.0	-1.0, 2.0	0.3343
WEEK 72	2	1.0	2.5 (0.71)	2.5	2.0, 3.0	1.5 (0.71)	1.5	1.0, 2.0	0.2048
Low dose	1	1.0	2.0 (N/A)	2.0	2.0, 2.0	1.0 (N/A)	1.0	1.0, 1.0	
High dose	1	1.0	3.0 (N/A)	3.0	3.0, 3.0	2.0 (N/A)	2.0	2.0, 2.0	
EQ-5D-5L Usual Activities									
BASELINE	81		2.1 (0.95)	2.0	1.0, 5.0				
Low dose	33		2.2 (0.95)	2.0	1.0, 4.0				
High dose	48		2.0 (0.95)	2.0	1.0, 5.0				
WEEK 24	70	2.0	2.2 (0.97)	2.0	1.0, 4.0	0.2 (0.93)	0.0	-2.0, 2.0	0.1605
Low dose	27	2.0	2.0 (0.90)	2.0	1.0, 4.0	0.0 (0.83)	0.0	-2.0, 2.0	>0.999
High dose	43	2.0	2.3 (1.01)	2.0	1.0, 4.0	0.3 (0.98)	0.0	-2.0, 2.0	0.0937
WEEK 48	24	1.9	2.1 (0.97)	2.0	1.0, 4.0	0.2 (0.88)	0.0	-1.0, 2.0	0.2599
Low dose	9	1.7	2.0 (0.87)	2.0	1.0, 4.0	0.3 (0.71)	0.0	-1.0, 1.0	0.1950
High dose	15	2.0	2.1 (1.06)	2.0	1.0, 4.0	0.1 (0.99)	0.0	-1.0, 2.0	0.6102
WEEK 72	2	1.5	3.5 (2.12)	3.5	2.0, 5.0	2.0 (2.83)	2.0	0.0, 4.0	0.5000
Low dose	1	2.0	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	1	1.0	5.0 (N/A)	5.0	5.0, 5.0	4.0 (N/A)	4.0	4.0, 4.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Pain/Discomfort									
BASELINE	81		1.9 (0.90)	2.0	1.0, 5.0				
Low dose	33		1.9 (1.00)	2.0	1.0, 5.0				
High dose	48		1.8 (0.83)	2.0	1.0, 4.0				
WEEK 24	70	1.8	1.9 (0.92)	2.0	1.0, 4.0	0.1 (0.78)	0.0	-2.0, 2.0	0.2890
Low dose	27	1.7	1.9 (0.91)	2.0	1.0, 4.0	0.1 (0.72)	0.0	-1.0, 2.0	0.2936
High dose	43	1.9	1.9 (0.94)	2.0	1.0, 4.0	0.1 (0.83)	0.0	-2.0, 2.0	0.5835
WEEK 48	24	1.8	2.1 (1.14)	2.0	1.0, 5.0	0.3 (0.82)	0.0	-1.0, 3.0	0.0574
Low dose	9	1.4	2.1 (1.36)	2.0	1.0, 5.0	0.7 (1.00)	0.0	0.0, 3.0	0.0805
High dose	15	1.9	2.1 (1.03)	2.0	1.0, 4.0	0.1 (0.64)	0.0	-1.0, 1.0	0.4332
WEEK 72	2	1.5	1.5 (0.71)	1.5	1.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
Low dose	1	2.0	2.0 (N/A)	2.0	2.0, 2.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
EQ-5D-5L Anxiety/Depression									
BASELINE	81		1.7 (0.70)	2.0	1.0, 4.0				
Low dose	33		1.7 (0.77)	2.0	1.0, 4.0				
High dose	48		1.7 (0.66)	2.0	1.0, 3.0				
WEEK 24	70	1.6	1.7 (0.90)	2.0	1.0, 4.0	0.1 (0.80)	0.0	-1.0, 3.0	0.1415
Low dose	27	1.6	1.8 (1.04)	1.0	1.0, 4.0	0.3 (0.86)	0.0	-1.0, 2.0	0.1289
High dose	43	1.6	1.7 (0.80)	2.0	1.0, 4.0	0.1 (0.77)	0.0	-1.0, 3.0	0.5547

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Anxiety/Depression									
WEEK 48	24	1.5	1.6 (0.92)	1.0	1.0, 4.0	0.1 (0.80)	0.0	-2.0, 2.0	0.4503
Low dose	9	1.1	1.6 (1.01)	1.0	1.0, 4.0	0.4 (0.73)	0.0	0.0, 2.0	0.1038
High dose	15	1.7	1.7 (0.90)	1.0	1.0, 4.0	-0.1 (0.80)	0.0	-2.0, 1.0	0.7513
WEEK 72	2	1.0	2.0 (1.41)	2.0	1.0, 3.0	1.0 (1.41)	1.0	0.0, 2.0	0.5000
Low dose	1	1.0	1.0 (N/A)	1.0	1.0, 1.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	1	1.0	3.0 (N/A)	3.0	3.0, 3.0	2.0 (N/A)	2.0	2.0, 2.0	
EQ-5D-5L VAS									
BASELINE	81		73.4 (14.67)	75.0	35.0, 100.0				
Low dose	33		73.2 (14.24)	75.0	35.0, 95.0				
High dose	48		73.6 (15.10)	75.0	38.0, 100.0				
WEEK 24	70	73.4	74.4 (14.60)	79.0	31.0, 99.0	1.0 (15.12)	0.0	-31.0, 45.0	0.5764
Low dose	27	74.7	72.9 (13.79)	72.0	48.0, 94.0	-1.8 (11.83)	-2.0	-30.0, 24.0	0.4326
High dose	43	72.6	75.4 (15.17)	79.0	31.0, 99.0	2.8 (16.75)	1.0	-31.0, 45.0	0.2807
WEEK 48	24	73.3	71.1 (15.27)	72.0	37.0, 92.0	-2.1 (16.61)	-5.0	-34.0, 40.0	0.5371
Low dose	9	82.6	72.3 (20.34)	78.0	37.0, 90.0	-10.2 (13.97)	-5.0	-34.0, 6.0	0.0595
High dose	15	67.7	70.4 (12.05)	70.0	53.0, 92.0	2.7 (16.57)	-2.0	-17.0, 40.0	0.5332
WEEK 72	2	81.5	60.5 (28.99)	60.5	40.0, 81.0	-21.0 (19.80)	-21.0	-35.0, -7.0	0.3743
Low dose	1	88.0	81.0 (N/A)	81.0	81.0, 81.0	-7.0 (N/A)	-7.0	-7.0, -7.0	
High dose	1	75.0	40.0 (N/A)	40.0	40.0, 40.0	-35.0 (N/A)	-35.0	-35.0, -35.0	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

TABLE 14.2 4

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed by EQ-5D-5L
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Summary Index - Based on USA									
BASELINE	81		0.765 (0.1472)	0.778	0.126, 1.000				
Low dose	33		0.752 (0.1493)	0.783	0.306, 1.000				
High dose	48		0.774 (0.1467)	0.766	0.126, 1.000				
WEEK 24	70	0.770	0.746 (0.1627)	0.778	0.343, 1.000	-0.025 (0.1218)	-0.005	-0.480, 0.241	0.0943
Low dose	27	0.772	0.741 (0.1812)	0.792	0.343, 1.000	-0.031 (0.1218)	0.000	-0.480, 0.161	0.1955
High dose	43	0.769	0.749 (0.1521)	0.765	0.367, 1.000	-0.021 (0.1231)	-0.032	-0.347, 0.241	0.2774
WEEK 48	24	0.792	0.724 (0.2080)	0.794	0.111, 1.000	-0.068 (0.1264)	-0.025	-0.520, 0.086	0.0152*
Low dose	9	0.860	0.742 (0.2173)	0.823	0.228, 1.000	-0.118 (0.1720)	-0.079	-0.520, 0.029	0.0745
High dose	15	0.751	0.713 (0.2093)	0.792	0.111, 0.888	-0.038 (0.0823)	-0.015	-0.201, 0.086	0.0976
WEEK 72	2	0.842	0.631 (0.1513)	0.631	0.524, 0.738	-0.211 (0.2058)	-0.211	-0.356, -0.065	0.3850
Low dose	1	0.803	0.738 (N/A)	0.738	0.738, 0.738	-0.065 (N/A)	-0.065	-0.065, -0.065	
High dose	1	0.880	0.524 (N/A)	0.524	0.524, 0.524	-0.356 (N/A)	-0.356	-0.356, -0.356	

&: P-value is obtained from two-sided paired-sample t-test.
N/A = Not Applicable.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]

表29　PDQ-39スコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Bodily Discomfort Domain Score									
BASELINE	7		21.4 (29.60)	8.3	0.0, 75.0				
Low dose	4		6.3 (7.98)	4.2	0.0, 16.7				
High dose	3		41.7 (38.19)	50.0	0.0, 75.0				
WEEK 24	5	26.7	20.0 (19.18)	25.0	0.0, 41.7	-6.7 (21.57)	0.0	-41.7, 16.7	0.5275
Low dose	2	4.2	12.5 (17.68)	12.5	0.0, 25.0	8.3 (11.79)	8.3	0.0, 16.7	0.5000
High dose	3	41.7	25.0 (22.05)	33.3	0.0, 41.7	-16.7 (22.05)	-8.3	-41.7, 0.0	0.3206
WEEK 48	4	31.3	33.3 (29.66)	29.2	8.3, 66.7	2.1 (7.98)	4.2	-8.3, 8.3	0.6376
Low dose	1	0.0	8.3 (N/A)	8.3	8.3, 8.3	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	41.7	41.7 (30.05)	50.0	8.3, 66.7	-0.0 (8.33)	0.0	-8.3, 8.3	>0.999
PDQ-Communication Domain Score									
BASELINE	7		29.8 (32.93)	25.0	0.0, 83.3				
Low dose	4		22.9 (31.46)	12.5	0.0, 66.7				
High dose	3		38.9 (39.38)	25.0	8.3, 83.3				
WEEK 24	5	36.7	23.3 (25.95)	16.7	0.0, 66.7	-13.3 (17.28)	-8.3	-41.7, 0.0	0.1596
Low dose	2	33.3	12.5 (17.68)	12.5	0.0, 25.0	-20.8 (29.46)	-20.8	-41.7, 0.0	0.5000
High dose	3	38.9	30.6 (31.55)	16.7	8.3, 66.7	-8.3 (8.33)	-8.3	-16.7, 0.0	0.2254
WEEK 48	4	29.2	27.1 (48.77)	4.2	0.0, 100.0	-2.1 (14.23)	-4.2	-16.7, 16.7	0.7888
Low dose	1	0.0	0.0 (N/A)	0.0	0.0, 0.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	38.9	36.1 (55.49)	8.3	0.0, 100.0	-2.8 (17.35)	-8.3	-16.7, 16.7	0.8075

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Social Support Domain Score									
BASELINE	7		7.1 (10.12)	0.0	0.0, 25.0				
Low dose	4		4.2 (8.33)	0.0	0.0, 16.7				
High dose	3		11.1 (12.73)	8.3	0.0, 25.0				
WEEK 24	5	10.0	26.7 (28.50)	25.0	0.0, 66.7	16.7 (17.68)	16.7	0.0, 41.7	0.1027
Low dose	2	8.3	20.8 (29.46)	20.8	0.0, 41.7	12.5 (17.68)	12.5	0.0, 25.0	0.5000
High dose	3	11.1	30.6 (33.68)	25.0	0.0, 66.7	19.4 (20.97)	16.7	0.0, 41.7	0.2495
WEEK 48	4	8.3	8.3 (16.67)	0.0	0.0, 33.3	-0.0 (6.80)	0.0	-8.3, 8.3	>0.999
Low dose	1	0.0	0.0 (N/A)	0.0	0.0, 0.0	0.0 (N/A)	0.0	0.0, 0.0	
High dose	3	11.1	11.1 (19.25)	0.0	0.0, 33.3	-0.0 (8.33)	0.0	-8.3, 8.3	>0.999
PDQ-Cognition Domain Score									
BASELINE	7		28.6 (15.25)	25.0	12.5, 50.0				
Low dose	4		23.4 (10.67)	21.9	12.5, 37.5				
High dose	3		35.4 (20.09)	43.8	12.5, 50.0				
WEEK 24	5	27.5	37.5 (17.12)	37.5	18.8, 62.5	10.0 (10.46)	12.5	-6.3, 18.8	0.0993
Low dose	2	15.6	28.1 (13.26)	28.1	18.8, 37.5	12.5 (8.84)	12.5	6.3, 18.8	0.2952
High dose	3	35.4	43.8 (18.75)	43.8	25.0, 62.5	8.3 (13.01)	12.5	-6.3, 18.8	0.3828
WEEK 48	4	29.7	26.6 (12.88)	25.0	12.5, 43.8	-3.1 (15.73)	0.0	-25.0, 12.5	0.7177
Low dose	1	12.5	25.0 (N/A)	25.0	25.0, 25.0	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	35.4	27.1 (15.73)	25.0	12.5, 43.8	-8.3 (14.43)	0.0	-25.0, 0.0	0.4226

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Stigma Domain Score									
BASELINE	7		20.5 (25.44)	18.8	0.0, 75.0				
Low dose	4		14.1 (9.38)	18.8	0.0, 18.8				
High dose	3		29.2 (40.18)	12.5	0.0, 75.0				
WEEK 24	5	21.3	30.0 (39.87)	12.5	6.3, 100.0	8.8 (17.46)	12.5	-12.5, 25.0	0.3251
Low dose	2	9.4	9.4 (4.42)	9.4	6.3, 12.5	0.0 (17.68)	0.0	-12.5, 12.5	>0.999
High dose	3	29.2	43.8 (49.61)	25.0	6.3, 100.0	14.6 (18.04)	25.0	-6.3, 25.0	0.2965
WEEK 48	4	21.9	29.7 (38.65)	12.5	6.3, 87.5	7.8 (5.98)	9.4	0.0, 12.5	0.0796
Low dose	1	0.0	12.5 (N/A)	12.5	12.5, 12.5	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	29.2	35.4 (45.21)	12.5	6.3, 87.5	6.3 (6.25)	6.3	0.0, 12.5	0.2254
PDQ-Activities of Daily Living Domain Score									
BASELINE	7		41.7 (29.07)	41.7	4.2, 87.5				
Low dose	4		34.4 (21.35)	39.6	4.2, 54.2				
High dose	3		51.4 (40.04)	58.3	8.3, 87.5				
WEEK 24	5	39.2	44.2 (25.28)	50.0	12.5, 75.0	5.0 (12.64)	4.2	-12.5, 20.8	0.4263
Low dose	2	20.8	37.5 (17.68)	37.5	25.0, 50.0	16.7 (5.89)	16.7	12.5, 20.8	0.1560
High dose	3	51.4	48.6 (32.36)	58.3	12.5, 75.0	-2.8 (8.67)	0.0	-12.5, 4.2	0.6349
WEEK 48	4	39.6	45.8 (42.08)	35.4	12.5, 100.0	6.3 (5.38)	6.3	0.0, 12.5	0.1027
Low dose	1	4.2	12.5 (N/A)	12.5	12.5, 12.5	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	51.4	56.9 (43.77)	58.3	12.5, 100.0	5.6 (6.36)	4.2	0.0, 12.5	0.2697

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Emotional Well-being Domain Score									
BASELINE	7		27.4 (22.16)	25.0	0.0, 70.8				
Low dose	4		19.8 (14.18)	22.9	0.0, 33.3				
High dose	3		37.5 (30.05)	29.2	12.5, 70.8				
WEEK 24	5	29.2	35.0 (22.94)	29.2	16.7, 75.0	5.8 (15.20)	4.2	-12.5, 25.0	0.4391
Low dose	2	16.7	27.1 (2.95)	27.1	25.0, 29.2	10.4 (20.62)	10.4	-4.2, 25.0	0.6051
High dose	3	37.5	40.3 (30.71)	29.2	16.7, 75.0	2.8 (14.63)	4.2	-12.5, 16.7	0.7735
WEEK 48	4	28.1	35.4 (22.95)	33.3	12.5, 62.5	7.3 (10.96)	10.4	-8.3, 16.7	0.2754
Low dose	1	0.0	12.5 (N/A)	12.5	12.5, 12.5	12.5 (N/A)	12.5	12.5, 12.5	
High dose	3	37.5	43.1 (20.97)	45.8	20.8, 62.5	5.6 (12.73)	8.3	-8.3, 16.7	0.5286
PDQ-Mobility Domain Score									
BASELINE	7		47.1 (34.95)	42.5	5.0, 100.0				
Low dose	4		45.6 (30.16)	51.3	5.0, 75.0				
High dose	3		49.2 (47.85)	42.5	5.0, 100.0				
WEEK 24	5	45.5	43.5 (35.82)	42.5	5.0, 100.0	-2.0 (16.14)	0.0	-27.5, 17.5	0.7955
Low dose	2	40.0	26.3 (30.05)	26.3	5.0, 47.5	-13.8 (19.45)	-13.8	-27.5, 0.0	0.5000
High dose	3	49.2	55.0 (40.23)	42.5	22.5, 100.0	5.8 (10.10)	0.0	0.0, 17.5	0.4226
WEEK 48	4	38.1	43.8 (40.13)	31.3	12.5, 100.0	5.6 (5.54)	5.0	0.0, 12.5	0.1354
Low dose	1	5.0	12.5 (N/A)	12.5	12.5, 12.5	7.5 (N/A)	7.5	7.5, 7.5	
High dose	3	49.2	54.2 (42.01)	45.0	17.5, 100.0	5.0 (6.61)	2.5	0.0, 12.5	0.3206

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Quality of Life as Assessed
by The PD Questionnaire-39 Items
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDQ-Summary Index Total Score									
BASELINE	7		32.2 (24.49)	34.6	3.2, 76.9				
Low dose	4		26.4 (16.53)	30.8	3.2, 41.0				
High dose	3		40.0 (35.11)	35.9	7.1, 76.9				
WEEK 24	5	32.8	35.6 (24.77)	34.0	12.2, 76.3	2.8 (7.67)	-0.6	-5.1, 12.8	0.4573
Low dose	2	22.1	24.0 (16.77)	24.0	12.2, 35.9	1.9 (9.97)	1.9	-5.1, 9.0	0.8305
High dose	3	40.0	43.4 (29.36)	34.0	19.9, 76.3	3.4 (8.17)	-0.6	-1.9, 12.8	0.5438
WEEK 48	4	30.8	34.8 (31.04)	25.0	11.5, 77.6	4.0 (3.45)	3.5	0.6, 8.3	0.1027
Low dose	1	3.2	11.5 (N/A)	11.5	11.5, 11.5	8.3 (N/A)	8.3	8.3, 8.3	
High dose	3	40.0	42.5 (32.94)	37.8	12.2, 77.6	2.6 (2.31)	1.9	0.6, 5.1	0.1946

&: P-value is obtained from two-sided paired-sample t-test.

Program Source Code: [redacted]

表30　EQ-5D-5Lスコア（FAS，日本人部分集団）：M15-737試験

[redacted]20[redacted] 04:20 <[redacted]>
ABBV-951
STUDY M15-737 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1639 - CLINICAL/STATISTICAL

TABLE 14.2__4.J

Change from Baseline to Each Planned Visit in Health-Related Quality of Life as Assessed
by EQ-5D-5L
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
EQ-5D-5L Mobility									
BASELINE	7		2.4 (1.40)	2.0	1.0, 5.0				
Low dose	4		2.3 (0.96)	2.5	1.0, 3.0				
High dose	3		2.7 (2.08)	2.0	1.0, 5.0				
WEEK 24	5	2.4	2.2 (1.64)	1.0	1.0, 4.0	-0.2 (1.48)	0.0	-2.0, 2.0	0.7780
Low dose	2	2.0	1.0 (0.00)	1.0	1.0, 1.0	-1.0 (1.41)	-1.0	-2.0, 0.0	0.5000
High dose	3	2.7	3.0 (1.73)	4.0	1.0, 4.0	0.3 (1.53)	0.0	-1.0, 2.0	0.7418
WEEK 48	4	2.3	2.5 (1.73)	2.0	1.0, 5.0	0.3 (0.50)	0.0	0.0, 1.0	0.3910
Low dose	1	1.0	2.0 (N/A)	2.0	2.0, 2.0	1.0 (N/A)	1.0	1.0, 1.0	
High dose	3	2.7	2.7 (2.08)	2.0	1.0, 5.0	0.0 (0.00)	0.0	0.0, 0.0	
EQ-5D-5L Self-care									
BASELINE	7		1.9 (1.07)	2.0	1.0, 4.0				
Low dose	4		1.5 (0.58)	1.5	1.0, 2.0				
High dose	3		2.3 (1.53)	2.0	1.0, 4.0				
WEEK 24	5	2.0	2.0 (1.22)	2.0	1.0, 4.0	0.0 (1.41)	0.0	-2.0, 2.0	>0.999
Low dose	2	1.5	1.5 (0.71)	1.5	1.0, 2.0	0.0 (0.00)	0.0	0.0, 0.0	
High dose	3	2.3	2.3 (1.53)	2.0	1.0, 4.0	0.0 (2.00)	0.0	-2.0, 2.0	>0.999
WEEK 48	4	2.0	3.0 (1.83)	3.0	1.0, 5.0	1.0 (0.82)	1.0	0.0, 2.0	0.0917
Low dose	1	1.0	2.0 (N/A)	2.0	2.0, 2.0	1.0 (N/A)	1.0	1.0, 1.0	
High dose	3	2.3	3.3 (2.08)	4.0	1.0, 5.0	1.0 (1.00)	1.0	0.0, 2.0	0.2254

&: P-value is obtained from two-sided paired-sample t-test.
* P-value <= 0.05; ** P-value <= 0.01; *** P-value <= 0.001.

Program Source Code: [redacted]