SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship 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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.17	0	0	0	0	[redacted]/1
ABBV-951 CSCI	0.22	0	0.17	0	0	[redacted]/2
ABBV-951 CSCI	0.22	0	0.17	0	0	[redacted]/3
ABBV-951 CSCI	0.27	0	0.17	0	0	[redacted]/4
ABBV-951 CSCI	0.3	0	0.22	0	0	[redacted]/7
ABBV-951 CSCI	0.36	0	0.22	0	0	[redacted]/8
ABBV-951 CSCI	0.36	0	0.22	0	0	[redacted]/10
ABBV-951 CSCI	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]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.375 mg	TID	Y-M: 20[redacted]
PRAMIPEXOLE	1.500 mg	BID	Y-M: 20[redacted]
SITAGLIPTIN PHOSPHATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted] / -257
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / -257
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -82
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted] / -82
CARBIDOPA MONOHYDRATE;LEVODOPA	75.000 mg	BID	Y-M: 20[redacted] / -82
MECOBALAMIN	0.5 mg	TID	Y-M: 20[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]	ONGOING
SITAGLIPTIN PHOSPHATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]	ONGOING
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted] / -257	ONGOING
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / -257	ONGOING
MECOBALAMIN	0.5 mg	TID	Y-M: 20[redacted] / -14	ONGOING
SODIUM BICARBONATE;SODIUM PHOSPHATE MONOBASIC (ANHYDROUS)	2.6 g	PRN	Y-M: 20[redacted] / 9	ONGOING
METFORMIN HYDROCHLORIDE	250 mg	BID	Y-M: 20[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	NOT RELATED

Infusion Pump	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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

Generated: [redacted]20[redacted]:19:57
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 CSCI	0.26	0	0.23	0	0	[redacted]/1
ABBV-951 CSCI	0.26	0	0.23	0	0	[redacted]/2
ABBV-951 CSCI	0.35	0	0.29	0	0	[redacted]/5
ABBV-951 CSCI	0.38	0	0.35	0	0	[redacted]/6
ABBV-951 CSCI	0.38	0	0.35	0	0	[redacted]/9
ABBV-951 CSCI	0.38	0	0.31	0	0	[redacted]/13
ABBV-951 CSCI	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: [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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.27	0.32	0.22	60	0.19	[redacted]/1
ABBV-951 CSCI	0.27	0.32	0.22	60	0.19	[redacted]/2
ABBV-951 CSCI	0.33	0.4	0.26	60	0.19	[redacted]/7
ABBV-951 CSCI	0.43	0.52	0.34	60	0.19	[redacted]/14
ABBV-951 CSCI	0.43	0.52	0.34	60	0.19	[redacted]/21
ABBV-951 CSCI	0.5	0.6	0.4	60	0.19	[redacted]/31
ABBV-951 CSCI	0.5	0.6	0.4	60	0.19	[redacted]/42
ABBV-951 CSCI	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] / 71	[redacted] / 71
ABBV-951	1821.90	SC /CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951	1797.99	SC /CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951	1886.78	SC /CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	1963.62	SC /CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	1878.25	SC /CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	1982.40	SC /CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	1639.2	SC /CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	1797.99	SC /CONTINUOUS	[redacted] / 79	[redacted] / 79
ABBV-951	1929.47	SC /CONTINUOUS	[redacted] / 80	[redacted] / 80
ABBV-951	1967.04	SC /CONTINUOUS	[redacted] / 81	[redacted] / 81
ABBV-951	1625.54	SC /CONTINUOUS	[redacted] / 82	[redacted] / 82
ABBV-951	1886.78	SC /CONTINUOUS	[redacted] / 83	[redacted] / 83
ABBV-951	2049	SC /CONTINUOUS	[redacted] / 84	[redacted] / 84
ABBV-951	1967.04	SC /CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951	1864.59	SC /CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951	1929.47	SC /CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951	2014.85	SC /CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951	2055.83	SC /CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951	1929.47	SC /CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	1639.2	SC /CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	1924.35	SC /CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	1873.12	SC /CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	1900.44	SC /CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2009.72	SC /CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951	1960.21	SC /CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	2049	SC /CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	1972.16	SC /CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	1932.03	SC /CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	1955.08	SC /CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	1849.22	SC /CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	1666.52	SC /CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	1507.72	SC /CONTINUOUS	[redacted] / 103	[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]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]
AMANTADINE	50.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	QD	Y-M: 20[redacted]
AMANTADINE	50.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.000 mg	TID	Y-M: 20[redacted]
ROTIGOTINE	27.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]
ASCORBIC ACID;CALCIUM PANTOTHENATE	200 mg	TID	Y-M: 20[redacted]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	BID	Y-M: 20[redacted]
ROTIGOTINE	22.500 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	150.000 mg	TID	Y-M: 20[redacted]
CLONAZEPAM	1 mg	QD	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
LOXOPROFEN SODIUM	100 mg	PRN	Y-M: 20[redacted]
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]
ROTIGOTINE	13.500 mg	QD	Y-M: 20[redacted]
SODIUM PICOSULFATE	APPLICATION OTHER: DROPS	PRN	Y-M: 20[redacted]
BETAMETHASONE BUTYRATE PROPIONATE	5 g	PRN	Y-M: 20[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.4	0.32	0.48	60	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.36	0.29	0.43	60	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	0.36	0.29	0.43	60	0.24	[redacted]20[redacted]/8
ABBV-951 CSCI	0.4	0.24	0.48	60	0.24	[redacted]20[redacted]/15
ABBV-951 CSCI	0.43	0.36	0.5	60	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/29
ABBV-951 CSCI	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/44
ABBV-951 CSCI	0.42	0.36	0.6	60	0.3	[redacted]20[redacted]/59
ABBV-951 CSCI	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]20[redacted] / 2	[redacted]20[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: [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]- [redacted] / 89	Y-M: 20[redacted]- [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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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+

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 66): SURGERY - INCISION AND DRAINAGE RIGHT ABDOMINAL WALL COLLECTION:INFECTED HAEMATOMA IN S/C TISSUE; [redacted]20[redacted] (RX DAY 67): EVACUATION OF ABDOMINAL WALL HAEMATOMA. DEBRIDEMENT OF ANTERIOR ABDOMINAL WALL WOUND:HEMATOMA EVACUATED FROM SUPERIOR ASPECT OF WOUND SMALL CUTANEOUS PERFORATED BLEEDING - DIATHERMIED

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+

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 66): SURGERY - INCISION AND DRAINAGE RIGHT ABDOMINAL WALL COLLECTION:INFECTED HAEMATOMA IN S/C TISSUE; [redacted]20[redacted] (RX DAY 67): EVACUATION OF ABDOMINAL WALL HAEMATOMA.　DEBRIDEMENT OF ANTERIOR ABDOMINAL WALL WOUND:HEMATOMA EVACUATED FROM SUPERIOR ASPECT OF WOUND SMALL CUTANEOUS PERFORATED BLEEDING - DIATHERMIED

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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 #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	
SAE Supplemental Procedure	
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 #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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 86): ABDOMINAL ULTRASOUND:SMALL SUBCUTANEOUS HYPOECHOIC COLLECTION WITHIN THE LEFT UPPER ABDOMINAL WALL MEASURING 2.98CM X 0.796CM CONTAINING SEVERAL HYPER-ECHOIC FOCI WHICH ARE LIKELY TO REPRESENT LOCULES OF GAS. APPEARANCE O F THE COLLECTION FAVOURS HAEMATOMA. SUPERFICIAL TO THIS IS AN AREA OF SUBCUTANEOUS OEDEMA.

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]20[redacted] / 86
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 86): ABDOMINAL ULTRASOUND:SMALL SUBCUTANEOUS HYPOECHOIC COLLECTION WITHIN THE LEFT UPPER ABDOMINAL WALL MEASURING 2.98CM X 0.796CM CONTAINING SEVERAL HYPER-ECHOIC FOCI WHICH ARE LIKELY TO REPRESENT LOCULES OF GAS. APPEARANCE O F THE COLLECTION FAVOURS HAEMATOMA. SUPERFICIAL TO THIS IS AN AREA OF SUBCUTANEOUS OEDEMA.

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]20[redacted]:19:57

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 CSCI	0.86	0	0	120	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.86	0	0	120	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	1	0	0.95	120	0.15	[redacted]20[redacted]/8
ABBV-951 CSCI	1	0	0.95	120	0.15	[redacted]20[redacted]/15
ABBV-951 CSCI	1	0	0.95	120	0.15	[redacted]20[redacted]/22
ABBV-951 CSCI	1	0	0.95	120	0.15	[redacted]20[redacted]/29
ABBV-951 CSCI	1	0	0.95	120	0.15	[redacted]20[redacted]/48
ABBV-951 CSCI	1	0	0.95	240	0.11	[redacted]20[redacted]/142
ABBV-951 CSCI	1	0	0.95	240	0.11	[redacted]20[redacted]/149
ABBV-951 CSCI	1	0	0.7	240	0.11	[redacted]20[redacted]/189
ABBV-951 CSCI	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]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 2	
ABBV-951	3494.91		SC /CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 3	
ABBV-951	3450.85		SC /CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	3524.28		SC /CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	3524.28		SC /CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	3524.28		SC /CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	3524.28		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 8	
ABBV-951	3524.28		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	3903.00		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	4063.85		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	3978.47		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	4080.92		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	4063.85		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 18	
ABBV-951	4063.85		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 19	
ABBV-951	4063.85		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	4046.77		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	3995.55		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	4080.92		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	4029.7		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[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
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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
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
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
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112

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ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	4098	SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
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
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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
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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

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ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
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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
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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
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ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	4098		SC /CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] /

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	3923.83	SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 191
ABBV-951	3671.12	SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 192
ABBV-951	3560.13	SC /CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 193
ABBV-951	3635.26	SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 194

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	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]

MONOHYDRATE;LEVODOPA			
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	10 TIMES PER DAY	Y-M: 20[redacted] / -172
PAROXETINE	20 mg	QD	Y-M: 20[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] / 142
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	ONE SACHET13.8G g	BID	Y-M: 20[redacted]	ONGOING
PAROXETINE	20 mg	QD	Y-M: 20[redacted] / -44	Y-M: 20[redacted] / 51
TRIAMCINOLONE ACETONIDE	200MICROGRAM/GRAM ug	PRN	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 64
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 33	Y-M: 20[redacted] / 43
PARACETAMOL	1000 mg	QID	Y-M: 20[redacted] / 43	ONGOING
CEFAZOLIN	2 g	QD	Y-M: 20[redacted] / 48	Y-M: 20[redacted] / 50
CIPROFLOXACIN	200 mg	QD	Y-M: 20[redacted] / 48	Y-M: 20[redacted] / 50
CLINDAMYCIN	450 mg	TID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 59
CIPROFLOXACIN	500 mg	QD	Y-M: 20[redacted] / 59	Y-M: 20[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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	POSSIBLE

[redacted] **Infusion Set**	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 50): INCISION AND DRAINAGE OF LEFT AND RIGHT ABDOMINAL WALL ABSCESSES. LEFT ABSCESS PUS DRAINED ++:RESOLVED SWAB FOR MICROBIOLOGY.

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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]:19:57
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 SPECIAL 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 CSCI	0.23	0.28	0.18	60	0.11	[redacted]/1
ABBV-951 CSCI	0.23	0.28	0.18	60	0.11	[redacted]/2
ABBV-951 CSCI	0.23	0.28	0.18	60	0.11	[redacted]/8
ABBV-951 CSCI	0.23	0.28	0.18	60	0.11	[redacted]/15
ABBV-951 CSCI	0.28	0.37	0.23	60	0.11	[redacted]/23
ABBV-951 CSCI	0.28	0.37	0.23	60	0.11	[redacted]/30
ABBV-951 CSCI	0.28	0.31	0.25	60	0.11	[redacted]/43
ABBV-951 CSCI	0.31	0.34	0.28	60	0.11	[redacted]/94
ABBV-951 CSCI	0.33	0.34	0.3	60	0.11	[redacted]/184
ABBV-951 CSCI	0.33	0.34	0.3	60	0.11	[redacted]/239
ABBV-951 CSCI	0.33	0.34	0.3	60	0.11	[redacted]/275
ABBV-951 CSCI	0.32	0.34	0.3	60	0.11	[redacted]/288
ABBV-951 CSCI	0.32	0.34	0.3	60	0.11	[redacted]/304
ABBV-951 CSCI	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
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 28	
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ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 35	
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 42	
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ABBV-951	1229.4	SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1229.4	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	1229.4	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	1229.4	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	1229.4		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
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
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]-[redacted] / -223	Y-M: 20[redacted]-[redacted] / 284
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted]-[redacted] / 72	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted]-[redacted] / 83	Y-M: 20[redacted]-[redacted] / 90
DOXYCYCLINE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 125	Y-M: 20[redacted]-[redacted] / 132
CHARCOAL, ACTIVATED	100 g	PRN	Y-M: 20[redacted]-[redacted] / 284	Y-M: 20[redacted]-[redacted] / 284
VENLAFAXINE	37.5 mg	QD	Y-M: 20[redacted]-[redacted] / 288	Y-M: 20[redacted]-[redacted] / 304

HYDROCHLORIDE				
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 20[redacted]-[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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.67	0.74	0.6	60	0.3	[redacted]/1
ABBV-951 CSCI	0.67	0.74	0.6	60	0.3	[redacted]/2
ABBV-951 CSCI	0.7	0.74	0.67	60	0.3	[redacted]/11
ABBV-951 CSCI	0.74	0.76	0.7	60	0.3	[redacted]/18
ABBV-951 CSCI	0.74	0.76	0.7	60	0.3	[redacted]/24
ABBV-951 CSCI	0.8	0.84	0.76	60	0.3	[redacted]/32
ABBV-951 CSCI	0.8	0.84	0.76	60	0.3	[redacted]/46
ABBV-951 CSCI	0.8	0.84	0.76	60	0.3	[redacted]/93
ABBV-951 CSCI	0.84	0.85	0.8	60	0.3	[redacted]/184
ABBV-951 CSCI	0.84	0.85	0.8	60	0.3	[redacted]/274
ABBV-951 CSCI	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
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316

ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353

ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
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ABBV-951	3278.4		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	3395.87		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;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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 72): CT BRAIN:NORMAL CT BRAIN

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

Generated: [redacted]20[redacted]:19:57

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，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 CSCI	0.34	0.35	0.31	60	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.34	0.35	0.31	60	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	0.36	0.37	0.32	60	0.19	[redacted]20[redacted]/8
ABBV-951 CSCI	0.38	0.4	0.32	60	0.19	[redacted]20[redacted]/15
ABBV-951 CSCI	0.36	0.37	0.32	60	0.19	[redacted]20[redacted]/22
ABBV-951 CSCI	0.34	0.35	0.28	60	0.19	[redacted]20[redacted]/23
ABBV-951 CSCI	0.36	0.37	0.32	60	0.19	[redacted]20[redacted]/26
ABBV-951 CSCI	0.32	0.33	0.26	60	0.19	[redacted]20[redacted]/29
ABBV-951 CSCI	0.3	0.32	0.25	60	0.19	[redacted]20[redacted]/43
ABBV-951 CSCI	0.3	0.32	0.25	60	0.19	[redacted]20[redacted]/91
ABBV-951 CSCI	0.32	0.33	0.25	60	0.19	[redacted]20[redacted]/182
ABBV-951 CSCI	0.37	0.38	0.25	60	0.19	[redacted]20[redacted]/238
ABBV-951 CSCI	0.39	0.4	0.24	60	0.19	[redacted]20[redacted]/273
ABBV-951 CSCI	0.38	0.4	0.15	60	0.19	[redacted]20[redacted]/357
ABBV-951 CSCI	0.34	0.4	0.15	60	0.19	[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		64.88	SC /ONCE	[redacted]20[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
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		129.77	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	1477.32		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1475.28		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
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
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45

ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193

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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
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ABBV-951	1557.24	SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1557.24	SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
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ABBV-951	1557.24	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
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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]-[redacted] / 322
PANTOPRAZOLE SODIUM SESQUIHYDRATE	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 258
EZETIMIBE;ROSUVA STATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]	ONGOING
DESVENLAFAXINE SUCCINATE MONOHYDRATE	50 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 195
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 2	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 27	Y-M: 20[redacted]-[redacted] / 28
QUETIAPINE	25 mg	BID	Y-M: 20[redacted]-[redacted] / 29	Y-M: 20[redacted]-[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;SODI	25 mL	QD	Y-M: 20[redacted] / 181	Y-M: 20[redacted] / 237

UM CHLORIDE				
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	

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	
SAE Supplemental Procedure	
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 Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship 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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.29	0.31	0.27	60	0.19	[redacted]/1
ABBV-951 CSCI	0.27	0.28	0.25	60	0.19	[redacted]/2
ABBV-951 CSCI	0.22	0.21	0.19	60	0.11	[redacted]/10
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/16
ABBV-951 CSCI	0.21	0.22	0.19	60	0.19	[redacted]/23
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/28
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/30
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/44
ABBV-951 CSCI	0.19	0.21	0.18	60	0.11	[redacted]/93
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/183
ABBV-951 CSCI	0.21	0.22	0.19	60	0.11	[redacted]/274
ABBV-951 CSCI	0.21	0.22	0.19	60	0.15	[redacted]/293
ABBV-951 CSCI	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
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
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
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
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
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
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
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	778.62		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73

ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	778.62	SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	291.98	SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	586.18	SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	801.84	SC /CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951	838.72	SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191

ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212

ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[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
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246

ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267

ABBV-951	901.56		SC /CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	901.56		SC /CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	901.56		SC /CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
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	
ABBV-951	754.71		SC /CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	817.03		SC /CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951	860.58		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	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	860.58		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	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299

ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
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ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
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ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
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ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
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ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
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ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 364	
ABBV-951	840.43		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
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]
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]
BOTULINUM TOXIN TYPE A	UNKNOWN IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: 20[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]	ONGOING
DICLOFENAC	50 mg	TID	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 26
MORPHINE	2.5 mg	PRN	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 26
DIAZEPAM	5 mg	PRN	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 181
MELOXICAM	15 mg	PRN	Y-M: 20[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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 26): PELVIC ULTRASOUND:NORMAL ULTRASOUND; RENAL CT:NORMAL CT SCAN; [redacted]20[redacted] (RX DAY 37): MRI SPINE:LEFT SACROILIAC JOINT INCOMPETENCE ASSOCIATED WITH SEVERAL TENDON ENTHESOPATHIES AND HIP IMPINGEMENT.; [redacted]20[redacted] (RX DAY 66): BONE SCAN:RESULT = LEFT SACROILIAC JOINT INCOMPETENCE ASSOCIATED WITH SEVERAL TENDON ENTHESOPATHIES AND HIP IMPINGEMENT.

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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.51	0.52	0.41	60	0.24	[redacted]/1
ABBV-951 CSCI	0.52	0.53	0.42	60	0.24	[redacted]/2
ABBV-951 CSCI	0.53	0.54	0.43	60	0	[redacted]/6
ABBV-951 CSCI	0.53	0.54	0.43	60	0.24	[redacted]/13
ABBV-951 CSCI	0.54	0.55	0.44	60	0.24	[redacted]/20
ABBV-951 CSCI	0.55	0.56	0.44	60	0.24	[redacted]/27
ABBV-951 CSCI	0.55	0.56	0.44	60	0.24	[redacted]/42
ABBV-951 CSCI	0.57	0.58	0.44	60	0.24	[redacted]/72
ABBV-951 CSCI	0.57	0.58	0.45	60	0.24	[redacted]/91
ABBV-951 CSCI	0.58	0.59	0.45	60	0.24	[redacted]/182
ABBV-951 CSCI	0.59	0.6	0.45	60	0.24	[redacted]/199
ABBV-951 CSCI	0.6	0.61	0.47	60	0.24	[redacted]/275
ABBV-951 CSCI	0.62	0.63	0.47	60	0.24	[redacted]/342

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] / 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]20[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]20[redacted] / 173
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 174
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 176
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 177
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 179
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 180
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 181
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 182
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 183
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 184
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 185
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 186
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 188
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 190
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 191
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 192
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 193
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 194
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 199
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 200
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 201
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 203
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 204
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 207
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 211
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 212
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 215
ABBV-951	81.96	SC /ONCE	[redacted]20[redacted] / 216
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 217
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 218
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 219
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 220
ABBV-951	40.98	SC /ONCE	[redacted]20[redacted] / 221
ABBV-951	122.94	SC /ONCE	[redacted]20[redacted] / 222
ABBV-951	122.94	SC /ONCE	[redacted]20[redacted] / 224
ABBV-951	81.96	SC /ONCE	[redacted]20[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

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	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	363 (3 DAYS AFTER LAST TREATMENT)
Duration of AE	358 DAYS
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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 51): MRI SPINE:L5 AND S1 COMPRESSIVE RADICULOPATHY; [redacted]20[redacted] (RX DAY 315): LEFT REDO L4-5 AND L5-S1 DECOMPRESSION/FORAMINOTOMY AND PARTIAL FACETECTOMY.:SURGERY PERFORMED ACCORDING TO PLAN - UNEVENTFUL PROCEDURE. SUBJECT DISCHARGED FROM HOSPITAL ON [redacted]20[redacted].

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	NOT RELATED

Infusion Pump	
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]:19:57

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 CSCI	0.23	0.26	0.2	60	0.24	[redacted]/1
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/2
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/9
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/16
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/23
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/28
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/42
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/99
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/182
ABBV-951 CSCI	0.26	0.28	0.23	60	0.24	[redacted]/275
ABBV-951 CSCI	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]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1099.63		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	458.97		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	769.74		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1128.31		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[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]-[redacted]
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 44): SWAB OF INFUSION SITE WOUND:NEGATIVE. NO GROWTH ON [redacted] [redacted] 20[redacted]; [redacted]20[redacted] (RX DAY 45): ABDOMINAL ULTRASOUND:CELLULITIS EQUIVOCAL 1.7ML COLLECTION, NO DEEP EXTENSION IS DEMONSTRATED. NO FOREIGN BODIES WERE NOTED ON THE RESULT.	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.83	0.91	0.75	120	0.3	[redacted]/1
ABBV-951 CSCI	0.83	0.91	0.75	120	0.3	[redacted]/2
ABBV-951 CSCI	0.91	1	0.82	120	0.3	[redacted]/8
ABBV-951 CSCI	1	1.09	0.91	120	0.3	[redacted]/15
ABBV-951 CSCI	0.95	1	0.91	120	0.3	[redacted]/22
ABBV-951 CSCI	0.95	1	0.91	120	0.3	[redacted]/29
ABBV-951 CSCI	0.95	1	0.91	120	0.3	[redacted]/43
ABBV-951 CSCI	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: [redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	QD	Y-M: [redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	150.000 mg	QD	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVOD	200.000 mg	7 TIMES PER DAY	Y-M: [redacted]

OPA			
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	250.000 mg	QD	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]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	125.000 mg	QD	Y-M: 20[redacted]-[redacted]
CYANOCOBALAMIN	1000 ug	OTHER: ONCE	Y-M: 20[redacted]-[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.47	0.51	0.43	120	0.3	[redacted]/1
ABBV-951 CSCI	0.47	0.51	0.43	120	0.3	[redacted]/2
ABBV-951 CSCI	0.47	0.51	0.43	120	0.3	[redacted]/9
ABBV-951 CSCI	0.45	0.5	0.4	120	0.3	[redacted]/16
ABBV-951 CSCI	0.44	0.46	0.42	120	0.3	[redacted]/23
ABBV-951 CSCI	0.43	0.44	0.42	120	0.3	[redacted]/30
ABBV-951 CSCI	0.43	0.44	0.42	120	0.3	[redacted]/44
ABBV-951 CSCI	0.43	0.44	0.42	120	0.3	[redacted]/92
ABBV-951 CSCI	0.43	0.44	0.42	120	0.3	[redacted]/160
ABBV-951 CSCI	0.43	0.44	0.42	120	0.3	[redacted]/174
ABBV-951 CSCI	0.44	0.43	0.45	120	0.3	[redacted]/264
ABBV-951 CSCI	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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	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

Generated: [redacted] 20[redacted]:19:57

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 CSCI	0.47	0.52	0.42	60	0.15	[redacted]/1
ABBV-951 CSCI	0.47	0.52	0.42	60	0.15	[redacted]/4
ABBV-951 CSCI	0.58	0.69	0.47	60	0.15	[redacted]/9
ABBV-951 CSCI	0.54	0.58	0.47	60	0.15	[redacted]/18
ABBV-951 CSCI	0.6	0.65	0.55	60	0.15	[redacted]/22
ABBV-951 CSCI	0.65	0.69	0.6	60	0.15	[redacted]/29
ABBV-951 CSCI	0.65	0.69	0.6	60	0.15	[redacted]/43
ABBV-951 CSCI	0.69	0.73	0.65	60	0.19	[redacted]/49
ABBV-951 CSCI	0.73	0.75	0.69	60	0.15	[redacted]/92
ABBV-951 CSCI	0.76	0.78	0.73	60	0.11	[redacted]/124
ABBV-951 CSCI	0.76	0.78	0.73	60	0.11	[redacted]/183
ABBV-951 CSCI	0.71	0.75	0.69	60	0.15	[redacted]/194
ABBV-951 CSCI	0.75	0.78	0.7	60	0.15	[redacted]/271
ABBV-951 CSCI	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
ABBV-951	2227.26		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2218.89		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	2267.56		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2393.91		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
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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]
MAGNESIUM HYDROXIDE	500 mg	PRN	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted]
ESTRADIOL	10 ug	OTHER: BIS	Y-M: 20[redacted]
PRAMIPEXOLE	0.520 mg	QID	Y-M: 20[redacted] / -110
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	PRN	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
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]	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]	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]	ONGOING
DOMPERIDONE	10 mg	PRN	Y-M: 20[redacted] / 4	ONGOING
DOCUSATE;SORBITOL	1 mL	OTHER: SD	Y-M: 20[redacted] / 7	Y-M: 20[redacted] / 7
INFLUENZA VACCINE	1 OTHER: NOT SPECIFIED.	OTHER: SD	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 8
ONDANSETRON	2 mg	PRN	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 35
TERBINAFINE HYDROCHLORIDE	250 mg	QD	Y-M: 20[redacted] / 64	Y-M: 20[redacted] / 71
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 103	Y-M: 20[redacted] / 111
LOSARTAN	50 mg	QD	Y-M: 20[redacted] / 106	ONGOING
PIVMECILLINAM	400 mg	TID	Y-M: 20[redacted] / 147	Y-M: 20[redacted] / 152
MELATONIN	2 mg	QD	Y-M: 20[redacted] / 153	Y-M: 20[redacted] / 163
DONEPEZIL	5 mg	QD	Y-M: 20[redacted] / 161	Y-M: 20[redacted] / 163

DONEPEZIL	5 mg	QD	Y-M: 20[redacted] / 165	Y-M: 20[redacted] / 192
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 283
QUETIAPINE FUMARATE	50 mg	QD	Y-M: 20[redacted] / 284	ONGOING
RIVASTIGMINE	4.6 mg	QD	Y-M: 20[redacted] / 313	Y-M: 20[redacted] / 362
DICLOXACILLIN	1000 mg	TID	Y-M: 20[redacted] / 322	Y-M: 20[redacted] / 329
RIVASTIGMINE	9.5 mg	QD	Y-M: 20[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.

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 34): HEMATOMA DRAINAGE/FLUSHING:WOUND IS HEALED

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.

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 34): HEMATOMA DRAINAGE/FLUSHING:WOUND IS HEALED

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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	
SAE Supplemental Procedure	
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 #6: 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	

SAE Supplemental Procedure

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 #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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.2	0.25	0.15	60	0.15	[redacted]/1
ABBV-951 CSCI	0.17	0.22	0.12	60	0.15	[redacted]/3
ABBV-951 CSCI	0.12	0.14	0.1	60	0.11	[redacted]/4
ABBV-951 CSCI	0.17	0.19	0.15	60	0.15	[redacted]/10
ABBV-951 CSCI	0.19	0.21	0.17	60	0.19	[redacted]/18
ABBV-951 CSCI	0.17	0.19	0.15	60	0.19	[redacted]/25
ABBV-951 CSCI	0.18	0.19	0.17	60	0.19	[redacted]/32
ABBV-951 CSCI	0.18	0.19	0.17	60	0.24	[redacted]/43
ABBV-951 CSCI	0.18	0.19	0.17	60	0.15	[redacted]/92
ABBV-951 CSCI	0.19	0.2	0.18	60	0.15	[redacted]/162
ABBV-951 CSCI	0.2	0.21	0.19	60	0.15	[redacted]/183
ABBV-951 CSCI	0.21	0.23	0.19	60	0.24	[redacted]/281
ABBV-951 CSCI	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]20[redacted] / 8	
ABBV-951	409.8		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		75.13	SC /ONCE	[redacted]20[redacted] / 9	
ABBV-951	450.78		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 10	
ABBV-951	573.72		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 11	
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ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 192	
ABBV-951	775.20		SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	816.18		SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 194	
ABBV-951	812.77		SC /CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 195	
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	812.77		SC /CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196

ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 198	
ABBV-951	802.52		SC /CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 199	
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951	812.77		SC /CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 202	
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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	
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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]
ENALAPRIL	20 mg	QD	Y-M: 20[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]
METHOTREXATE	2.5 mg	QD	Y-M: 20[redacted]
AMITRIPTYLINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted]
METRONIDAZOLE	0.75%	BID	Y-M: 20[redacted] / -314
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -283
CALCIUM	1 OTHER: TABLET	QD	Y-M: 20[redacted] / -70
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / -70
POTASSIUM CHLORIDE	750 mg	QD	Y-M: 20[redacted] / -70
FUROSEMIDE	40 mg	QD	Y-M: 20[redacted] / -50
ATORVASTATIN	40 mg	QD	Y-M: 20[redacted] / -32
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	PRN	Y-M: 20[redacted] / -28
RASAGILINE	1.000 mg	PRN	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
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	

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.

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 262): ULTRA SOUND GUIDET PUNKTURE OG KNEE:N.A.; [redacted]20[redacted] (RX DAY 263): ULTRASOUND, ABDOMEN:SUBCUTANOUS EDEMA, SHOWING SMALL LOCAL FLUID CONCENTRATIONS CORRESPONDING WITH INFLAMMATION ON THE SKIN.; [redacted]20[redacted] (RX DAY 265): X-RAY OF THORAX:NOTHING ABNORMALE.; [redacted]20[redacted] (RX DAY 270): ULTRASOUND OF RIGHT SHOLDER-:BURSITIS; [redacted]20[redacted] (RX DAY 273): X-RAY RIGHT PATELLA:OSTEOARTHRITIS

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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

Generated: [redacted]20[redacted]:19:57
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
注入部位損傷	X	X		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 CSCI	0.43	0	0	60	0.15	[redacted]/1
ABBV-951 CSCI	0.39	0	0	60	0.15	[redacted]/2
ABBV-951 CSCI	0.41	0	0	60	0.15	[redacted]/8
ABBV-951 CSCI	0.43	0	0	60	0.19	[redacted]/15
ABBV-951 CSCI	0.5	0	0	60	0.19	[redacted]/22
ABBV-951 CSCI	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]20[redacted] / 15	[redacted]20[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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 Adversary 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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 43): INCISION OF SUBCUTANEOUS ABSCESS:PUS DRAINING

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

Event #7: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PERFORATION OF SKIN AT INFUSION SITE
Preferred Term	注入部位損傷
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 43): INCISION OF SUBCUTANEOUS ABSCESS:PUS DRAINING

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]:19:57

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，注入部位の皮下膿瘍，注入部位の皮膚の穿孔を発現した。

Event 6 及び 7 の臨床経過：

関連する病歴は，パーキンソン病，下肢の浮腫，元喫煙者（1 日 6 本を 15 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，被験者は注入部位の皮下膿瘍，注入部位の皮膚の穿孔を発現した。投与 70 日目，注入部位の皮下膿瘍，注入部位の皮膚の穿孔は消失した。

投与 28 日目，被験者は注入部位に紅斑，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。10 cm の注射部位膿瘍が認められた。膿瘍は左下腹部にあった。膿瘍の 3 cm の領域に特発性の穿孔も観察された。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。

被験者にクリンダマイシン，フェノキシメチルペニシリン及びベンジルペニシリンが投与された。

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.24.0] [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 injury (10076070) (Infusion site injury (10076070)) [v.24.0] [10076070]

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, PERFORATION OF SKIN 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 CSCI	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/1
ABBV-951 CSCI	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/2
ABBV-951 CSCI	0.34	0.4	0.27	60	0.19	[redacted]20[redacted]/8
ABBV-951 CSCI	0.4	0.46	0.34	60	0.24	[redacted]20[redacted]/17
ABBV-951 CSCI	0.4	0.46	0.34	60	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.51	0.54	0.46	60	0.3	[redacted]20[redacted]/29
ABBV-951 CSCI	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]20[redacted] / 10	
ABBV-951	1357.12		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 11	
ABBV-951	1293.77		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 12	
ABBV-951	1339.36		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1306.92		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1319.38		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	1425.76		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 16	
ABBV-951	1340.89		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 17	
ABBV-951	1639.37		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 18	
ABBV-951	1567.14		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 19	
ABBV-951	1516.94		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	1546.99		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1579.43		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	1690.76		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1689.05		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 24	
ABBV-951	1721.84		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 25	
ABBV-951	1593.78		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	1694.86		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	1667.20		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	1678.13		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28

ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 29	
ABBV-951	1890.03		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 30	
ABBV-951	2032.26		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951	2049.51		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 32	
ABBV-951	2042.51		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 33	
ABBV-951	1965.33		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 34	
ABBV-951	1981.72		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	1981.38		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 36	
ABBV-951	2072.56		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951	2062.83		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 38	
ABBV-951	2087.41		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 39	
ABBV-951	2114.56		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2135.05		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		256.12	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	2127.37		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	2114.05		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	2121.73		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 44	
ABBV-951	2072.56		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 45	
ABBV-951	2016.72		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 46	
ABBV-951	2088.27		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 47	
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[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]-[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 [redacted].[redacted].20[redacted]	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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 38): CT CRANIAL AND ANGIO:NO FRESH ISCHEMIA, NO INTERCRANIAL BLEEDING; [redacted]20[redacted] (RX DAY 39): MRT CRANIAL:NO FRESH ISCHEMIA; [redacted]20[redacted] (RX DAY 44): NLG/EMG:NO NOTE FOR PNP, SENSOMOTORIC KTS BOTH SIDES

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

SAE Supplemental Procedure

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	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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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]:19:57

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] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

ISICOM 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], [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], [redacted] 20[redacted] - [redacted] 20[redacted], Started [redacted] 20[redacted])

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

MADOPAR DISPERSIBLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[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] **COVID 19 TEST:** nasopharyngeal swab, tested negative

[redacted] **CT ANGIO:** no fresh ischemia, no intercranial bleeding

[redacted] **CT CRANIAL:** no fresh ischemia, no intercranial bleeding

[redacted] **MRI CRANIAL:** no Fresh ischemia

[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])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted])

LEVOCOMP for PARKINSON'S DISEASE ([redacted])

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE for PARKINSON'S DISEASE ([redacted])

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

IPX203 CD/LD for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[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 SPECIAL 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 CSCI	0.19	0	0	0	0	[redacted]/1
ABBV-951 CSCI	0.19	0	0	60	0.11	[redacted]/2
ABBV-951 CSCI	0.19	0	0	60	0.11	[redacted]/8
ABBV-951 CSCI	0.21	0	0	60	0.15	[redacted]/15
ABBV-951 CSCI	0.24	0	0	60	0.19	[redacted]/28
ABBV-951 CSCI	0.24	0	0	60	0.15	[redacted]/36
ABBV-951 CSCI	0.24	0	0	60	0.15	[redacted]/42
ABBV-951 CSCI	0.26	0	0	60	0.15	[redacted]/91
ABBV-951 CSCI	0.26	0	0	60	0.15	[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	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
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ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 164	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 165	
ABBV-951	1029.96		SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 166	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 167	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 168	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 169	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 170	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 171	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 172	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 173	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 174	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 175	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 176	

ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 177	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 178	
ABBV-951	1029.96		SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 179	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 180	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 181	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 182	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 183	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 184	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 185	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 186	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 187	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 188	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 189	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 190	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 191	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 192	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 193	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 194	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194

ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 195	
ABBV-951	1029.96		SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 196	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 197	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 198	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 199	
ABBV-951	1043.28		SC /CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 200	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 201	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 202	
ABBV-951	1065.48		SC /CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 203	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 204	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 205	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 206	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 207	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 208	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 209	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 210	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 211	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 212	
ABBV-951	1052.16		SC /CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 213	

ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 214	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 215	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 216	
ABBV-951	1016.64		SC /CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 217	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 218	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 219	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 220	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 221	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 222	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 223	
ABBV-951	1029.96		SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 224	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 225	
ABBV-951	1065.48		SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 226	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 227	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 228	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 229	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 230	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 231	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231

ABBV-951		102.45	SC /ONCE	[redacted] / 232	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 232	[redacted] / 232
ABBV-951		102.45	SC /ONCE	[redacted] / 233	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 233	[redacted] / 233
ABBV-951		102.45	SC /ONCE	[redacted] / 234	
ABBV-951	1025.52		SC /CONTINUOUS	[redacted] / 234	[redacted] / 234
ABBV-951		128.06	SC /ONCE	[redacted] / 235	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted] / 235	[redacted] / 235
ABBV-951		25.61	SC /ONCE	[redacted] / 236	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 236	[redacted] / 236
ABBV-951		128.06	SC /ONCE	[redacted] / 237	
ABBV-951	1056.60		SC /CONTINUOUS	[redacted] / 237	[redacted] / 237
ABBV-951		128.06	SC /ONCE	[redacted] / 238	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 238	[redacted] / 238
ABBV-951		128.06	SC /ONCE	[redacted] / 239	
ABBV-951	1021.08		SC /CONTINUOUS	[redacted] / 239	[redacted] / 239
ABBV-951		76.83	SC /ONCE	[redacted] / 240	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 240	[redacted] / 240
ABBV-951		128.06	SC /ONCE	[redacted] / 241	
ABBV-951	1061.04		SC /CONTINUOUS	[redacted] / 241	[redacted] / 241

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]-[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted]-[redacted]
ROPINIROLE	4.000 mg	BID	Y-M: 20[redacted]-[redacted]
VITAMIN B12 NOS	1000 ug	OTHER: 2X / WEEK	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
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 36): SURGICAL TREATMENT OF THE SUBCUTANEOUS ABDOMINAL ABSCESS:THE ABSCESS WAS OPENED AND FLUSHED. THE INFECTION WAS TREATED WITH ANTIBIOTICS (CEPHAZOLIN 2 G 1-1-1); [redacted]20[redacted] (RX DAY 129): THE WOUND WAS CLEANED AND IRRIGATED:WOUND IS CLEANED

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 132): COLOSCOPY:POSSIBLE ISCHAEMIC COLITIS, POLYP IN THE MIDDLE OF COLON TRANSVERSUM, SOME DIVERTICULI. ISCHAEMIC COLITIS HISTOLOGICALLY CONFIRMED, NO FURTHER TREATMENT NECESSARY. ANOTHER UNRELATED FINDING IST A TUBU LLARY ADENOMA OF THE COLON MUCOSA IN TRANSVERSUM WITH DISKRETE INTRAEPITHELIAL NEOPLASIA. POLYP WAS REMOVED DURING COLOSCOPY.

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	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	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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 132): COLOSCOPY:POSSIBLE ISCHAEMIC COLITIS, POLYP IN THE MIDDLE OF COLON TRANSVERSUM, SOME DIVERTICULI. ISCHAEMIC COLITIS HISTOLOGICALLY CONFIRMED, NO FURTHER TREATMENT NECESSARY. ANOTHER UNRELATED FINDING IST A TUBU LLARY ADENOMA OF THE COLON MUCOSA IN TRANSVERSUM WITH DISKRETE INTRAEPITHELIAL NEOPLASIA. POLYP WAS REMOVED DURING COLOSCOPY.

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	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	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: 64.97 [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; URINE LEUKOCYTES: POSITIVE-70

SAE Supplemental Procedure

NOT REPORTED

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]:19:57
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

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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
注入部位紅斑				X
敗血症	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 CSCI	0.57	0.68	0.46	60	0.24	20[redacted]/1
ABBV-951 CSCI	0.57	0.52	0.46	60	0.24	20[redacted]/2
ABBV-951 CSCI	0.57	0.54	0.52	60	0.24	20[redacted]/8
ABBV-951 CSCI	0.57	0.54	0.52	60	0.24	20[redacted]/15
ABBV-951 CSCI	0.57	0.54	0.5	60	0.3	20[redacted]/21
ABBV-951 CSCI	0.57	0.54	0.5	60	0.3	20[redacted]/29
ABBV-951 CSCI	0.57	0.54	0.5	60	0.3	20[redacted]/43
ABBV-951 CSCI	0.57	0.54	0.58	60	0.3	20[redacted]/64
ABBV-951 CSCI	0.57	0.58	0.54	60	0.3	20[redacted]/78
ABBV-951 CSCI	0.57	0.58	0.54	60	0.3	20[redacted]/98
ABBV-951 CSCI	0.57	0.6	0.54	60	0.3	20[redacted]/106
ABBV-951 CSCI	0.58	0.62	0.54	60	0.24	20[redacted]/133
ABBV-951 CSCI	0.62	0.65	0.58	60	0.24	20[redacted]/147

ABBV-951 CSCI	0.65	0.68	0.62	60	0.24	[redacted]/162
ABBV-951 CSCI	0.68	0.71	0.65	60	0.24	[redacted]/183

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	[redacted] / 20
ABBV-951	2212.92		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	2212.92		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22

ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		256.12	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	2166.47		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 34	
ABBV-951	2216.33		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	2006.31		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		51.22	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	2019.63		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	2245.70		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53

ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
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ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
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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
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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	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
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ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
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ABBV-951	2588.22		SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 181	
ABBV-951	2775.02		SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 182	
ABBV-951	2658.91		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
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

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	
SAE Supplemental Procedure	
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	SEPSIS
Preferred Term	敗血症

AE Onset Date / RX Day	[redacted]20[redacted] / 228
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
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	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]:19:57
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，敗血症を発現した。

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，被験者は敗血症を発現した。

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，被験者は敗血症のため入院した。入院中，被験者は外科手術を受け，汚れた木片が除去された。

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])

Causality for ABBV-951 (Open Label)

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1) 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: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SEPSIS

- 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 CSCI	0.2	0.24	0.16	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.19	0.22	0.17	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.22	0.23	0.21	60	0.11	[redacted]20[redacted]/3
ABBV-951 CSCI	0.22	0.23	0.21	60	0.11	[redacted]20[redacted]/9
ABBV-951 CSCI	0.23	0.24	0.22	60	0.15	[redacted]20[redacted]/11
ABBV-951 CSCI	0.24	0.26	0.23	60	0.11	[redacted]20[redacted]/15
ABBV-951 CSCI	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

SAE Supplemental Procedure

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]:19:57

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 CSCI	0.33	0.4	0.27	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.33	0.4	0.27	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.4	0.48	0.33	60	0.15	[redacted]20[redacted]/9
ABBV-951 CSCI	0.37	0.48	0.33	60	0.11	[redacted]20[redacted]/11
ABBV-951 CSCI	0.38	0.48	0.33	60	0.24	[redacted]20[redacted]/16
ABBV-951 CSCI	0.42	0.48	0.33	60	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.42	0.48	0.33	60	0.3	[redacted]20[redacted]/30
ABBV-951 CSCI	0.47	0.48	0.33	60	0.3	[redacted]20[redacted]/38
ABBV-951 CSCI	0.55	0.66	0.48	60	0.3	[redacted]20[redacted]/44

ABBV-951 CSCI	0.55	0.66	0.33	60	0.3	[redacted]20[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]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 2	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951		131.47	SC /ONCE	[redacted]20[redacted] / 3	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951		93.91	SC /ONCE	[redacted]20[redacted] / 4	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951		75.13	SC /ONCE	[redacted]20[redacted] / 5	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951		150.26	SC /ONCE	[redacted]20[redacted] / 6	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951		206.60	SC /ONCE	[redacted]20[redacted] / 7	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		131.47	SC /ONCE	[redacted]20[redacted] / 8	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 9	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 10	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 11	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		93.91	SC /ONCE	[redacted]20[redacted] / 12	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 17	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[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]-[redacted]
APOMORPHINE	1.000 mg	16 TIMES PER DAY	Y-M: 20[redacted]
CLOZAPINE	37 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted]-[redacted] / -265
MACROGOL	10 g	PRN	Y-M: 20[redacted]-[redacted] / -104
SIMVASTATIN	40 mg	QD	Y-M: 20[redacted]-[redacted] / -45
TRIAMCINOLONE ACETONIDE	1 mg	QD	Y-M: 20[redacted]-[redacted] / -45
BETAMETHASONE	1 mg	QD	Y-M: 20[redacted]-[redacted] / -42
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -42
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted]-[redacted] / -42
CYANOCOBALAMIN	DOSE VIT B12 INJ IS UNKNOWN OTHER: UNKNOWN	OTHER: ONCE A WEEK	Y-M: 20[redacted]-[redacted] / -26
CETOMACROGOL;PARAFFIN, LIQUID;PROPYLENE GLYCOL;WHITE SOFT PARAFFIN	20 mg	BID	Y-M: 20[redacted]-[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]-[redacted]	ONGOING
CLOZAPINE	37 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
MACROGOL	10 g	PRN	Y-M: 20[redacted]-[redacted] / -104	ONGOING
TRIAMCINOLONE ACETONIDE	1 mg	QD	Y-M: 20[redacted]-[redacted] / -45	ONGOING

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 73): PLACEMENT OF A PEG J-TUBE:PLACEMENT WENT WITHOUT COMPLICATIONS.	
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]:19:57
Program Source Code: [redacted]

Investigator No.: [redacted]#[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)

---

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 SPECIAL INTEREST

Weight Decreased: Day 1 weight 7[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. No other 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 CSCI	0.73	0.8	0.53	60	0.11	[redacted]/1
ABBV-951 CSCI	0.67	0.8	0.53	60	0.15	[redacted]/2
ABBV-951 CSCI	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	
SAE Supplemental Procedure	
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 #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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 5): ECG:SINUS RITME, INTERMEDIAIRE HEART AXIS, PEAK T WAVES, NORMAL CONDUCTION TIMES, NO ST-DEPRESSION OR ST-ELEVATIONS.

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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 5): ECG:SINUS RITME, INTERMEDIAIRE HEART AXIS, PEAK T WAVES, NORMAL CONDUCTION TIMES, NO ST-DEPRESSION OR ST-ELEVATIONS.	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.73	0	0.59	60	0.19	[redacted]20[redacted]/1
ABBV-951 CSCI	0.77	0	0.62	60	0.19	[redacted]20[redacted]/2
ABBV-951 CSCI	0.6	0.62	0.5	60	0.19	[redacted]20[redacted]/6
ABBV-951 CSCI	0.62	0.65	0.5	60	0.19	[redacted]20[redacted]/13
ABBV-951 CSCI	0.62	0.65	0.5	60	0.19	[redacted]20[redacted]/21
ABBV-951 CSCI	0.63	0.65	0.53	60	0.19	[redacted]20[redacted]/28
ABBV-951 CSCI	0.6	0.62	0.53	60	0.19	[redacted]20[redacted]/42
ABBV-951 CSCI	0.55	0.58	0.5	60	0.15	[redacted]20[redacted]/48

ABBV-951 CSCI	0.45	0.48	0.4	60	0.15	[redacted]/62
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/70
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/76
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/91
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/105
ABBV-951 CSCI	0.37	0.39	0.31	60	0.15	[redacted]/146
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/182
ABBV-951 CSCI	0.35	0.37	0.3	60	0.15	[redacted]/233
ABBV-951 CSCI	0.33	0.35	0.3	60	0.15	[redacted]/273
ABBV-951 CSCI	0.31	0.33	0.28	60	0.15	[redacted]/329
ABBV-951 CSCI	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
ABBV-951	2540.76		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	2529.66		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	2370.52		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	2555.10		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	2465.97		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	2377.52		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	2275.75		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45

ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 60	
ABBV-951	2140.18		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 61	
ABBV-951	2085.71		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 62	
ABBV-951	1775.8		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1639.2		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	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79

ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
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ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 290
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	1352.34		SC /CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299

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ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
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
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336

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ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
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ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
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ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1352.34	SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1261.33	SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
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]-[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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 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	
SAE Supplemental Procedure	
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 #16: 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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted])

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

MADOPAR for PARKINSON'S DISEASE ([redacted])

ENTACAPONE 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.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 CSCI	0.53	0.64	0.42	60	0.11	[redacted]/1
ABBV-951 CSCI	0.47	0.56	0.37	60	0.11	[redacted]/2
ABBV-951 CSCI	0.6	0.72	0.45	60	0.15	[redacted]/9
ABBV-951 CSCI	0.75	0.9	0.6	60	0.19	[redacted]/10
ABBV-951 CSCI	0.9	0.93	0.87	60	0.24	[redacted]/16
ABBV-951 CSCI	0.8	0.96	0.64	60	0.24	[redacted]/23
ABBV-951 CSCI	0.86	0.89	0.83	60	0.3	[redacted]/26
ABBV-951 CSCI	0.83	0.86	0.8	60	0.3	[redacted]/28
ABBV-951 CSCI	0.86	0.89	0.83	60	0.3	[redacted]/39
ABBV-951 CSCI	0.83	0.86	0.8	60	0.3	[redacted]/77
ABBV-951 CSCI	0.83	0.86	0.8	60	0.3	[redacted]/94
ABBV-951 CSCI	0.83	0.86	0.8	75	0.3	[redacted]/120
ABBV-951 CSCI	0.83	0.86	0.8	60	0.3	[redacted]/184
ABBV-951 CSCI	0.7	0.75	0.58	90	0.3	[redacted]/234
ABBV-951 CSCI	0.63	0.7	0.58	90	0.3	[redacted]/248
ABBV-951 CSCI	0.6	0.63	0.58	90	0.3	[redacted]/276

ABBV-951 CSCI	0.53	0.58	0.42	60	0.3	[redacted]20[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]20[redacted] / 8	
ABBV-951	1482.11		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 9	
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	3072.81		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	3688.2		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	3605.72		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	3401.34		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[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]-[redacted]
METFORMIN	850 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]-[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	2.100 mg	QD	Y-M: 20[redacted]-[redacted]
SIMVASTATIN	10 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]-[redacted]

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;THIAMINE HYDROCHLORIDE	1 OTHER: TABLET	QD	Y-M: 20[redacted] / 24	ONGOING

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 28): ABDOMINAL ULTRASOUNDS:NOT ABSCESS. SUBCUTANEOUS TISSUE CHANGES RELATED TO CELLULITIS PROCES

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.23	0.28	0.18	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/7
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/14
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/21
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/26
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/42
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/91
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/181
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/217
ABBV-951 CSCI	0.25	0.28	0.2	60	0.11	[redacted]20[redacted]/280
ABBV-951 CSCI	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]20[redacted] / 7	[redacted]20[redacted] / 7

ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	307.35	SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	721.41	SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	298.81	SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	670.19	SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	396.99	SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	704.34	SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
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ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 179	
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 180	
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 188
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 205
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 212	[redacted]20[redacted] / 212

ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 213	[redacted] / 213
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 214	[redacted] / 214
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 215	[redacted] / 215
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 216	[redacted] / 216
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 217	[redacted] / 217
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 218	[redacted] / 218
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 219	[redacted] / 219
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 220	[redacted] / 220
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 221	[redacted] / 221
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 222	[redacted] / 222
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 223	[redacted] / 223
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 224	[redacted] / 224
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 225	[redacted] / 225
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 226	[redacted] / 226
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 227	[redacted] / 227
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 228	[redacted] / 228
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 229	[redacted] / 229
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 230	[redacted] / 230
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 231	[redacted] / 231
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 232	[redacted] / 232
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 233	[redacted] / 233
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 234	[redacted] / 234
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 235	[redacted] / 235
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 236	[redacted] / 236
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 237	[redacted] / 237
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 238	[redacted] / 238
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 239	[redacted] / 239
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 240	[redacted] / 240
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 241	[redacted] / 241
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 242	[redacted] / 242
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 243	[redacted] / 243
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 244	[redacted] / 244
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 245	[redacted] / 245
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 246	[redacted] / 246
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 247	[redacted] / 247
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 248	[redacted] / 248
ABBV-951	1024.5	SC /CONTINUOUS	[redacted] / 249	[redacted] / 249

ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	414.06	SC /CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	695.80	SC /CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	286.00	SC /CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	665.92	SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	439.68	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
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] / 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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 217): ABDOMEN X-RAY:NO FINDINGS; CHEST X-RAY:PARENCHYMAL OPACITIES OF RETROCARDIAC LOCATION AND LEFT BASAL LUNG THAT COULD BE RELATED TO INCIPIENT INFECTIOUS PROCESS; [redacted]20[redacted] (RX DAY 222): CHEST CT:SUPERINFECTED BRONCHIECTASIS; [redacted]20[redacted] (RX DAY 231): WHOLE-BODY PET-SCAN:BILATERAL BRONCHIECTASIS PROBABLY SUPERINFECTED

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]:19:57

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] 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 SPECIAL INTEREST

Weight Decreased: Day 1 weight 6[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 CSCI	0.5	0	0	720	0.19	[redacted]/1
ABBV-951 CSCI	0.5	0	0	720	0.19	[redacted]/2
ABBV-951 CSCI	0.45	0	0	720	0.19	[redacted]/3
ABBV-951 CSCI	0.45	0	0	720	0.19	[redacted]/9
ABBV-951 CSCI	0.45	0.41	0.37	720	0.19	[redacted]/16
ABBV-951 CSCI	0.45	0.41	0.37	720	0.19	[redacted]/23
ABBV-951 CSCI	0.41	0	0	720	0.19	[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] / 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	1828.73		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	1680.18		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		32.44	SC /ONCE	[redacted] / 23	
ABBV-951	1516.26		SC /CONTINUOUS	[redacted] / 23	[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]
CARBIDOPA MONOHYDRATE;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]
TRIHEXYPHENIDYL	2.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.700 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
CYANOCOBALAMIN	1000 ug	OTHER: MONTHLY	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -263
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted] / -231
APOMORPHINE	3.000 mg	PRN	Y-M: 20[redacted] / -140
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted] / -31
CYANOCOBALAMIN	1000 ug	OTHER: EVERY WEEK	Y-M: 20[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]	ONGOING
CYANOCOBALAMIN	1000 ug	QD	Y-M: 20[redacted] / -31	Y-M: 20[redacted] / -25
CYANOCOBALAMIN	1000 ug	OTHER: EVERY WEEK	Y-M: 20[redacted] / -24	ONGOING
LORAZEPAM	1 mg	QD	Y-M: 20[redacted] / 2	Y-M: 20[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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 2): CRANIAL CT-SCAN:NORMAL	
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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 2): CRANIAL CT-SCAN:NORMAL	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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 CSCI	0.37	0	0	60	0.3	[redacted]20[redacted]/1
ABBV-951 CSCI	0.3	0	0	60	0.3	[redacted]20[redacted]/2
ABBV-951 CSCI	0.33	0	0	60	0.3	[redacted]20[redacted]/8
ABBV-951 CSCI	0.33	0	0	60	0.3	[redacted]20[redacted]/15
ABBV-951 CSCI	0.3	0	0	60	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.33	0	0	60	0.3	[redacted]20[redacted]/29
ABBV-951 CSCI	0.33	0	0	60	0.3	[redacted]20[redacted]/43
ABBV-951 CSCI	0.33	0	0	60	0.3	[redacted]20[redacted]/92
ABBV-951 CSCI	0.25	0	0	60	0.3	[redacted]20[redacted]/156
ABBV-951 CSCI	0.27	0	0	60	0.3	[redacted]20[redacted]/176
ABBV-951 CSCI	0.27	0	0	60	0.3	[redacted]20[redacted]/184
ABBV-951 CSCI	0.3	0	0	60	0.3	[redacted]20[redacted]/281
ABBV-951 CSCI	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] / 18	[redacted] / 18
ABBV-951		204.9	SC /ONCE	[redacted] / 19	
ABBV-951	1324.16		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		204.9	SC /ONCE	[redacted] / 20	
ABBV-951	1267.81		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		256.12	SC /ONCE	[redacted] / 21	
ABBV-951	1312.89		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		256.12	SC /ONCE	[redacted] / 22	
ABBV-951	1200.71		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		256.12	SC /ONCE	[redacted] / 23	
ABBV-951	1178.17		SC /CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		153.67	SC /ONCE	[redacted] / 24	
ABBV-951	1162.80		SC /CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		358.57	SC /ONCE	[redacted] / 25	
ABBV-951	1178.17		SC /CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951		256.12	SC /ONCE	[redacted] / 26	
ABBV-951	1193.54		SC /CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		153.67	SC /ONCE	[redacted] / 27	
ABBV-951	1024.5		SC /CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		102.45	SC /ONCE	[redacted] / 28	
ABBV-951	1173.05		SC /CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951		51.22	SC /ONCE	[redacted] / 29	
ABBV-951	1257.57		SC /CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951		51.22	SC /ONCE	[redacted] / 30	
ABBV-951	1346.70		SC /CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		256.12	SC /ONCE	[redacted] / 31	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951		102.45	SC /ONCE	[redacted] / 32	
ABBV-951	1329.80		SC /CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951		51.22	SC /ONCE	[redacted] / 33	
ABBV-951	1250.91		SC /CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951		102.45	SC /ONCE	[redacted] / 34	
ABBV-951	1312.89		SC /CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951		256.12	SC /ONCE	[redacted] / 35	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951		153.67	SC /ONCE	[redacted] / 36	
ABBV-951	1318.53		SC /CONTINUOUS	[redacted] / 36	[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
ABBV-951		51.22	SC /ONCE	[redacted] / 85	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951		51.22	SC /ONCE	[redacted] / 86	
ABBV-951	828.30		SC /CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951		102.45	SC /ONCE	[redacted] / 87	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		51.22	SC /ONCE	[redacted] / 88	
ABBV-951	1183.29		SC /CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		153.67	SC /ONCE	[redacted] / 89	
ABBV-951	1070.60		SC /CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951		102.45	SC /ONCE	[redacted] / 90	
ABBV-951	1239.64		SC /CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951		153.67	SC /ONCE	[redacted] / 91	
ABBV-951	50.71		SC /CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951		256.12	SC /ONCE	[redacted] / 92	
ABBV-951	1031.15		SC /CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		51.22	SC /ONCE	[redacted] / 93	

ABBV-951	1267.81		SC /CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		102.45	SC /ONCE	[redacted] / 94	
ABBV-951	1279.08		SC /CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951		51.22	SC /ONCE	[redacted] / 95	
ABBV-951	1312.89		SC /CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		153.67	SC /ONCE	[redacted] / 96	
ABBV-951	1188.93		SC /CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		102.45	SC /ONCE	[redacted] / 97	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951		256.12	SC /ONCE	[redacted] / 98	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951		102.45	SC /ONCE	[redacted] / 99	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951		153.67	SC /ONCE	[redacted] / 100	
ABBV-951	1256.54		SC /CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951		153.67	SC /ONCE	[redacted] / 101	
ABBV-951	1329.80		SC /CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951		204.9	SC /ONCE	[redacted] / 102	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951		102.45	SC /ONCE	[redacted] / 103	
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951		153.67	SC /ONCE	[redacted] / 104	
ABBV-951	1318.53		SC /CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951		204.9	SC /ONCE	[redacted] / 105	
ABBV-951	1008.62		SC /CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951		153.67	SC /ONCE	[redacted] / 106	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 106	[redacted] / 106
ABBV-951		153.67	SC /ONCE	[redacted] / 107	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951		51.22	SC /ONCE	[redacted] / 108	
ABBV-951	1239.64		SC /CONTINUOUS	[redacted] / 108	[redacted] / 108
ABBV-951		153.67	SC /ONCE	[redacted] / 109	
ABBV-951	1324.16		SC /CONTINUOUS	[redacted] / 109	[redacted] / 109
ABBV-951		358.57	SC /ONCE	[redacted] / 110	
ABBV-951	1183.29		SC /CONTINUOUS	[redacted] / 110	[redacted] / 110
ABBV-951		153.67	SC /ONCE	[redacted] / 111	
ABBV-951	1295.99		SC /CONTINUOUS	[redacted] / 111	[redacted] / 111

ABBV-951		153.67	SC /ONCE	[redacted] / 112
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 112 [redacted] / 112
ABBV-951		51.22	SC /ONCE	[redacted] / 113
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 113 [redacted] / 113
ABBV-951		153.67	SC /ONCE	[redacted] / 114
ABBV-951	1036.79		SC /CONTINUOUS	[redacted] / 114 [redacted] / 114
ABBV-951		204.9	SC /ONCE	[redacted] / 115
ABBV-951	822.67		SC /CONTINUOUS	[redacted] / 115 [redacted] / 115
ABBV-951		204.9	SC /ONCE	[redacted] / 116
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 116 [redacted] / 116
ABBV-951		153.67	SC /ONCE	[redacted] / 117
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 117 [redacted] / 117
ABBV-951		102.45	SC /ONCE	[redacted] / 118
ABBV-951	1290.35		SC /CONTINUOUS	[redacted] / 118 [redacted] / 118
ABBV-951		153.67	SC /ONCE	[redacted] / 119
ABBV-951	1352.34		SC /CONTINUOUS	[redacted] / 119 [redacted] / 119
ABBV-951		256.12	SC /ONCE	[redacted] / 120
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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] / 343	[redacted] / 343
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 344	[redacted] / 344
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 345	[redacted] / 345
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 346	[redacted] / 346
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 347	[redacted] / 347
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 348	[redacted] / 348
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 349	[redacted] / 349
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 350	[redacted] / 350
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 351	[redacted] / 351
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 352	[redacted] / 352
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 353	[redacted] / 353
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 354	[redacted] / 354
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 355	[redacted] / 355
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 356	[redacted] / 356
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 357	[redacted] / 357
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 358	[redacted] / 358
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 359	[redacted] / 359
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 360	[redacted] / 360
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 361	[redacted] / 361
ABBV-951	1126.95	SC /CONTINUOUS	[redacted] / 362	[redacted] / 362
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	1229.4	SC /CONTINUOUS	[redacted] / 364	[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]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
ROTIGOTINE	NOT REPORTED	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	3.000 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	100.000 mg	QD	Y-M: 20[redacted]
APOMORPHINE	16.000 mg	QD	Y-M: 20[redacted]
ALPRAZOLAM	0.25 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	1.050 mg	QD	Y-M: 20[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 259): ABDOMINAL CT:TRABECULATION OF RIGHT GLUTEAL FAT WITH FLUID SHEET AND AIR BUBBLE SUGGESTIVE OF ABSCESS; DEBRIDEMENT OF THE ABSCESS IN THE GLUTEUS MAXIMUS:THE ABSCESS WAS CLEAN

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	
SAE Supplemental Procedure	
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-CV-2: NEGATIVE	
SAE Supplemental Procedure	
NOT REPORTED	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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])

AMANTADINE for PARKINSON'S DISEASE ([redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted])

STALEVO for PARKINSONS DISEASE ([redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted])

ZONISAMIDE for PARKINSON'S DISEASE ([redacted])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted])

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

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([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 SPECIAL 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 CSCI	0.5	0.6	0.4	5	0.3	[redacted]20[redacted]/1
ABBV-951 CSCI	0.5	0.55	0.45	5	0.3	[redacted]20[redacted]/3
ABBV-951 CSCI	0.55	0.6	0.5	5	0.3	[redacted]20[redacted]/8
ABBV-951 CSCI	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/15
ABBV-951 CSCI	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.6	0.65	0.55	5	0.3	[redacted]20[redacted]/29
ABBV-951 CSCI	0.58	0.65	0.55	5	0.3	[redacted]20[redacted]/45
ABBV-951 CSCI	0.58	0.61	0.55	60	0.3	[redacted]20[redacted]/92
ABBV-951 CSCI	0.62	0.63	0.61	60	0.24	[redacted]20[redacted]/135
ABBV-951 CSCI	0.58	0.61	0.55	60	0.15	[redacted]20[redacted]/183
ABBV-951 CSCI	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
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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
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ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
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ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
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ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[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]-[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 HYDROXOCOBALAMINHYDROCHLORIDE, 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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 267): CHEST X-RAY:NO RADIOLOGICAL SIGNS OF ACUTE PLEUROPULMONARY PATHOLOGY.; [redacted]20[redacted] (RX DAY 274): CHEST X-RAY.:NO RADIOLOGICAL SIGNS OF ACUTE PLEUROPULMONARY PATHOLOGY.; [redacted]20[redacted] (RX DAY 275): CRANIAL CT:NO RADIOLOGICAL SIGNS OF ACUTE INTRACRANIAL PATHOLOGY.; [redacted]20[redacted] (RX DAY 287): CHEST X-RAY:NO RADIOLOGICAL SIGNS OF ACUTE PLEUROPULMONARY PATHOLOGY.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 277): EEG:NO PAROXISTIC ACTIVITY.; [redacted]20[redacted] (RX DAY 300): ECG:NORMAL.; [redacted]20[redacted] (RX DAY 303): EEG:NO PAROXISTIC ACTIVITY.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 267): CHEST X-RAY:NO RADIOLOGICAL SIGNS OF ACUTE PLEUROPULMONARY PATHOLOGY.; [redacted]20[redacted] (RX DAY 274): CHEST X-RAY.:NO RADIOLOGICAL SIGNS OF ACUTE

PLEUROPULMONARY PATHOLOGY.; [redacted]20[redacted] (RX DAY 275): CRANIAL CT:NO RADIOLOGICAL SIGNS OF ACUTE INTRACRANIAL PATHOLOGY.; [redacted]20[redacted] (RX DAY 287): CHEST X-RAY:NO RADIOLOGICAL SIGNS OF ACUTE PLEUROPULMONARY PATHOLOGY.

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]:19:57

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 SPECIAL INTEREST

Cachexia: Day 1 weight 6[redacted].[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 2007).	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 CSCI	0.6	0.63	0.57	60	0.3	[redacted]/1
ABBV-951 CSCI	0.62	0.65	0.59	60	0.3	[redacted]/3
ABBV-951 CSCI	0.58	0.59	0.57	60	0.3	[redacted]/5
ABBV-951 CSCI	0.55	0.56	0.54	60	0.3	[redacted]/8
ABBV-951 CSCI	0.55	0.56	0.54	60	0.3	[redacted]/10
ABBV-951 CSCI	0.5	0.53	0.47	60	0.3	[redacted]/11
ABBV-951 CSCI	0.56	0.59	0.53	30	0.3	[redacted]/15
ABBV-951 CSCI	0.56	0.59	0.53	30	0.3	[redacted]/22
ABBV-951 CSCI	0.56	0.58	0.54	60	0.3	[redacted]/26
ABBV-951 CSCI	0.54	0.58	0.5	60	0.3	[redacted]/29
ABBV-951 CSCI	0.5	0.51	0.49	60	0.3	[redacted]/32
ABBV-951 CSCI	0.49	0.5	0.48	60	0.3	[redacted]/46
ABBV-951 CSCI	0.45	0.46	0.44	60	0.3	[redacted]/80
ABBV-951 CSCI	0.45	0.46	0.44	60	0.3	[redacted]/92
ABBV-951 CSCI	0.41	0.42	0.4	60	0.3	[redacted]/170
ABBV-951 CSCI	0.41	0.42	0.4	60	0.3	[redacted]/183
ABBV-951 CSCI	0.41	0.42	0.4	60	0.3	[redacted]/274
ABBV-951 CSCI	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

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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
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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
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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
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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
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ABBV-951	1680.18	SC /CONTINUOUS	[redacted] / 332	[redacted] / 332
ABBV-951	1680.18	SC /CONTINUOUS	[redacted] / 333	[redacted] / 333
ABBV-951	1680.18	SC /CONTINUOUS	[redacted] / 334	[redacted] / 334
ABBV-951	1680.18	SC /CONTINUOUS	[redacted] / 335	[redacted] / 335
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ABBV-951	1645.17	SC /CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	1645.17	SC /CONTINUOUS	[redacted] / 364	[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]
FLUOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.700 mg	QID	Y-M: 20[redacted]
OLANZAPINE	2.5 mg	QD	Y-M: 20[redacted]
TROSPIUM CHLORIDE	20 mg	BID	Y-M: 20[redacted]
LEVOTHYROXINE SODIUM	50 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	BID	Y-M: 20[redacted]
SAFINAMIDE	100.000 mg	QD	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	QID	Y-M: 20[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted] / -152
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / -117
HYDROXOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE;THIAMINE HYDROCHLORIDE	250/250/500 mg	TID	Y-M: 20[redacted] / -117

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 SPECIAL INTEREST

Weight Decreased: Day 1 weight 9[redacted].[redacted] kg, weight at time of event 8[redacted].[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 CSCI	0.37	0.44	0	60	0.3	[redacted]/1
ABBV-951 CSCI	0.37	0.44	0	60	0.3	[redacted]/2
ABBV-951 CSCI	0.37	0.44	0	60	0.3	[redacted]/3
ABBV-951 CSCI	0.45	0.54	0	60	0.3	[redacted]/9
ABBV-951 CSCI	0.5	0.6	0	60	0.3	[redacted]/12
ABBV-951 CSCI	0.38	0.45	0	60	0.3	[redacted]/15
ABBV-951 CSCI	0.38	0.45	0	60	0.3	[redacted]/22
ABBV-951 CSCI	0.41	0.49	0	60	0.3	[redacted]/25
ABBV-951 CSCI	0.52	0.6	0.49	60	0.3	[redacted]/28
ABBV-951 CSCI	0.52	0.6	0.49	60	0.3	[redacted]/32
ABBV-951 CSCI	0.6	0.65	0.5	60	0.3	[redacted]/43
ABBV-951 CSCI	0.6	0.65	0.55	60	0.3	[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] / 1	[redacted] / 1
ABBV-951	1503.62		SC /CONTINUOUS	[redacted] / 2	[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 HYDROCHLORIDE	3 mg	PRN	Y-M: 20[redacted] / 119	ONGOING
MORPHINE HYDROCHLORIDE	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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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 #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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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: 0.31 [0.4 - 1.1] 10^9/L; MONOCYTES: 0.3 [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 [4.1 - 5.9] MMOL/L; GLUCOSE: 10 [3.9 - 6.1] MMOL/L; GLUCOSE: 7 [4.6 - 6.4] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 104 [120 - 155] G/L; HEMOGLOBIN: 109 [120 - 160] 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: 109 [120 - 160] G/L; HEMOGLOBIN: 106 [120 - 155] 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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 58): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY; [redacted]20[redacted] (RX DAY 59): BRAIN MAGNETIC RESONANCE:CORTICO-SUBCORTICAL ATROPHY WITH FRONTAL PREDOMINANCE STAGE 1 CHRONIC SMALL VESSEL ISCHEMIA; NASOGASTRIC INTUBATION:NASOGASTRIC TUBE END PLACED IN GASTRIC CHAMBER; [redacted]20[redacted] (RX DAY 60): X-RAY ABDOMEN:ABUNDANT FECAL IMPACTION IN RECTAL AMPOULE MILD DISTENSION OF THE TRANSVERSE COLON NASOGASTRIC TUBE END IN GASTRIC CHAMBER; [redacted]20[redacted] (RX DAY 64): CHEST ABDOMEN PELVIS CT SCAN WITH CONTRAST:CHEST: DEFECTS IN PULMONARY VASCULARIZATION IN RELATION TO VTE ABDOMEN-PELVIS: OBSTRUCTIVE LITHIASIS URINARY IN DISTAL THIRD (6-7MM) ABUNDANT FECALOID CONTENTS IN RECTAL AMPOULE; VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY TO A LESSER DEGREE THAN PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 65): DOPPLER COLOR ECHOCARDIOGRAPHY:MILD LEFT VENTRICULAR HYPERTROPHY; NASODUODENAL TUBE:PLACED NASODUODENAL TUBE; [redacted]20[redacted] (RX DAY 66): NASOGASTRIC TUBE:PLACED NASOGASTRIC TUBE; VENOUS DOPPLER LOWER LIMBS:RESULTS COMPATIBLE WITH DEEP VEIN THROMBOSIS; [redacted]20[redacted] (RX DAY 67): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY TO A GREATER DEGREE WITH ELECTROPHYSIOLOGICAL WORSENING; [redacted]20[redacted] (RX DAY 68): ANGIO-MAGNETIC RESONANCE IMAGING OF SUPRA-AORTIC TRUNKS:STUDY WITHOUT SIGNIFICANT RESULTS; ANGIO-MAGNETIC RESONANCE IMAGING OF WILLIS POLYGON:NO SIGNIFICANT RESULTS; BRAIN MAGNETIC RESONANCE:UNCHANGED COMPARED TO PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 72): VIDEO-ELECTROENCEPHALOGRAPHY:WITHOUT ELECTROPHYSIOLOGICAL CHANGES WITH RESPECT TO PREVIOUS CONTROL ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 80): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY WITH MARKED IMPROVEMENT IN BRAIN BIOELECTRICAL ACTIVITY; [redacted]20[redacted] (RX DAY 100): BRAIN MAGNETIC RESONANCE IMAGING:UNCHANGED FROM PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 106): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY WITH WORSENING ELECTROPHYSIOLOGICAL RECORD

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	
SAE Supplemental Procedure	
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: 0.31 [0.4 - 1.1] 10^9/L; MONOCYTES: 0.3 [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 [4.1 - 5.9] MMOL/L; GLUCOSE: 10 [3.9 - 6.1] MMOL/L; GLUCOSE: 7 [4.6 - 6.4] MMOL/L; HEMATOCRIT: 0.33 [0.35 - 0.45] FRACTION OF 1; HEMOGLOBIN: 104 [120 - 155] G/L; HEMOGLOBIN: 109 [120 - 160] 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: 109 [120 - 160] G/L; HEMOGLOBIN: 106 [120 - 155] 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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 58): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY; [redacted]20[redacted] (RX DAY 59): BRAIN MAGNETIC RESONANCE:CORTICO-SUBCORTICAL ATROPHY WITH FRONTAL PREDOMINANCE STAGE 1 CHRONIC SMALL VESSEL ISCHEMIA; NASOGASTRIC INTUBATION:NASOGASTRIC TUBE END PLACED IN GASTRIC CHAMBER; [redacted]20[redacted] (RX DAY 60): X-RAY ABDOMEN:ABUNDANT FECAL IMPACTION IN RECTAL AMPOULE MILD DISTENSION OF THE TRANSVERSE COLON NASOGASTRIC TUBE END IN GASTRIC CHAMBER; [redacted]20[redacted] (RX DAY 64): CHEST ABDOMEN PELVIS CT SCAN WITH CONTRAST:CHEST: DEFECTS IN PULMONARY VASCULARIZATION IN RELATION TO VTE ABDOMEN-PELVIS: OBSTRUCTIVE LITHIASIS URINARY IN DISTAL THIRD (6-7MM) ABUNDANT FECALOID CONTENTS IN RECTAL AMPOULE; VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY TO A LESSER DEGREE THAN PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 65): DOPPLER COLOR ECHOCARDIOGRAPHY:MILD LEFT VENTRICULAR HYPERTROPHY; NASODUODENAL TUBE:PLACED NASODUODENAL TUBE; [redacted]20[redacted] (RX DAY 66): NASOGASTRIC TUBE:PLACED NASOGASTRIC TUBE; VENOUS DOPPLER LOWER LIMBS:RESULTS COMPATIBLE WITH DEEP VEIN THROMBOSIS; [redacted]20[redacted] (RX DAY 67): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY TO A GREATER DEGREE WITH ELECTROPHYSIOLOGICAL WORSENING; [redacted]20[redacted] (RX DAY 68): ANGIO-MAGNETIC RESONANCE IMAGING OF SUPRA-AORTIC TRUNKS:STUDY WITHOUT SIGNIFICANT RESULTS; ANGIO-MAGNETIC RESONANCE IMAGING OF WILLIS POLYGON:NO SIGNIFICANT RESULTS; BRAIN MAGNETIC RESONANCE:UNCHANGED COMPARED TO PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 72): VIDEO-ELECTROENCEPHALOGRAPHY:WITHOUT ELECTROPHYSIOLOGICAL CHANGES WITH RESPECT TO PREVIOUS CONTROL ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 80): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY WITH MARKED IMPROVEMENT IN BRAIN BIOELECTRICAL ACTIVITY; [redacted]20[redacted] (RX DAY 100): BRAIN MAGNETIC RESONANCE IMAGING:UNCHANGED FROM PREVIOUS STUDY ([redacted]/[redacted]/20[redacted]); [redacted]20[redacted] (RX DAY 106): VIDEO-ELECTROENCEPHALOGRAPHY:ENCEPHALOPATHY WITH WORSENING ELECTROPHYSIOLOGICAL RECORD

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]:19:57
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] 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 CSCI	0.3	0.36	0	60	0.3	[redacted]/1
ABBV-951 CSCI	0.29	0.35	0	60	0.3	[redacted]/2
ABBV-951 CSCI	0.35	0.42	0	60	0.3	[redacted]/8
ABBV-951 CSCI	0.48	0.57	0.4	60	0.3	[redacted]/11
ABBV-951 CSCI	0.48	0.57	0.4	60	0.3	[redacted]/15
ABBV-951 CSCI	0.61	0.7	0.55	60	0.3	[redacted]/25
ABBV-951 CSCI	0.65	0.7	0.6	60	0.3	[redacted]/29
ABBV-951 CSCI	0.65	0.7	0.6	60	0.3	[redacted]/35
ABBV-951 CSCI	0.75	0.8	0.7	60	0.3	[redacted]/42
ABBV-951 CSCI	0.7	0.75	0.65	60	0.3	[redacted]/44
ABBV-951 CSCI	0.75	0.8	0.7	60	0.3	[redacted]/71
ABBV-951 CSCI	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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	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 #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	
SAE Supplemental Procedure	
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 Adversary 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	
SAE Supplemental Procedure	
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]:19:57
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])

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted])

RASAGILINE for PARKINSON'S DISEASE ([redacted])

MADOPAR for PARKINSON'S DISEASE ([redacted])

SINEMET CR for PARKINSON'S DISEASE ([redacted])

SAFINAMIDE for PARKINSON'S DISEASE ([redacted])

APOMORPHINE for PARKINSON'S DISEASE ([redacted])

DUODOPA for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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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 CSCI	0.37	0.45	0.3	60	0.3	[redacted]/1
ABBV-951 CSCI	0.4	0.45	0.35	60	0.3	[redacted]/2
ABBV-951 CSCI	0.45	0.5	0.4	60	0.3	[redacted]/8
ABBV-951 CSCI	0.43	0.47	0.4	60	0.3	[redacted]/17
ABBV-951 CSCI	0.43	0.47	0.4	60	0.3	[redacted]/24
ABBV-951 CSCI	0.43	0.47	0.4	60	0.3	[redacted]/31
ABBV-951 CSCI	0.4	0.43	0.37	60	0.3	[redacted]/85
ABBV-951 CSCI	0.35	0.4	0.28	60	0.19	[redacted]/95
ABBV-951 CSCI	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] / 31	[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]20[redacted] / 68	[redacted]20[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] / 105	[redacted] / 105

ABBV-951	1516.26	SC /CONTINUOUS	[redacted] / 106	[redacted] / 106
ABBV-951	1516.26	SC /CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951	1516.26	SC /CONTINUOUS	[redacted] / 108	[redacted] / 108
ABBV-951	1470.15	SC /CONTINUOUS	[redacted] / 109	[redacted] / 109
ABBV-951	1386.49	SC /CONTINUOUS	[redacted] / 110	[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: [redacted]
LORAZEPAM	1 mg	BID	Y-M: [redacted]
LEVOTHYROXINE SODIUM	25 ug	QD	Y-M: [redacted]
ROTIGOTINE	16.000 mg	QD	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	TID	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	TID	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	125.000 mg	QID	Y-M: [redacted]
OPICAPONE	50.000 mg	QD	Y-M: [redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	125.000 mg	BID	Y-M: [redacted] / -255
CARBIDOPA MONOHYDRATE;LEVODOPA	250.000 mg	BID	Y-M: [redacted] / -255
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	QID	Y-M: [redacted] / -244
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	5 TIMES PER DAY	Y-M: [redacted] / -236
CYANOCOBALAMIN	1000 ug	QD	Y-M: [redacted] / -46
FOLIC ACID	5 mg	QD	Y-M: [redacted] / -46
CYANOCOBALAMIN	1000 ug	QD	Y-M: [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: [redacted]	ONGOING
LORAZEPAM	1 mg	BID	Y-M: [redacted]	ONGOING
LEVOTHYROXINE SODIUM	25 ug	QD	Y-M: [redacted]	ONGOING
FOLIC ACID	5 mg	QD	Y-M: [redacted] / -46	Y-M: [redacted] / -17
CYANOCOBALAMIN	1000 ug	QD	Y-M: [redacted] / -6	Y-M: [redacted] / -1
CEFUROXIME AXETIL	500 mg	BID	Y-M: [redacted] / 17	Y-M: [redacted] / 23
CIPROFLOXACIN	400 mg	BID	Y-M: [redacted] / 25	Y-M: [redacted] / 27
OLANZAPINE	10 mg	PRN	Y-M: [redacted] / 25	Y-M: [redacted] / 27
PARACETAMOL	1000 mg	PRN	Y-M: [redacted] / 25	Y-M: [redacted] / 27
TIAPRIDE	100 mg	PRN	Y-M: [redacted] / 25	Y-M: [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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 17): CHEST X-RAY:NO CONDENSATIONS OR SPILLS

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	
SAE Supplemental Procedure	
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: 135 [120 - 160] G/L; HEMOGLOBIN: 133 [120 - 155] 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

SAE Supplemental Procedure

NOT REPORTED

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: 135 [120 - 160] G/L; HEMOGLOBIN: 133 [120 - 155] 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

SAE Supplemental Procedure

NOT REPORTED

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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] 20[redacted] - [redacted] 20[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 CSCI	0.38	0.41	0.33	60	0.24	[redacted]/1
ABBV-951 CSCI	0.38	0.41	0.33	60	0.24	[redacted]/2
ABBV-951 CSCI	0.45	0.5	0.41	60	0.3	[redacted]/8
ABBV-951 CSCI	0.5	0.55	0.45	60	0.3	[redacted]/15
ABBV-951 CSCI	0.5	0.55	0.45	60	0.3	[redacted]/23
ABBV-951 CSCI	0.5	0.55	0.45	60	0.3	[redacted]/30
ABBV-951 CSCI	0.5	0.55	0.45	60	0.3	[redacted]/44
ABBV-951 CSCI	0.55	0.62	0.5	60	0.3	[redacted]/93
ABBV-951 CSCI	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] / 27	[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	
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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]-[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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 155): ELECTRO CONVULSIVE THERAPY, ECT FOUR TREATMENTS: [redacted]20[redacted], [redacted]20[redacted], [redacted]20[redacted] AND [redacted]20[redacted]:COMPLETE REMISSION OF PARANOID DELUSIONS

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]:19:57
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
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 CSCI	0.47	0.48	0.46	60	0.19	[redacted]/1
ABBV-951 CSCI	0.47	0.48	0.46	60	0.19	[redacted]/2
ABBV-951 CSCI	0.47	0.48	0.46	60	0.19	[redacted]/8
ABBV-951 CSCI	0.47	0.48	0.46	60	0.19	[redacted]/15
ABBV-951 CSCI	0.49	0.5	0.48	60	0.24	[redacted]/22
ABBV-951 CSCI	0.49	0.5	0.48	60	0.24	[redacted]/27
ABBV-951 CSCI	0.5	0.51	0.48	60	0.24	[redacted]/44
ABBV-951 CSCI	0.51	0.52	0.5	60	0.3	[redacted]/62
ABBV-951 CSCI	0.51	0.52	0.5	60	0.3	[redacted]/93
ABBV-951 CSCI	0.52	0.53	0.51	60	0.3	[redacted]/101
ABBV-951 CSCI	0.53	0.54	0.52	60	0.3	[redacted]/175
ABBV-951 CSCI	0.55	0.56	0.54	60	0.3	[redacted]/183
ABBV-951 CSCI	0.58	0.59	0.57	60	0.3	[redacted]/213
ABBV-951 CSCI	0.6	0.61	0.58	60	0.3	[redacted]/239
ABBV-951 CSCI	0.62	0.63	0.59	60	0.3	[redacted]/266
ABBV-951 CSCI	0.62	0.63	0.59	60	0.3	[redacted]/274
ABBV-951 CSCI	0.63	0.64	0.62	60	0.3	[redacted]/309
ABBV-951 CSCI	0.64	0.65	0.63	60	0.3	[redacted]/316

ABBV-951 CSCI	0.65	0.66	0.64	60	0.3	[redacted]/357
ABBV-951 CSCI	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] / 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
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ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
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ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
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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
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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
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ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 362	

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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] / 176	Y-M: 20[redacted] / 176
LOW MOLECULAR WEIGHT HEPARIN	60 mg	OTHER: ONCE	Y-M: 20[redacted] / 176	Y-M: 20[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	
SAE Supplemental Procedure	
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 [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	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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 169): CHEST X-RAY:NO KNOWN PROBLEMS RECORDED ON CRF; ECG:SAME AS BASELINE - (SINUS BRADYCARDIA AND RBBB NOTED).

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 169): CHEST X-RAY:NO KNOWN PROBLEMS RECORDED ON CRF; ECG:SAME AS BASELINE - (SINUS BRADYCARDIA AND RBBB NOTED).

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 169): CHEST X-RAY:NO KNOWN PROBLEMS RECORDED ON CRF; ECG:SAME AS BASELINE - (SINUS BRADYCARDIA AND RBBB NOTED).

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	
SAE Supplemental Procedure	
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 [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship 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	
SAE Supplemental Procedure	
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 Adverse 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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 249): CHEST X-RAY:THE HEART SIZE AND MEDIASTINAL CONTOURS ARE NORMAL. THE LUNGS ARE CLEAR.; ECG:SINUS RHYTHM WITH RIGHT BRANCH BUNDLE BLOCK (NOT NEW); HEART ECHO:SHOWED EF 71% AND NO STRUCTURAL HEART PROBLEMS. NORMAL VALVE FUNCTION.

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57
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])

LEVODOPA/BENSERAZIDE CONTROLLED RELEASE for PARKINSONS DISEASE ([redacted])

LEVODOPA/BENSERAZIDE DISPERSIBLE for PARKINSON'S DISEASE and RESCUE MEDICINE ([redacted])

LEVODOPA/BENSERAZIDE STANDARD for PARKINSONS DISEASE ([redacted])

OPICAPONE for PARKINSON'S DISEASE ([redacted])

ROTIGOTINE for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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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 CSCI	0.4	0	0	0	0	[redacted]/1
ABBV-951 CSCI	0.5	0	0	0	0	[redacted]/2
ABBV-951 CSCI	0.65	0	0	60	0.11	[redacted]/9
ABBV-951 CSCI	0.65	0	0	60	0.11	[redacted]/16
ABBV-951 CSCI	0	0	0	0	0	[redacted]/22

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 CSCI	0.45	0	0	60	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.55	0	0	60	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	0.55	0	0	60	0.15	[redacted]20[redacted]/42
ABBV-951 CSCI	0.45	0.55	0.35	61	0.15	[redacted]20[redacted]/43
ABBV-951 CSCI	0.4	0.5	0.3	60	0.15	[redacted]20[redacted]/209
ABBV-951 CSCI	0.3	0.25	0.35	360	0.11	[redacted]20[redacted]/306
ABBV-951 CSCI	0.3	0.25	0.35	360	0.11	[redacted]20[redacted]/387
ABBV-951 CSCI	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]20[redacted] / 1	
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1844.1		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	1844.1		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	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1844.1		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[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
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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
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ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 234	
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ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 235	
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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	
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ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 241	
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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	
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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	
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ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 261	
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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
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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	
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ABBV-951	1214.03		SC /CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
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ABBV-951	1167.93		SC /CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
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ABBV-951	1224.27		SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
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ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 331	
ABBV-951	1224.27		SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
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ABBV-951	1224.27		SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 335	
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ABBV-951	1126.95		SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 337	
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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
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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
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ABBV-951		18.78	SC /ONCE	[redacted] / 356	
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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
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ABBV-951	1229.4		SC /CONTINUOUS	[redacted] / 362	[redacted] / 362
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ABBV-951		37.56	SC /ONCE	[redacted] / 364	
ABBV-951	1224.27		SC /CONTINUOUS	[redacted] / 364	[redacted] / 364
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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
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ABBV-951	1229.4		SC /CONTINUOUS	[redacted] / 381	[redacted] / 381
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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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 4): VENTILATION ON ICU BECAUSE OF RESPIRATORY FAILURE:WEANED FROM NIV ON [redacted]/[redacted]/20[redacted]. RESPIRATORY FAILURE IMPROVED AND NO LONGER REQUIRING VENTILATION.

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	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 #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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 268): COVID-19 PCR:NEGATIVE; HEAD CT:DID NOT SHOW ANY ACUTE CHANGES (NORMAL)

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	
SAE Supplemental Procedure	
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]:19:57

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].[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 CSCI	0.33	0.27	0.4	60	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.4	0.27	0.33	60	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	0.45	0.27	0.4	60	0.15	[redacted]20[redacted]/8
ABBV-951 CSCI	0.45	0.27	0.4	60	0.15	[redacted]20[redacted]/15
ABBV-951 CSCI	0.5	0.4	0.27	60	0.15	[redacted]20[redacted]/22
ABBV-951 CSCI	0.5	0.4	0.33	60	0.15	[redacted]20[redacted]/27
ABBV-951 CSCI	0.5	0.4	0.33	60	0.15	[redacted]20[redacted]/48
ABBV-951 CSCI	0.5	0.4	0.33	60	0.15	[redacted]20[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]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	1220.00		SC /CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951	1459.40		SC /CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1208.56		SC /CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	1450.35		SC /CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1439.42		SC /CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	477.07		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 8	
ABBV-951	1658.15		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 15): ANTICOAGULATION:NIL (THIS IS THE LITERAL TEXT, NO FURTHER INFO PROVIDED); CEREBRAL CT:SOME AGE APPROPRIATE ATROPHY, NO SIGNS OF ISCHAEMIA, NO HAEMORRHAGE, NORMAL WHITE-GREY MATTER DIFFERENTIATION.; CHEST X-RAY:LARGE HIATUS HERNIA, NO ABNORMALITIES IN THE LUNGS.; CT SPINE:DEGENERATIVE CHANGES THROUGHOUT THE CERVICAL SPINE WITH MULTILEVEL DISC NARROWING AND ANTERIOR SLIP C7/T1. MILD NARROWING OF CANAL C4 TO T1 BU NO COMPRESSION OF SPINAL CORD. SUPERIOR END-PLATE FRACTUR E T3 WITH SCHMORL'S NODE. NO FRACTURES OR PREVERTEBRAL TISSUE SWELLING.

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	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 15): ANTICOAGULATION:NIL (THIS IS THE LITERAL TEXT, NO FURTHER INFO PROVIDED); CEREBRAL CT:SOME AGE APPROPRIATE ATROPHY, NO SIGNS OF ISCHAEMIA, NO HAEMORRHAGE, NORMAL WHITE-GREY MATTER DIFFERENTIATION.; CHEST X-RAY:LARGE HIATUS HERNIA, NO ABNORMALITIES IN THE LUNGS.; CT SPINE:DEGENERATIVE CHANGES THROUGHOUT THE CERVICAL SPINE WITH MULTILEVEL DISC NARROWING AND ANTERIOR SLIP C7/T1. MILD NARROWING OF CANAL C4 TO T1 BU NO COMPRESSION OF SPINAL CORD. SUPERIOR END-PLATE FRACTUR E T3 WITH SCHMORL'S NODE. NO FRACTURES OR PREVERTEBRAL TISSUE SWELLING.	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 15): ANTICOAGULATION:NIL (THIS IS THE LITERAL TEXT, NO FURTHER INFO PROVIDED); CEREBRAL CT:SOME AGE APPROPRIATE ATROPHY, NO SIGNS OF ISCHAEMIA, NO HAEMORRHAGE, NORMAL WHITE-GREY MATTER DIFFERENTIATION.; CHEST X-RAY:LARGE HIATUS HERNIA, NO ABNORMALITIES IN THE LUNGS.; CT SPINE:DEGENERATIVE CHANGES THROUGHOUT THE CERVICAL SPINE WITH MULTILEVEL DISC NARROWING AND ANTERIOR SLIP C7/T1. MILD NARROWING OF CANAL C4 TO T1 BU NO COMPRESSION OF SPINAL CORD. SUPERIOR END-PLATE FRACTUR E T3 WITH SCHMORL'S NODE. NO FRACTURES OR PREVERTEBRAL TISSUE SWELLING.

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 167): CT BRAIN:NORMAL

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

SAE Supplemental Procedure

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	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

Generated: [redacted] 20[redacted]:19:57
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 CSCI	0.27	0.32	0.24	60	0.19	[redacted]20[redacted]/1
ABBV-951 CSCI	0.27	0.32	0.22	60	0.19	[redacted]20[redacted]/4
ABBV-951 CSCI	0.3	0.33	0.27	60	0.19	[redacted]20[redacted]/11
ABBV-951 CSCI	0.3	0.33	0.27	60	0.19	[redacted]20[redacted]/15
ABBV-951 CSCI	0.33	0.37	0.27	60	0.19	[redacted]20[redacted]/25
ABBV-951 CSCI	0.37	0.43	0.33	60	0.19	[redacted]20[redacted]/32
ABBV-951 CSCI	0.37	0.43	0.33	60	0.19	[redacted]20[redacted]/40
ABBV-951 CSCI	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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): CHEST X-RAY:UNREMARKABLE; ECG:UNREMARKABLE

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

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): CHEST X-RAY:UNREMARKABLE; ECG:UNREMARKABLE

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

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	

SAE Supplemental Procedure

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

SAE Supplemental Procedure

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	
SAE Supplemental Procedure	
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	
SAE Supplemental Procedure	
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]:19:57

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 SPECIAL 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.

M15-741 試験（更新時）

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 52 週間，非盲検，単群試験	
施設数 / 実施国名： 60 施設 / オーストラリア，ベルギー，カナダ，デンマーク，ドイツ，イタリア，日本，オランダ，ロシア，スペイン，スウェーデン，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) ： 3 件の抄録	
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： 主要目的： 最大 52 週間，1 日 24 時間持続皮下注入（以下「CSCI」）したときの ABBV-951 の局所及び全身の安全性及び忍容性を評価する。 副次目的： 患者報告及び評価者が評価した有効性評価項目を指標として ABBV-951 の有効性を評価する。	
被験者数 (計画時と解析時) ： 計画時：約 240 例，解析時：244 例	
診断と主要な組入れ基準： レボドパ反応性の特発性パーキンソン病と診断され，経口治療薬では運動症状の日内変動を十分にコントロールできない 30 歳以上の患者。 識別可能なオフとオンの状態（運動症状の日内変動）があり，本試験登録前のパーキンソン病日誌により 1 日あたりのオフ時間が 2.5 時間以上ある患者。	
治験方法： 本試験は，パーキンソン病の被験者に 1 日 24 時間 CSCI 投与した ABBV-951 の安全性及び忍容性を評価するためにデザインされた，非盲検，単群試験であった。 被験者は，10 日から 42 日間のスクリーニング期を経て 52 週間の投与期に移行した。投与期は，4 週間の最適化期と，48 週間の維持期で構成された。最適化期には，治験責任医師は，個々の被験者に最適な臨床効果が得られるよう，治験薬の標準注入速度の他に事前に設定された追加の低い注入速度及び追加の高い注入速度を被験者が使用できるようにすることを含め，各被験者の ABBV-951 用量について必要な調節を行った。最適な臨床効果とは，1 日あたりのオン時間を最大にし，オフ症状の発現数及び期間並びに日常生活に支障のあるジスキネジアを伴うオン時間を最小にすることと定義した。被験者の併用パーキンソン病治療薬（ドパミンアゴニスト，選択的モノアミン酸化酵素 B 阻害薬，アマンタジン，サフィナミド）は，治験責任医師の判断で被験者の症状コントロールに最善な治療法が提供できるよう，添付文書に従った漸減又は休薬が可能であった。維持期には，ABBV-951 の最適治療用量を投与した。ABBV-951 の投与量は，投与期間を通して調節可能であったが，併用パーキンソン病治療薬は，治験責任医師が医学的に必要と判断した場合を除き，安定して使用することとした。 M15-741 試験で 52 週間の投与期を完了し，適格基準を満たし続けていた被験者は，別の継続試験（M15-737 試験）に移行し，ABBV-951 を更に 96 週間継続投与することが可能であった。	

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，携帯式ポンプに接続した注入セットを介して 1 日 24 時間 CSCI により投与した。用量は，最適化期に必要な調節を行った後，維持期に最適治療用量を投与した。なお，維持期の投与開始前に，経口レボドパ + ドパ脱炭酸酵素阻害薬（以下「DDCI」）の負荷投与を行った。

バルクロット番号：[redacted] delivery system

治療期間：最大 52 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の副次評価項目であり，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，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」）の Part I から IV により評価したパーキンソン病症状，パーキンソン病における睡眠評価尺度改訂版（以下「PDSS-2」）により評価した睡眠症状，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，並びに 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について，ベースラインから治験終了時までの変化量により評価した。

安全性：

安全性評価項目は本試験の主要評価項目であり，有害事象を発現した被験者の割合，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治験終了時までの変化量を評価した。局所安全性を注入部位評価尺度（Infusion Site Evaluation Scale）により評価した。更に，自殺傾向及び衝動的強迫行動を，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」）によりそれぞれ評価した。

統計手法：

有効性：

最大の解析対象集団（以下「FAS」）は，ABBV-951 の注入を 1 回以上受け，かつ有効性の結果指標に関するベースライン及び投与期間中の 1 つ以上の観測値が得られたすべての被験者からなり，すべての有効性解析についてこれを用いた。ベースラインからの変化量については，対応のある t 検定を実施した。

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ベースラインから各規定来院時までの変化量を記述的に要約した。要約統計量には，観察回数，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：

安全性解析対象集団は，ABBV-951 の注入を受けたすべての被験者からなり，すべての安全性解析についてこれを用いた。有害事象は，ABBV-951 の CSCI 投与開始日以降，最終注入後 30 日までに発現又は悪化したすべての事象と定義した。安全性評価項目に関するすべての解析は，有害事象と注入部位評価尺度を除いて，ABBV-951 の最終投与後 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。

安全性に関して，評価項目が連続変数の場合は，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量を，評価時点ごとに記述的に要約した。評価項目がカテゴリー変数の場合は，各用量群及び被験者全体における各カテゴリーの被験者数及び被験者の割合を評価時点ごとに要約した。仮説検定は実施しなかった。

表 1. 治験実施スケジュール

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
問診及び質問票															
被験者情報及び同意取得	√														
適格基準	√	√	√ (投与前)												
病歴	√														
臨床評価	√														
進行期パーキンソン病の臨床医による評価	√														
注入部位の評価 (該当する場合は皮膚科学的評価)			√ (投与後)	√	√	√	√	√	√	√	√	√	√		
薬物及びアルコールスクリーニング	√														

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
有害事象の確認	√	√	√ (投与後)	√	√	√	√	√	√	√	√	√	√	√	
製品に関する苦情・不具合			√ (投与前後)	√	√	√	√	√	√	√	√	√	√		
前治療 / 併用療法	√	√	√ (投与前後)	√	√	√	√	√	√	√	√	√	√		
患者報告アウトカム															
患者による評価 (既定の時点) :															
被験者投与日誌					来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √		

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
パーキンソン病日誌	√ (一致評価)		来院前 2 日間 √		来院前 2 日間 √				来院前 2 日間 √		来院前 2 日間 √	来院前 2 日間 √	来院前 2 日間 √		
[redacted]	√[a]	√[a]	√[a]	√	√	√	√	√	√	√	√	任意	任意		
EQ-5D-5L			√ (投与前)						√	√	√	√	√		
評価者による評価 (既定の時点) :															
C-SSRS	√	√	√ (投与前)	√	√	√	√	√	√	√	√	√	√		
PDQ-39			√ (投与前)						√	√	√	√	√		

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
MDS-UPDRS / UPDRS	√		√ (投与前後)	√	√	√	√	√	√	√	√	√	√		
PDSS-2			√ (投与前)						√	√	√	√	√		
MMSE	√														
QUIP-RS			√ (投与前)						√	√	√	√	√		
検査及び診察															
臨床検査	√		√ (投与前)						√		√	√	√		

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
特別な臨床検査 (ビタミン B6，ビタミン B12，葉酸，メチルマロン酸，ホモシステイン)	√		√ (投与前)						√		√		√		
任意のバイオマーカー (薬理遺伝学 DNA)			√ (投与前)								√				
12 誘導心電図	√		√ (投与後)						√				√		
身長 (V1 のみ) 及び体重	√		√ (投与前)						√		√		√		
バイタルサイン (立位)			√ (投与後)		√				√		√		√		
バイタルサイン	√	√		√		√	√	√		√		√			

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
身体検査	√		√ (投与前)						√		√		√		
神経学的検査	√		√ (投与前)						√	√	√	√	√		
中央検査機関での血清妊娠検査	√														
実施医療機関での尿妊娠検査[b]			√ (投与前)										√		
治療															
治験薬投与システム使用のトレーニング		√	√												
治験薬投与			√	√	√	√	√	√	√	√	√	√			

表 1. 治験実施スケジュール（続き）

治験の実施項目	スクリーニング (V1)	スクリーニング (V2)	投与期											試験終了後 / 早期中止時の電話による追跡調査[d]	交付来院[c]
			最適化期 4 週間						維持期 48 週間						
			登録 投与 1 日目 (V3)	投与 2 日目 (V4)	投与 1 週時 (V5)	投与 2 週時 (V6)	投与 3 週時 (V7)	投与 4 週時 (V8)	投与 6 週時 (V9)	投与 13 週時 (V10)	投与 26 週時 (V11)	投与 39 週時 (V12)	投与 52 週 (V13) / 早期中止		
治験薬，治験用機器及び付属品の供給確認			√	√	√	√	√	√	√	√	√	√			√
薬剤及び治験用機器の照合確認			√	√	√	√	√	√	√	√	√	√	√		√
治験薬投与システムの交付 / 返却			治験薬は投与 1 日目，投与 1 週時，それ以降は投与 51 週時まで 2 週間ごとに交付した。 被験者は前回の来院時に交付されたバイアル (使用済み及び未使用分) を投与 1 週時，それ以降は 2 週間ごとに返却した。 また，被験者は治験薬投与システムのすべての部品を投与 52 週 / 早期中止時に返却した。												
治験薬処方記録			√	√	√	√	√	√	√	√	√	√			

MMSE = ミニメンタルステート検査，[redacted] = [redacted]，V = 来院

a. 各国の規制で許容される場合，[redacted]を受領した実施医療機関は，V1 後から観察期開始前までに本デバイスを被験者に提供した。実施医療機関での[redacted]受領後，V3 までのいずれかの時点で 6 日間の観察期を開始し，6 日以上連日で実施した。また，パーキンソン病日誌もこの 6 日間の観察期に 2 日以上連日で記入した。[redacted]が未承認の国では，パーキンソン病日誌の記入及び注入ポンプのトレーニングを考慮し，観察期を少なくとも 2 日間に短縮可能であった。

b. 妊娠可能な女性の場合，毎月，尿妊娠検査を行った。予定された来院がある場合，実施医療機関にて検査を行った。予定された来院がない場合は，規定外来院時又は自宅にて検査を行ってもよいこととした。
c. 交付来院は，来院の有無に関わらず実施可能であった。
d. 被験者の同意を得た上で，電話による試験終了後 / 早期中止時の追跡調査を，試験中止の 30 日後又は継続試験に参加しない被験者については投与 52 週完了の 30 日後に実施した。

すべての日本人被験者が 52 週間の投与期を完了又は早期中止した時点でデータカットオフし，中間解析を実施した。

被験者の内訳

被験者の内訳を表 2 に示す。
本試験では，244 例が登録され，全被験者が治験薬を投与された。
解析対象集団については，FAS が 244 例であった。
治験薬の投与を完了した被験者は 125 例（51.2%），投与継続中は 12 例（4.9%），また，治験薬投与中止は 107 例（43.9%）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 56 例（23.0%）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。
本試験では，27 例の日本人被験者が登録され，全被験者が治験薬を投与された。
解析対象集団については，FAS が 27 例であった。
治験薬の投与を完了した被験者は 12 例（44.4%），投与継続中は 0 例，また，治験薬投与中止は 15 例（55.6%）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及び同意撤回であり，各 6 例（22.2%）であった。

治験薬投与開始後 12 週間の登録時期別の被験者の内訳を表 4 に示す。
本試験では，予想を上回る脱落・中止例が認められ，その根本原因は注入部位の有害事象の発現及び投与システム使用の困難が考えられたことから，無菌操作を含む注入セットの使用方法に関する再教育を実施するとともに，使いやすさがより優れていると考えられる注入セット（Neria Guard）も使用できるように治験実施計画書の改訂（20[redacted] 年 [redacted] 月 [redacted] 日）を行った。これらの改善策は 20[redacted] 年 [redacted] 月 [redacted] 日までに完全に実施されたことから，それよりも前に登録された被験者（以下「Sample 1」），及びそれ以降に登録された被験者（以下「Sample 2」）ごとに評価項目を要約した。
投与開始後 12 週時点の被験者の治験薬投与状況は，Sample 1（157 例）では，治験薬の投与を中止した被験者の割合は 49 例（31.2%），投与継続中は 108 例（68.8%）であった。一方，Sample 2（87 例）では，治験薬の投与を中止した被験者の割合は 17 例（19.5%），投与継続中は 70 例（80.5%）であった。Sample 2 の中止率（19.5%）は，Sample 1 の中止率（31.2%）と比較して低かった。

日本人部分集団における治験薬投与開始後 12 週間の登録時期別の被験者の内訳を表 5 に示す。
投与開始後 12 週時点の被験者の治験薬投与状況は，Sample 1（18 例）では，治験薬の投与を中止した被験者の割合は 9 例（50.0%），投与継続中は 9 例（50.0%）であった。一方，Sample 2（9 例）では，治験薬の投与を中止した被験者の割合は 1 例（11.1%），投与継続中は 8 例

（88.9%）であった。Sample 2 の中止率（11.1%）は，Sample 1 の中止率（50.0%）と比較して低かった。

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 6 に示す。

本試験対象集団は，年齢の平均値が 63.9 歳（範囲：34～86 歳），65 歳以上の割合が 51.2%，体重の平均値が 72.10 kg（範囲：34.1～120.7 kg），居住地域は欧米及びオーストラリア合わせて 88.9%，女性が 40.2%，民族は非ヒスパニック（非ラテン含む）が 91.8%，人種は白人が 84.8%，アジア人が 13.9%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 7 に示す。

本試験対象集団は，年齢の平均値が 63.3 歳（範囲：46～83 歳），65 歳以上の割合が 44.4%，体重の平均値が 56.23 kg（範囲：34.1～82.5 kg），女性が 51.9%であった。

パーキンソン病の病歴を表 8 に示す。

パーキンソン病と診断されて 10 年未満の被験者は 131 例（53.7%），10 年以上の被験者は 113 例（46.3%）であり同程度であった。レボドパによるジスキネジアの既往歴のある被験者は 192 例（78.7%），レボドパ反応性が 5 年を超える期間にわたり認められる被験者は 207 例（84.8%）であった。ベースライン時の Hoehn-Yahr 重症度分類はすべての被験者（欠測を除く）で 2 以上であった。

併用薬

治験実施計画書の規定に基づき，すべての被験者は治験開始時に経口レボドパ含有製剤を使用していた。ベースライン時，1 種類のパーキンソン病治療薬（ドーパ及びドーパ誘導体，又はドパミンアゴニスト）を併用していた被験者は 34 例（13.9%），2 種類のパーキンソン病治療薬を併用していた被験者は 80 例（32.8%），3 種類のパーキンソン病治療薬を併用していた被験者は 80 例（32.8%），4 種類のパーキンソン病治療薬を併用していた被験者は 43 例（17.6%），5 種類以上のパーキンソン病治療薬を併用していた被験者は 7 例（2.9%）であった（M15-741 試験 CSR update Table 14.1__3.2.3）。

ABBV-951 の投与開始後，最適化期終了時点で他のパーキンソン病治療薬を併用していなかった被験者は 51 例（23.8%），他のパーキンソン病治療薬を 1 種類併用していた被験者は 72 例（33.6%），他のパーキンソン病治療薬を 2 種類併用していた被験者は 62 例（29.0%），他のパーキンソン病治療薬を 3 種類併用していた被験者は 25 例（11.7%），他のパーキンソン病治療薬を 4 種類併用していた被験者は 3 例（1.4%），他のパーキンソン病治療薬を 5 種類以上併用していた被験者は 1 例（0.5%）であった（M15-741 試験 CSR update Table 14.1__3.2.7）。

曝露状況

各被験者の ABBV-951 開始用量は，平均的な 1 日（覚醒時間 16 時間）に摂取した経口レボドパの総量（又はレボドパ換算投与量），並びにホスレボドパ中のレボドパの分子量，製剤濃度，24 時間曝露時間及び薬物動態データを考慮した換算アルゴリズムに従って算出された。

レボドパの 1 日あたりの規定投与量を表 9 に示す。
最適化期終了時には，デザイン上の意図どおり，標準注入速度を下げた被験者よりも上げた被験者の方が多く，標準注入速度の開始時から最適化期終了時又は維持期終了時の平均変化量は，それぞれわずかレボドパ 10.3 mg/hr 又はレボドパ 14.1 mg/hr に相当し，換算アルゴリズムの正確度が確認された。

日本人部分集団におけるレボドパの 1 日あたりの規定投与量を表 10 に示す。
全体集団と同様に，最適化期終了時には標準注入速度を下げた被験者よりも上げた被験者の方が多く，標準注入速度の開始時から最適化期終了時又は維持期終了時の平均変化量は，それぞれわずかレボドパ 7.6 mg/hr 又はレボドパ 9.0 mg/hr に相当し，換算アルゴリズムの正確度が確認された。

規定注入速度を表 11 に示す。
各被験者の標準及び追加の注入速度で最も頻繁に設定されたものを示した。最も頻繁に設定された注入速度は約 0.30 mL/hr から 0.60 mL/hr の範囲であり，これはレボドパ換算で 1 日あたり約 1200 mg から 2400 mg 投与するものであった。注入速度の全範囲（0.17 ～1.01 mL/hr）は，第 I 相試験及び他の第 III 相試験で観察されたものと同様である。実際の，レボドパの 1 日あたりの投与量は，696.7 mg から 4180.0 mg の範囲であった（表 9）。

レボドパの 1 日あたりの投与量を表 12 に示す。
救済療法が必要になった場合に備えて，すべての被験者は治験責任医師又は一般開業医から，経口レボドパ＋DDCI 速放性錠又はレボドパ吸入粉末を処方されることとした。ABBV-951 の治療が開始された後の救済療法の使用は，ABBV-951 の追加投与に反応しない運動症状の急激な悪化など，重大な医学的必要性がある場合に限ることとした。

日本人部分集団におけるレボドパの 1 日あたりの投与量を表 13 に示す。

レボドパの 1 日あたりの最頻投与量を表 14 に示す。
被験者ごとに，レボドパ換算で 100 mg 間隔の最頻（最も頻度の高い）1 日投与量を算出した。レボドパ換算投与量は，被験者投与日誌の記録に基づき，各被験者が使用した実際の注入速度と注入時間から算出した。最頻投与量の用量分布はレボドパ換算で 1 日あたり約 600 mg から 4100 mg であり，第 I 相試験及び他の第 III 相試験（ABBV-951 が進行期パーキンソン病患者の運

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用量をカバーできることが確認された）で観察された用量分布と類似していた。

ABBV-951 及び併用薬のレボドパ換算 1 日投与量を表 15 に示す。

治験薬曝露期間を表 16 に示す。
被験者が治験薬に曝露された日数の平均は，投与中断を除いて 232.0 日，投与中断を含めて 238.2 日であった。投与中断を除いた場合と含めた場合のいずれにおいても，274 日以上治験薬に曝露されていた被験者は約 55%，92 日以上治験薬に曝露されていた被験者は約 70%であった。投与中断を含めて 6 ヵ月（180 日）以上治験薬に曝露された被験者は 153 例，投与中断を除いて 6 ヵ月（180 日）以上治験薬に曝露された被験者は 145 例であった。なお，治験総括報告書のデータカットオフ日までに 52 週間の投与を完了した被験者は 125 例であった（表 2）。

日本人部分集団における治験薬曝露期間を表 17 に示す。
被験者が治験薬に曝露された日数の平均は，投与中断を除いて 189.8 日，投与中断を含めて 200.7 日であった。投与中断を除いた場合と含めた場合のいずれにおいても，274 日以上治験薬に曝露されていた被験者は 44.4%，92 日以上治験薬に曝露されていた被験者は約 60%であった。投与中断を含めて 6 ヵ月（180 日）以上治験薬に曝露された被験者は 14 例，投与中断を除いて 6 ヵ月（180 日）以上治験薬に曝露された被験者は 12 例であった。なお，治験総括報告書のデータカットオフ日までに 52 週間の投与を完了した被験者は 12 例であった（表 3）。

治験薬投与中断理由を表 18 に示す。
投与中断が報告された被験者は 94 例であった（表 20）。そのうち投与中断理由が示された被験者は 91 例であった。投与中断理由は，その他（49 例），新型コロナウイルス感染症（以下「COVID-19」）以外の有害事象（39 例），ポンプの故障（20 例）及び COVID-19 による物流上の制約（3 例）であった。投与中断理由の「その他」の大部分は，個人的な衛生 / シャワー若しくは水泳，偶発的なポンプの停止に気付かなかった，不注意によりポンプの再起動を忘れた，カニューレ / コネクターの問題，又は被験者の体調不良であった。

日本人部分集団における治験薬投与中断理由を表 19 に示す。
治験薬の投与を中断した被験者は 9 例であった。投与中断理由は，その他（6 例），COVID-19 以外の有害事象（3 例）及びポンプの故障（1 例）であった。

治験薬投与中断期間を表 20 に示す。
投与中断期間を，1 日未満から 30 日以上までの日数間隔で分類した。治験薬の投与を中断した 94 例の被験者のうち，62.8%が 2 日未満で投与中断した。なお，経口の負荷投与を必要とした被験者は，いずれの時点においても Sample 1 と Sample 2 ともに 10 例以下であった（表 12）。

有効性の結果

パーキンソン病日誌

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を表 21 に示す。

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，日常生活に支障がないジスキネジアを伴うオン，日常生活に支障のあるジスキネジアを伴うオン，又はオフの状態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て，1 日あたりのオン時間とオフ時間を一般的な覚醒時間（16 時間）に標準化した。本試験では，起床時の朝一番の症状がオフの場合，朝の無動とした。

本試験で ABBV-951 を投与した結果，日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間（ジスキネジアを伴わない平均オン時間と日常生活に支障のないジスキネジアを伴う平均オン時間の合計）及び標準化した 1 日あたりの平均オフ時間は，ベースラインと比較してすべての評価時点において改善した（nominal $P < 0.001$）。これらの改善は，ベースライン後の最初の評価時点である投与 1 週時から認められ，投与 26 週時まで経時的に改善し，その後安定した。投与 52 週時における日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間の平均増加量は 3.46 時間，標準化した 1 日あたりの平均オフ時間の平均減少量は 3.36 時間であった。標準化した 1 日あたりの平均オフ時間及びジスキネジアを伴う標準化した 1 日あたりの平均オン時間（日常生活に支障のあるなしを問わない）はともに減少し，それに伴い，最も望ましい状態であるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間も増加した。投与 52 週時のジスキネジアを伴わない標準化した 1 日あたりの平均オン時間の平均増加量は 3.79 時間であった。未治療の解析対象集団を対象とした解析でも同様の結果が認められた（M15-741 試験 CSR update Table 14.2__1.2）。

日本人被験者では，日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間（ジスキネジアを伴わない平均オン時間と日常生活に支障のないジスキネジアを伴う平均オン時間の合計）は，投与 1 週時（nominal $P < 0.05$），6 週時（nominal $P < 0.05$），39 週時（nominal $P < 0.01$）及び 52 週時（nominal $P < 0.01$）にベースラインと比較して改善が認められた。投与 52 週時における日常生活に支障のあるジスキネジアを伴わない標準化した 1 日あたりの平均オン時間の平均増加量は 2.74 時間，標準化した 1 日あたりの平均オフ時間の平均減少量は 2.41 時間であった。投与 52 週時のジスキネジアを伴わない標準化した 1 日あたりの平均オン時間の平均増加量は 4.22 時間であった（表 22）。

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部分集団解析を表 22 に示す。

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を以下の部分集団ごとに解析した。

- 性別（男性又は女性）
- 人種（白人，アジア人，又はその他）
- 年齢（65 歳未満又は 65 歳以上）
- 地域（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（診断後経過期間）（10 年未満又は 10 年以上）

部分集団解析の結果，有効性の主要解析結果とおおむね一致したが，白人以外の人種及び一部の地域（日本）の被験者数は少なかった。

パーキンソン病日誌に基づく，早朝覚醒時状態の分布を表 23 に示す。

ABBV-951 の投与開始後，朝の起床時にオフ状態であると回答した被験者の割合はベースラインから大きく減少した。ベースラインでは 77.7%の被験者がオフ状態で起床していたが，投与 1 週時には 31.0%の被験者がオフ状態で起床し，50.0%の被験者がジスキネジアを伴わないオン状態で起床した。ベースラインと比較したこれらの改善は，52 週間を通して認められた。

日本人部分集団における，パーキンソン病日誌に基づく早朝覚醒時状態の分布を表 24 に示す。

ABBV-951 の投与開始後，朝の起床時にオフ状態であると回答した被験者の割合はベースラインから大きく減少した。ベースラインでは 93.3%の被験者がオフ状態で起床していたが，投与 1 週時には 29.4%の被験者がオフ状態で起床し，41.2%の被験者がジスキネジアを伴わないオン状態で起床した。ベースラインと比較したこれらの改善は，52 週間を通して認められた。

MDS-UPDRS

MDS-UPDRS スコアを表 25 に示す。

MDS-UPDRS は以下のパートで構成される。

- パート I：日常生活における非運動症状（nM-EDL）
- パート II：日常生活における運動症状（以下「M-EDL」）
- パート III：運動症状の調査（Hoehn-Yahr 重症度分類を含む）
- パート IV：運動合併症

MDS-UPDRS 合計スコア（パート I～III）は 0 から 236 の範囲で，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 は投与 1 日目を除き，被験者の最良のオン状態で評価することとした。投与 1 日目は，治験薬投与開始前の被験者の実質的なオフ状態で評価された。

本試験で ABBV-951 を投与した結果，MDS-UPDRS パート II（M-EDL スコア）に関して，ベースラインと比較してすべての評価時点で改善が認められた（nominal $P < 0.001$）。また，MDS-UPDRS パート IV（運動合併症スコア）についても，ベースラインと比較してすべての時

点で改善が認められた（nominal $P < 0.001$）。これらの改善は，ベースライン後の最初の評価時点である投与 2 日目という早い段階から認められた。

日本人部分集団における MDS-UPDRS スコアを表 26 に示す。
日本人被験者では，MDS-UPDRS のいずれのパートにおいても継続的に統計学的有意差が認められた項目はなかったものの，いくつかの時点でベースラインからの改善が認められた。

MDS-UPDRS スコア（Hoehn-Yahr 重症度分類）を表 27 に示す。

PDSS-2

PDSS-2 スコアを表 28 に示す。
PDSS-2 の目的は，パーキンソン病患者における夜間睡眠障害の様々な側面を明らかにすることである。PDSS-2 評価ツールは信頼性が高く，有効かつ正確であり，パーキンソン病の夜間症状及び睡眠障害の評価において治療に対する反応性を示す有望な評価ツールであることが明らかにされている。PDSS-2 は，夜間及び覚醒時の運動症状及び非運動症状，並びに睡眠障害を評価する 15 項目の質問からなり，これらの質問は夜間の運動症状（5 項目），夜間のパーキンソン病症状（5 項目）及び睡眠障害（5 項目）の 3 つのドメインに分類される。点数が低いほど，夜間の症状が少なく睡眠障害が少ないことを示している。具体的には，これらの質問で全般的な睡眠の質，不眠症，睡眠断片化，下肢静止不能症候群及び睡眠時周期性四肢運動，レム睡眠行動障害，幻覚，夜間頻尿，夜間不動，疼痛及び痙攣，朝の無動，振戦，並びに睡眠時無呼吸を評価する。
本試験で ABBV-951 を投与した結果，PDSS-2 合計スコアに関してすべての時点で改善が認められた（nominal $P < 0.001$）。また，夜間の運動症状スコア，夜間のパーキンソン病症状スコア，及び睡眠中断スコアについても改善が認められた。

日本人部分集団における PDSS-2 スコアを表 29 に示す。
日本人部分集団では，PDSS-2 合計スコア，夜間の運動症状スコア，夜間のパーキンソン病症状スコア，及び睡眠中断スコアは，すべての評価時点においてベースラインとほぼ同様であった。

生活の質

PDQ-39 スコアを表 30 に，EQ-5D-5L スコアを表 31 に示す。
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 項目の疾患別評価ツールである。要約指標スコア及び各ドメインの要約スコアは 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 記述システムと EQ 視覚的評価尺度（以下「EQ VAS」）の 2 部から構成される標準化された測定ツールである。EQ-5D 記述システムは，「移動の程度」「身の回りの管理」「ふだんの活動」「痛み / 不快感」「不安 / ふさぎ込み」の 5 項目から構成される。

5 項目それぞれの障害を 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，国別に重み付けした評価アルゴリズムを用いて要約指標に変換した。米国の要約指標は最悪値–0.109 から最良値 1 であった。

EQ VAS は，被験者の自己評価による健康状態を垂直方向の視覚的評価尺度（VAS）を用いて記録するものであり，尺度の範囲は「想像できる最高の健康状態」から「想像できる最悪の健康状態」である。

本試験で ABBV-951 を投与した結果，PDQ-39 要約指標（具体的には，運動能力，日常生活動作，恥辱感及び身体的苦痛のドメインスコア），EQ-5D-5L 要約指標及び EQ VAS によって測定されたパーキンソン病及び健康関連の生活の質において改善が認められた（nominal $P < 0.05$）。

日本人部分集団における PDQ-39 スコアを表 32 に，日本人部分集団における EQ-5D-5L スコアを表 33 に示す。

PDQ-39 要約指標では統計学的な有意差は認められなかったが，EQ-5D-5L 要約指標では投与 13 週時以外の全時点及び EQ VAS の全時点において改善が認められた（nominal $P < 0.05$）。

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 94.3%（230 / 244 例）であった。発現割合が 10%以上の有害事象は，注入部位紅斑 51.6%（126 / 244 例），注入部位結節 28.3%（69 / 244 例），注入部位蜂巣炎 23.0%（56 / 244 例），注入部位浮腫 19.3%（47 / 244 例），幻覚 17.2%（42 / 244 例），転倒 16.4%（40 / 244 例），注入部位疼痛 15.6%（38 / 244 例），注入部位反応 12.3%（30 / 244 例），不安 11.9%（29 / 244 例），注入部位膿瘍 11.1%（27/ 244 例），及び浮動性めまい 10.2%（25 / 244 例）であった。

治験薬と関連ありの有害事象の発現割合は 91.8%（224/ 244 例）であった。発現割合が 10%以上の治験薬と関連ありの有害事象は，注入部位紅斑 48.8%（119 / 244 例），注入部位結節 28.3%（69 / 244 例），注入部位蜂巣炎 21.3%（52 / 244 例），注入部位浮腫 18.9%（46 / 244 例），幻覚 15.2%（37 / 244 例），注入部位疼痛 13.9%（34 / 244 例），注入部位反応 12.3%（30 / 244 例），及び注入部位膿瘍 10.2%（25/ 244 例）であった。

ABBV-951 の最終投与 30 日以内に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。治験責任（分担）医師により，いずれの事象も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 25.8%（63 / 244 例）であった。発現割合が 2%以上の重篤な有害事象は，注入部位蜂巣炎 4.1%（10 / 244 例），注入部位膿瘍 3.3%（8 / 244 例），幻覚 2.9%（7 / 244 例），並びにパーキンソン病及び精神病性障害が各 2.5%（6 / 244 例）であった。

中止に至った有害事象の発現割合は 25.8%（63 / 244 例）であった。3 例以上に発現した中止に至った有害事象は，幻覚 4.1%（10 / 244 例），注入部位紅斑及び注入部位蜂巣炎が各 3.7%（9 / 244 例），注入部位結節及びジスキネジアが各 2.0%（5 / 244 例），注入部位浮腫 1.6%

（4 / 244 例），並びに注入部位反応，注入部位膿瘍，オンオフ現象及びパーキンソン病が各 1.2%（3 / 244 例）であった。

発現時期別の有害事象の発現割合は，投与開始後 90 日までが 92.2%（225 / 244 例）と最も高く，その後，発現割合は減少した。有病割合は，発現時期別の有害事象の発現割合と同様に，投与開始後 90 日までが 92.2%（225 / 244 例）と最も高く，その後減少した。

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 92.6%（25 / 27 例）であった。発現割合が 10%以上の有害事象は，注入部位紅斑 37.0%（10 / 27 例），幻覚 33.3%（9 / 27 例），転倒 29.6%（8 / 27 例），注入部位硬結及び妄想が各 18.5%（5 / 27 例），下痢，注入部位蜂巣炎及びパーキンソン病が各 14.8%（4 / 27 例），並びに注入部位腫瘤及び浮動性めまいが各 11.1%（3 / 27 例）であった。

治験薬と関連ありの有害事象の発現割合は 92.6%（25 / 27 例）であった。発現割合が 10%以上の有害事象は，注入部位紅斑及び幻覚が各 33.3%（9 / 27 例），注入部位硬結及び妄想が各 18.5%（5 / 27 例），注入部位蜂巣炎 14.8%（4 / 27 例），並びに注入部位腫瘤及び浮動性めまいが各 11.1%（3 / 27 例）であった。

死亡した被験者はいなかった。

重篤な有害事象の発現割合は 25.9%（7 / 27 例）であった。認められた重篤な有害事象は，パーキンソン病及び幻覚が各 11.1%（3 / 27 例），並びに蜂巣炎，横紋筋融解症，意識消失及び妄想が各 3.7%（1 / 27 例）であった。

中止に至った有害事象の発現割合は 25.9%（7 / 27 例）であった。認められた中止に至った有害事象は，パーキンソン病 7.4%（2 / 27 例），並びに注入部位腫瘤，注入部位発疹，横紋筋融解症，パーキンソニズム，幻覚，幻視及び蕁麻疹が各 3.7%（1 / 27 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 34	表 42
すべての有害事象	表 35	表 43
治験薬との因果関係別の有害事象	表 36	表 44
死亡した被験者一覧	表 37	–
重篤な有害事象	表 38	表 45
中止に至った有害事象	表 39	表 46
有害事象の 90 日間ごとの初回発現割合の推移	表 40	–
有害事象の 90 日間ごとの有病割合の推移	表 41	–

結論

ABBV-951 の投与により，日常生活に支障のあるジスキネジアを伴わないオン時間及びオフ時間において 1 日を通して臨床的に意義のある改善が認められた。これらの改善は主に，最も望ましい状態であるジスキネジアを伴わないオン時間への移行によるものであった。また，MDS-UPDRS パート II（M-EDL スコア）及びパート IV（運動合併症スコア）においても改善が認められた。朝の無動及び睡眠症状で認められた臨床的に意義のある改善は，ABBV-951 の 24 時間使用によって期待される効果と一致するものである。ABBV-951 の投与により，PDQ-39 及び EQ-5D-5L によって測定されたパーキンソン病及び健康関連の生活の質の改善が認められた。

ABBV-951 は全般的に安全であり，忍容性は良好であった。大部分の被験者において，注入部位の有害事象は非重篤であり，重症度は軽度又は中等度，転帰は回復であった。ABBV-951 の全身性安全性プロファイルは，レボドパ / カルビドパ療法の確立した安全性プロファイルとおおむね一致していた。その他の安全性に関する新たな懸念は認められなかった。

表2　被験者の内訳（All Enrolled Subjects）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 1.1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=132) n (%)	High Dose (N=112) n (%)	All Subjects (N=244) n (%)
Total subjects enrolled	132 (100)	112 (100)	244 (100)
Subjects previously received ABBV-951	2 (1.5)	5 (4.5)	7 (2.9)
Analysis population			
Full analysis set	132 (100)	112 (100)	244 (100)
Treatment naive analysis set	130 (98.5)	107 (95.5)	237 (97.1)
Safety analysis set	132 (100)	112 (100)	244 (100)
ABBV-951 ongoing	8 (6.1)	4 (3.6)	12 (4.9)
Sample 1	0	0	0
Sample 2	8 (6.1)	4 (3.6)	12 (4.9)
ABBV-951 completed	69 (52.3)	56 (50.0)	125 (51.2)
Sample 1	42 (31.8)	39 (34.8)	81 (33.2)
Sample 2	27 (20.5)	17 (15.2)	44 (18.0)
ABBV-951 prematurely discontinued	55 (41.7)	52 (46.4)	107 (43.9)
Sample 1	37 (28.0)	39 (34.8)	76 (31.1)
Sample 2	18 (13.6)	13 (11.6)	31 (12.7)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=132) n (%)	Dose Category: High Dose (N=112) n (%)	All Subjects (N=244) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	28 (21.2)	28 (25.0)	56 (23.0)
Infusion site related infections	5 (3.8)	7 (6.3)	12 (4.9)
Infusion site related non infection reactions	11 (8.3)	7 (6.3)	18 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	7 (5.3)	5 (4.5)	12 (4.9)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	19 (14.4)	11 (9.8)	30 (12.3)
Lost to follow-up	0	1 (0.9)	1 (0.4)
Lack of efficacy	4 (3.0)	7 (6.3)	11 (4.5)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.5)	3 (2.7)	5 (2.0)
Other	2 (1.5)	2 (1.8)	4 (1.6)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category: Low Dose (N=132) n (%)	Dose Category: High Dose (N=112) n (%)	All Subjects (N=244) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	32 (24.2)	31 (27.7)	63 (25.8)
Infusion site related infections	5 (3.8)	7 (6.3)	12 (4.9)
Infusion site related non infection reactions	13 (9.8)	7 (6.3)	20 (8.2)
Polyneuropathy	1 (0.8)	0	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	7 (5.3)	6 (5.4)	13 (5.3)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	22 (16.7)	17 (15.2)	39 (16.0)
Lost to follow-up	1 (0.8)	1 (0.9)	2 (0.8)
Lack of efficacy	9 (6.8)	9 (8.0)	18 (7.4)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.5)	3 (2.7)	5 (2.0)
Other	5 (3.8)	6 (5.4)	11 (4.5)
Study ongoing	11 (8.3)	5 (4.5)	16 (6.6)
Sample 1	0	0	0
Sample 2	11 (8.3)	5 (4.5)	16 (6.6)
Study completed	75 (56.8)	59 (52.7)	134 (54.9)
Sample 1	49 (37.1)	41 (36.6)	90 (36.9)
Sample 2	26 (19.7)	18 (16.1)	44 (18.0)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=132) n (%)	High Dose (N=112) n (%)	All Subjects (N=244) n (%)
Study prematurely discontinued	46 (34.8)	48 (42.9)	94 (38.5)
Sample 1	30 (22.7)	37 (33.0)	67 (27.5)
Sample 2	16 (12.1)	11 (9.8)	27 (11.1)
Primary reasons for study discontinuation #			
Adverse event	22 (16.7)	25 (22.3)	47 (19.3)
Withdrew consent	16 (12.1)	12 (10.7)	28 (11.5)
Lost to follow-up	0	1 (0.9)	1 (0.4)
Lack of efficacy	4 (3.0)	5 (4.5)	9 (3.7)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.5)	3 (2.7)	5 (2.0)
Other	2 (1.5)	2 (1.8)	4 (1.6)
All reasons for study discontinuation $			
Adverse event	26 (19.7)	26 (23.2)	52 (21.3)
Withdrew consent	23 (17.4)	20 (17.9)	43 (17.6)
Lost to follow-up	0	2 (1.8)	2 (0.8)
Lack of efficacy	8 (6.1)	6 (5.4)	14 (5.7)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.5)	5 (4.5)	7 (2.9)
Other	8 (6.1)	8 (7.1)	16 (6.6)
Number of sites that screened at least 1 subject			60

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1

Subject Disposition
(All Enrolled Subjects)

	Dose Category		
	Low Dose (N=132) n (%)	High Dose (N=112) n (%)	All Subjects (N=244) n (%)
Number of sites that enrolled at least 1 subject			60
Number of country that screened at least 1 subject			13
Number of country that enrolled at least 1 subject			13

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 1.1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=22) n (%)	High Dose (N=5) n (%)	All Subjects (N=27) n (%)
Total subjects enrolled	22 (100)	5 (100)	27 (100)
Analysis population			
Full analysis set	22 (100)	5 (100)	27 (100)
Treatment naive analysis set	22 (100)	5 (100)	27 (100)
Safety analysis set	22 (100)	5 (100)	27 (100)
ABBV-951 ongoing	0	0	0
Sample 1	0	0	0
Sample 2	0	0	0
ABBV-951 completed	9 (40.9)	3 (60.0)	12 (44.4)
Sample 1	2 (9.1)	3 (60.0)	5 (18.5)
Sample 2	7 (31.8)	0	7 (25.9)
ABBV-951 prematurely discontinued	13 (59.1)	2 (40.0)	15 (55.6)
Sample 1	11 (50.0)	2 (40.0)	13 (48.1)
Sample 2	2 (9.1)	0	2 (7.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=22) n (%)	Dose Category: High Dose (N=5) n (%)	All Subjects (N=27) n (%)
Primary reasons for ABBV-951 prematurely discontinuation #			
Adverse event	6 (27.3)	0	6 (22.2)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (9.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	2 (9.1)	0	2 (7.4)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	5 (22.7)	1 (20.0)	6 (22.2)
Lost to follow-up	0	0	0
Lack of efficacy	1 (4.5)	1 (20.0)	2 (7.4)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	1 (4.5)	0	1 (3.7)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=22) n (%)	Dose Category: High Dose (N=5) n (%)	All Subjects (N=27) n (%)
All reasons for ABBV-951 prematurely discontinuation $			
Adverse event	6 (27.3)	1 (20.0)	7 (25.9)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (9.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	2 (9.1)	0	2 (7.4)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	6 (27.3)	1 (20.0)	7 (25.9)
Lost to follow-up	0	0	0
Lack of efficacy	3 (13.6)	1 (20.0)	4 (14.8)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	2 (9.1)	0	2 (7.4)
Study ongoing	0	0	0
Sample 1	0	0	0
Sample 2	0	0	0
Study completed	9 (40.9)	3 (60.0)	12 (44.4)
Sample 1	2 (9.1)	3 (60.0)	5 (18.5)
Sample 2	7 (31.8)	0	7 (25.9)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category: Low Dose (N=22) n (%)	Dose Category: High Dose (N=5) n (%)	All Subjects (N=27) n (%)
Study prematurely discontinued	13 (59.1)	2 (40.0)	15 (55.6)
Sample 1	11 (50.0)	2 (40.0)	13 (48.1)
Sample 2	2 (9.1)	0	2 (7.4)
Primary reasons for study discontinuation #			
Adverse event	6 (27.3)	0	6 (22.2)
Withdrew consent	5 (22.7)	1 (20.0)	6 (22.2)
Lost to follow-up	0	0	0
Lack of efficacy	1 (4.5)	1 (20.0)	2 (7.4)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	1 (4.5)	0	1 (3.7)
All reasons for study discontinuation $			
Adverse event	6 (27.3)	0	6 (22.2)
Withdrew consent	8 (36.4)	1 (20.0)	9 (33.3)
Lost to follow-up	0	0	0
Lack of efficacy	3 (13.6)	1 (20.0)	4 (14.8)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	0	0	0
Other	2 (9.1)	0	2 (7.4)
Number of sites that screened at least 1 subject			5

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.1.J

Subject Disposition
(Enrolled Japan Subjects)

	Dose Category		
	Low Dose (N=22) n (%)	High Dose (N=5) n (%)	All Subjects (N=27) n (%)
Number of sites that enrolled at least 1 subject			5
Number of country that screened at least 1 subject			1
Number of country that enrolled at least 1 subject			1

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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　治験薬投与開始後12週間の登録時期別の被験者の内訳（All Enrolled Subjects）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 12 weeks of study	49 (31.2)	17 (19.5)	66 (27.0)
ABBV-951 ongoing within first 12 weeks of study	108 (68.8)	70 (80.5)	178 (73.0)
Primary reasons #			
Adverse event	26 (16.6)	7 (8.0)	33 (13.5)
Infusion site related infections	8 (5.1)	0	8 (3.3)
Infusion site related non infection reactions	9 (5.7)	1 (1.1)	10 (4.1)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	6 (3.8)	2 (2.3)	8 (3.3)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	14 (8.9)	5 (5.7)	19 (7.8)
Lost to follow-up	1 (0.6)	0	1 (0.4)
Lack of efficacy	5 (3.2)	3 (3.4)	8 (3.3)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	3 (1.9)	1 (1.1)	4 (1.6)
Other	0	1 (1.1)	1 (0.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 12 weeks of study (cont'd)			
All reasons $			
Adverse event	29 (18.5)	8 (9.2)	37 (15.2)
Infusion site related infections	8 (5.1)	0	8 (3.3)
Infusion site related non infection reactions	10 (6.4)	1 (1.1)	11 (4.5)
Polyneuropathy	0	1 (1.1)	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	6 (3.8)	2 (2.3)	8 (3.3)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	18 (11.5)	7 (8.0)	25 (10.2)
Lost to follow-up	2 (1.3)	0	2 (0.8)
Lack of efficacy	9 (5.7)	5 (5.7)	14 (5.7)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	3 (1.9)	1 (1.1)	4 (1.6)
Other	2 (1.3)	3 (3.4)	5 (2.0)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 10 weeks of study	49 (31.2)	17 (19.5)	66 (27.0)
ABBV-951 ongoing within first 10 weeks of study	108 (68.8)	70 (80.5)	178 (73.0)
Primary reasons #			
Adverse event	26 (16.6)	7 (8.0)	33 (13.5)
Infusion site related infections	8 (5.1)	0	8 (3.3)
Infusion site related non infection reactions	9 (5.7)	1 (1.1)	10 (4.1)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	6 (3.8)	2 (2.3)	8 (3.3)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	14 (8.9)	5 (5.7)	19 (7.8)
Lost to follow-up	1 (0.6)	0	1 (0.4)
Lack of efficacy	5 (3.2)	3 (3.4)	8 (3.3)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	3 (1.9)	1 (1.1)	4 (1.6)
Other	0	1 (1.1)	1 (0.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 10 weeks of study (cont'd)			
All reasons $			
Adverse event	29 (18.5)	8 (9.2)	37 (15.2)
Infusion site related infections	8 (5.1)	0	8 (3.3)
Infusion site related non infection reactions	10 (6.4)	1 (1.1)	11 (4.5)
Polyneuropathy	0	1 (1.1)	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	6 (3.8)	2 (2.3)	8 (3.3)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	18 (11.5)	7 (8.0)	25 (10.2)
Lost to follow-up	2 (1.3)	0	2 (0.8)
Lack of efficacy	9 (5.7)	5 (5.7)	14 (5.7)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	3 (1.9)	1 (1.1)	4 (1.6)
Other	2 (1.3)	3 (3.4)	5 (2.0)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 6 weeks of study	36 (22.9)	13 (14.9)	49 (20.1)
ABBV-951 ongoing within first 6 weeks of study	121 (77.1)	74 (85.1)	195 (79.9)
Primary reasons #			
Adverse event	17 (10.8)	5 (5.7)	22 (9.0)
Infusion site related infections	7 (4.5)	0	7 (2.9)
Infusion site related non infection reactions	6 (3.8)	1 (1.1)	7 (2.9)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	4 (2.5)	2 (2.3)	6 (2.5)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	13 (8.3)	4 (4.6)	17 (7.0)
Lost to follow-up	1 (0.6)	0	1 (0.4)
Lack of efficacy	3 (1.9)	2 (2.3)	5 (2.0)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.3)	1 (1.1)	3 (1.2)
Other	0	1 (1.1)	1 (0.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 6 weeks of study (cont'd)			
All reasons $			
Adverse event	20 (12.7)	6 (6.9)	26 (10.7)
Infusion site related infections	7 (4.5)	0	7 (2.9)
Infusion site related non infection reactions	7 (4.5)	1 (1.1)	8 (3.3)
Polyneuropathy	0	1 (1.1)	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	4 (2.5)	2 (2.3)	6 (2.5)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	17 (10.8)	5 (5.7)	22 (9.0)
Lost to follow-up	2 (1.3)	0	2 (0.8)
Lack of efficacy	6 (3.8)	2 (2.3)	8 (3.3)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.3)	1 (1.1)	3 (1.2)
Other	1 (0.6)	2 (2.3)	3 (1.2)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 4 weeks of study	28 (17.8)	10 (11.5)	38 (15.6)
ABBV-951 ongoing within first 4 weeks of study	129 (82.2)	77 (88.5)	206 (84.4)
Primary reasons #			
Adverse event	14 (8.9)	2 (2.3)	16 (6.6)
Infusion site related infections	6 (3.8)	0	6 (2.5)
Infusion site related non infection reactions	5 (3.2)	0	5 (2.0)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	3 (1.9)	0	3 (1.2)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	9 (5.7)	4 (4.6)	13 (5.3)
Lost to follow-up	1 (0.6)	0	1 (0.4)
Lack of efficacy	2 (1.3)	2 (2.3)	4 (1.6)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.3)	1 (1.1)	3 (1.2)
Other	0	1 (1.1)	1 (0.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 4 weeks of study (cont'd)			
All reasons $			
Adverse event	17 (10.8)	3 (3.4)	20 (8.2)
Infusion site related infections	6 (3.8)	0	6 (2.5)
Infusion site related non infection reactions	6 (3.8)	0	6 (2.5)
Polyneuropathy	0	1 (1.1)	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	3 (1.9)	0	3 (1.2)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	12 (7.6)	5 (5.7)	17 (7.0)
Lost to follow-up	2 (1.3)	0	2 (0.8)
Lack of efficacy	4 (2.5)	2 (2.3)	6 (2.5)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	2 (1.3)	1 (1.1)	3 (1.2)
Other	1 (0.6)	2 (2.3)	3 (1.2)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 2 weeks of study	10 (6.4)	7 (8.0)	17 (7.0)
ABBV-951 ongoing within first 2 weeks of study	147 (93.6)	80 (92.0)	227 (93.0)
Primary reasons #			
Adverse event	5 (3.2)	2 (2.3)	7 (2.9)
Infusion site related infections	2 (1.3)	0	2 (0.8)
Infusion site related non infection reactions	1 (0.6)	0	1 (0.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (0.6)	0	1 (0.4)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	4 (2.5)	2 (2.3)	6 (2.5)
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.1)	1 (0.4)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	1 (0.6)	1 (1.1)	2 (0.8)
Other	0	1 (1.1)	1 (0.4)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 2 weeks of study (cont'd)			
All reasons $			
Adverse event	5 (3.2)	3 (3.4)	8 (3.3)
Infusion site related infections	2 (1.3)	0	2 (0.8)
Infusion site related non infection reactions	1 (0.6)	0	1 (0.4)
Polyneuropathy	0	1 (1.1)	1 (0.4)
Weight loss	0	0	0
Hallucinations/psychosis	1 (0.6)	0	1 (0.4)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	6 (3.8)	3 (3.4)	9 (3.7)
Lost to follow-up	0	0	0
Lack of efficacy	0	1 (1.1)	1 (0.4)
COVID-19 infection	0	0	0
COVID-19 logistical restrictions	0	0	0
Difficulty with drug delivery system	1 (0.6)	1 (1.1)	2 (0.8)
Other	1 (0.6)	2 (2.3)	3 (1.2)

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 1 week of study	5 (3.2)	2 (2.3)	7 (2.9)
ABBV-951 ongoing within first 1 week of study	152 (96.8)	85 (97.7)	237 (97.1)
Primary reasons #			
Adverse event	1 (0.6)	1 (1.1)	2 (0.8)
Infusion site related infections	1 (0.6)	0	1 (0.4)
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	3 (1.9)	0	3 (1.2)
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	1 (0.6)	1 (1.1)	2 (0.8)
Other	0	0	0

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(All Enrolled Subjects)

	Sample 1 (N=157) n (%)	Sample 2 (N=87) n (%)	All Subjects (N=244) n (%)
ABBV-951 prematurely discontinued within first 1 week of study (cont'd)			
All reasons $			
Adverse event	1 (0.6)	1 (1.1)	2 (0.8)
Infusion site related infections	1 (0.6)	0	1 (0.4)
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	3 (1.9)	0	3 (1.2)
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	1 (0.6)	1 (1.1)	2 (0.8)
Other	0	0	0

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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5　治験薬投与開始後12週間の登録時期別の被験者の内訳（All Enrolled Subjects，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 12 weeks of study	9 (50.0)	1 (11.1)	10 (37.0)
ABBV-951 ongoing within first 12 weeks of study	9 (50.0)	8 (88.9)	17 (63.0)
Primary reasons #			
Adverse event	4 (22.2)	0	4 (14.8)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	2 (11.1)	0	2 (7.4)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 12 weeks of study (cont'd)			
All reasons $			
Adverse event	5 (27.8)	0	5 (18.5)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	4 (22.2)	0	4 (14.8)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 10 weeks of study	9 (50.0)	1 (11.1)	10 (37.0)
ABBV-951 ongoing within first 10 weeks of study	9 (50.0)	8 (88.9)	17 (63.0)
Primary reasons #			
Adverse event	4 (22.2)	0	4 (14.8)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	2 (11.1)	0	2 (7.4)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 10 weeks of study (cont'd)			
All reasons $			
Adverse event	5 (27.8)	0	5 (18.5)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	4 (22.2)	0	4 (14.8)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 6 weeks of study	8 (44.4)	1 (11.1)	9 (33.3)
ABBV-951 ongoing within first 6 weeks of study	10 (55.6)	8 (88.9)	18 (66.7)
Primary reasons #			
Adverse event	4 (22.2)	0	4 (14.8)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	1 (5.6)	0	1 (3.7)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 6 weeks of study (cont'd)			
All reasons $			
Adverse event	5 (27.8)	0	5 (18.5)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	2 (11.1)	0	2 (7.4)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	3 (16.7)	1 (11.1)	4 (14.8)
Lost to follow-up	0	0	0
Lack of efficacy	3 (16.7)	0	3 (11.1)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 4 weeks of study	6 (33.3)	1 (11.1)	7 (25.9)
ABBV-951 ongoing within first 4 weeks of study	12 (66.7)	8 (88.9)	20 (74.1)
Primary reasons #			
Adverse event	3 (16.7)	0	3 (11.1)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	1 (5.6)	0	1 (3.7)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	2 (11.1)	1 (11.1)	3 (11.1)
Lost to follow-up	0	0	0
Lack of efficacy	1 (5.6)	0	1 (3.7)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 4 weeks of study (cont'd)			
All reasons $			
Adverse event	4 (22.2)	0	4 (14.8)
Infusion site related infections	0	0	0
Infusion site related non infection reactions	1 (5.6)	0	1 (3.7)
Polyneuropathy	0	0	0
Weight loss	0	0	0
Hallucinations/psychosis	1 (5.6)	0	1 (3.7)
Somnolence	0	0	0
Falls and associated injuries	0	0	0
Withdrew consent	2 (11.1)	1 (11.1)	3 (11.1)
Lost to follow-up	0	0	0
Lack of efficacy	3 (16.7)	0	3 (11.1)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 2 weeks of study	1 (5.6)	1 (11.1)	2 (7.4)
ABBV-951 ongoing within first 2 weeks of study	17 (94.4)	8 (88.9)	25 (92.6)
Primary reasons #			
Adverse event	0	0	0
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	1 (5.6)	1 (11.1)	2 (7.4)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 2 weeks of study (cont'd)			
All reasons $			
Adverse event	0	0	0
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	1 (5.6)	1 (11.1)	2 (7.4)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 1 week of study	1 (5.6)	0	1 (3.7)
ABBV-951 ongoing within first 1 week of study	17 (94.4)	9 (100)	26 (96.3)
Primary reasons #			
Adverse event	0	0	0
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	1 (5.6)	0	1 (3.7)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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__1.1.2.J

Subject Disposition During the First 12 Weeks of Study by Enrollment Sample by Time Interval
(Enrolled Japan Subjects)

	Sample 1 (N=18) n (%)	Sample 2 (N=9) n (%)	All Subjects (N=27) n (%)
ABBV-951 prematurely discontinued within first 1 week of study (cont'd)			
All reasons $			
Adverse event	0	0	0
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	1 (5.6)	0	1 (3.7)
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

Note: Sample 1 contains subjects who were enrolled prior to [redacted]20[redacted].
Sample 2 contains subjects who were enrolled on or after [redacted]20[redacted].
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）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 2.1

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Age (year)			
n	132	112	244
Mean (SD)	63.6 (8.89)	64.3 (9.53)	63.9 (9.18)
Median	65.0	64.0	65.0
Min, Max	34, 83	43, 86	34, 86
Age (year) - n (%)			
< 65	62 (47.0)	57 (50.9)	119 (48.8)
>= 65	70 (53.0)	55 (49.1)	125 (51.2)
Age (year) - n (%)			
< 75	121 (91.7)	96 (85.7)	217 (88.9)
>= 75	11 (8.3)	16 (14.3)	27 (11.1)
Weight (kg)			
n	132	112	244
Mean (SD)	68.28 (17.338)	76.59 (16.366)	72.10 (17.367)
Median	67.50	78.25	72.00
Min, Max	34.1, 120.7	41.4, 110.9	34.1, 120.7
Height (cm)			
n	130	111	241
Mean (SD)	166.38 (10.498)	172.45 (10.341)	169.18 (10.838)
Median	166.00	172.20	170.00
Min, Max	140.1, 189.0	142.2, 197.5	140.1, 197.5

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]

TABLE 14.1__2.1

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
BMI (kg/m^2)			
n	130	111	241
Mean (SD)	24.41 (5.031)	25.59 (4.485)	24.95 (4.814)
Median	23.55	25.24	24.41
Min, Max	14.1, 39.9	16.5, 35.1	14.1, 39.9
BMI (kg/m^2) - n (%)			
< 18.5	8 (6.2)	5 (4.5)	13 (5.4)
18.5 - < 25.0	72 (55.4)	46 (41.4)	118 (49.0)
25.0 - < 30.0	28 (21.5)	39 (35.1)	67 (27.8)
>= 30.0	22 (16.9)	21 (18.9)	43 (17.8)
Missing	2	1	3
Mini-Mental State Examination (MMSE) total score			
n	131	111	242
Mean (SD)	28.83 (1.575)	28.55 (1.877)	28.70 (1.722)
Median	29.00	29.00	29.00
Min, Max	20.0, 30.0	21.0, 30.0	20.0, 30.0

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__2.1

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Country - n (%)			
AUSTRALIA	18 (13.6)	9 (8.0)	27 (11.1)
BELGIUM	4 (3.0)	3 (2.7)	7 (2.9)
CANADA	4 (3.0)	5 (4.5)	9 (3.7)
DENMARK	3 (2.3)	6 (5.4)	9 (3.7)
GERMANY	8 (6.1)	7 (6.3)	15 (6.1)
ITALY	5 (3.8)	1 (0.9)	6 (2.5)
JAPAN	22 (16.7)	5 (4.5)	27 (11.1)
NETHERLANDS	4 (3.0)	2 (1.8)	6 (2.5)
RUSSIA	6 (4.5)	2 (1.8)	8 (3.3)
SPAIN	12 (9.1)	16 (14.3)	28 (11.5)
SWEDEN	5 (3.8)	3 (2.7)	8 (3.3)
UNITED KINGDOM	5 (3.8)	8 (7.1)	13 (5.3)
UNITED STATES	36 (27.3)	45 (40.2)	81 (33.2)
Geographic region - n (%)			
North America	40 (30.3)	50 (44.6)	90 (36.9)
Europe and Australia	70 (53.0)	57 (50.9)	127 (52.0)
Japan	22 (16.7)	5 (4.5)	27 (11.1)
Sex - n (%)			
Female	66 (50.0)	32 (28.6)	98 (40.2)
Male	66 (50.0)	80 (71.4)	146 (59.8)
Ethnicity - n (%)			
Hispanic or Latino	8 (6.1)	12 (10.7)	20 (8.2)
Not Hispanic or Latino	124 (93.9)	100 (89.3)	224 (91.8)

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__2.1

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Race - n (%)			
White	103 (78.0)	104 (92.9)	207 (84.8)
Black or African American	0	1 (0.9)	1 (0.4)
Asian	27 (20.5)	7 (6.3)	34 (13.9)
American Indian or Alaska Native	1 (0.8)	0	1 (0.4)
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	1 (0.8)	0	1 (0.4)
Tobacco - n (%)			
Current	10 (7.6)	5 (4.5)	15 (6.1)
Former	38 (28.8)	36 (32.1)	74 (30.3)
Never	84 (63.6)	71 (63.4)	155 (63.5)
Unknown	0	0	0
Alcohol - n (%)			
Current	86 (65.2)	65 (58.0)	151 (61.9)
Former	19 (14.4)	14 (12.5)	33 (13.5)
Never	27 (20.5)	33 (29.5)	60 (24.6)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	130 (98.5)	108 (96.4)	238 (97.5)
Abnormal	2 (1.5)	4 (3.6)	6 (2.5)
Cranial nerves - n (%)			
Normal	122 (92.4)	102 (91.1)	224 (91.8)
Abnormal	10 (7.6)	10 (8.9)	20 (8.2)

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__2.1

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Motor system - n (%)			
Normal	63 (47.7)	66 (58.9)	129 (52.9)
Abnormal	69 (52.3)	46 (41.1)	115 (47.1)
Sensory system - n (%)			
Normal	120 (92.3)	96 (85.7)	216 (89.3)
Abnormal	10 (7.7)	16 (14.3)	26 (10.7)
Missing	2	0	2
Reflexes - n (%)			
Normal	120 (92.3)	95 (84.8)	215 (88.8)
Abnormal	10 (7.7)	17 (15.2)	27 (11.2)
Missing	2	0	2
Coordination - n (%)			
Normal	110 (84.6)	96 (85.7)	206 (85.1)
Abnormal	20 (15.4)	16 (14.3)	36 (14.9)
Missing	2	0	2
Gait - n (%)			
Normal	51 (38.6)	52 (46.4)	103 (42.2)
Abnormal	81 (61.4)	60 (53.6)	141 (57.8)
Station - n (%)			
Normal	96 (74.4)	80 (74.1)	176 (74.3)
Abnormal	33 (25.6)	28 (25.9)	61 (25.7)
Missing	3	4	7

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　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）：M15-741試験

[redacted]20[redacted] 10:42 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 2.1.J

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
Age (year)			
n	22	5	27
Mean (SD)	62.5 (9.43)	66.8 (6.10)	63.3 (8.97)
Median	62.0	69.0	62.0
Min, Max	46, 83	57, 72	46, 83
Age (year) - n (%)			
< 65	14 (63.6)	1 (20.0)	15 (55.6)
>= 65	8 (36.4)	4 (80.0)	12 (44.4)
Age (year) - n (%)			
< 75	20 (90.9)	5 (100)	25 (92.6)
>= 75	2 (9.1)	0	2 (7.4)
Weight (kg)			
n	22	5	27
Mean (SD)	53.32 (12.482)	69.06 (16.463)	56.23 (14.365)
Median	48.65	75.80	58.00
Min, Max	34.1, 73.0	41.4, 82.5	34.1, 82.5
Height (cm)			
n	22	5	27
Mean (SD)	159.73 (11.147)	161.98 (10.690)	160.15 (10.897)
Median	160.05	165.10	160.10
Min, Max	140.1, 177.4	149.6, 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__2.1.J

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
BMI (kg/m^2)			
n	22	5	27
Mean (SD)	20.70 (3.347)	26.05 (4.634)	21.69 (4.103)
Median	20.43	27.16	20.70
Min, Max	14.1, 27.4	18.5, 30.3	14.1, 30.3
BMI (kg/m^2) - n (%)			
< 18.5	6 (27.3)	1 (20.0)	7 (25.9)
18.5 - < 25.0	13 (59.1)	0	13 (48.1)
25.0 - < 30.0	3 (13.6)	3 (60.0)	6 (22.2)
>= 30.0	0	1 (20.0)	1 (3.7)
Mini-Mental State Examination (MMSE) total score			
n	22	5	27
Mean (SD)	29.00 (1.024)	29.40 (0.548)	29.07 (0.958)
Median	29.00	29.00	29.00
Min, Max	27.0, 30.0	29.0, 30.0	27.0, 30.0
Country - n (%)			
JAPAN	22 (100)	5 (100)	27 (100)
Geographic region - n (%)			
Japan	22 (100)	5 (100)	27 (100)
Sex - n (%)			
Female	13 (59.1)	1 (20.0)	14 (51.9)
Male	9 (40.9)	4 (80.0)	13 (48.1)

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__2.1.J

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
Ethnicity - n (%)			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	22 (100)	5 (100)	27 (100)
Race - n (%)			
White	0	0	0
Black or African American	0	0	0
Asian	22 (100)	5 (100)	27 (100)
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Multiple	0	0	0
Tobacco - n (%)			
Current	1 (4.5)	0	1 (3.7)
Former	6 (27.3)	3 (60.0)	9 (33.3)
Never	15 (68.2)	2 (40.0)	17 (63.0)
Unknown	0	0	0
Alcohol - n (%)			
Current	11 (50.0)	4 (80.0)	15 (55.6)
Former	6 (27.3)	0	6 (22.2)
Never	5 (22.7)	1 (20.0)	6 (22.2)
Unknown	0	0	0
Brief neurological examination			
Mental status - n (%)			
Normal	22 (100)	4 (80.0)	26 (96.3)
Abnormal	0	1 (20.0)	1 (3.7)

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__2.1.J

Demographic and Baseline Characteristics by Dose Category
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
Cranial nerves - n (%)			
Normal	21 (95.5)	5 (100)	26 (96.3)
Abnormal	1 (4.5)	0	1 (3.7)
Motor system - n (%)			
Normal	12 (54.5)	3 (60.0)	15 (55.6)
Abnormal	10 (45.5)	2 (40.0)	12 (44.4)
Sensory system - n (%)			
Normal	21 (95.5)	5 (100)	26 (96.3)
Abnormal	1 (4.5)	0	1 (3.7)
Reflexes - n (%)			
Normal	21 (95.5)	5 (100)	26 (96.3)
Abnormal	1 (4.5)	0	1 (3.7)
Coordination - n (%)			
Normal	15 (68.2)	3 (60.0)	18 (66.7)
Abnormal	7 (31.8)	2 (40.0)	9 (33.3)
Gait - n (%)			
Normal	9 (40.9)	1 (20.0)	10 (37.0)
Abnormal	13 (59.1)	4 (80.0)	17 (63.0)
Station - n (%)			
Normal	14 (63.6)	2 (40.0)	16 (59.3)
Abnormal	8 (36.4)	3 (60.0)	11 (40.7)

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8　パーキンソン病の病歴（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 3.1.1

Parkinson's Disease History by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Duration of PD since diagnosis - n (%)			
< 10 years	67 (50.8)	64 (57.1)	131 (53.7)
>= 10 years	65 (49.2)	48 (42.9)	113 (46.3)
History of levodopa induced dyskinesia - n (%)			
Yes	107 (81.1)	85 (75.9)	192 (78.7)
No	25 (18.9)	27 (24.1)	52 (21.3)
Levodopa response for more than 5 years - n (%)			
Yes	117 (88.6)	90 (80.4)	207 (84.8)
No	15 (11.4)	22 (19.6)	37 (15.2)
Baseline parkinson's disease Hoehn and Yahr Stage (MDS-UPDRS) - n (%)			
0	0	0	0
1	0	0	0
2	70 (53.4)	52 (46.8)	122 (50.4)
3	34 (26.0)	31 (27.9)	65 (26.9)
4	19 (14.5)	18 (16.2)	37 (15.3)
5	8 (6.1)	10 (9.0)	18 (7.4)
Missing	1	1	2
Age at PD onset (years)			
n	132	112	244
Mean (SD)	51.6 (9.12)	52.9 (9.70)	52.2 (9.40)
Median	53.0	53.0	53.0
Min, Max	21, 74	34, 77	21, 77

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1__3.1.1

Parkinson's Disease History by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Duration of PD since onset (years)			
n	132	112	244
Mean (SD)	12.60 (5.477)	11.86 (5.112)	12.26 (5.315)
Median	11.85	10.20	11.33
Min, Max	2.7, 32.4	2.1, 25.0	2.1, 32.4
Age at first diagnosis by a physician (years)			
n	132	112	244
Mean (SD)	53.2 (9.02)	54.4 (9.25)	53.8 (9.13)
Median	55.0	54.2	54.9
Min, Max	27, 74	37, 79	27, 79
Duration of PD since first diagnosis by a physician (years)			
n	132	112	244
Mean (SD)	10.96 (5.396)	10.33 (5.007)	10.67 (5.220)
Median	9.92	9.07	9.56
Min, Max	1.6, 32.4	2.1, 23.7	1.6, 32.4
Age at onset of motor fluctuation (years)			
n	132	111	243
Mean (SD)	57.3 (9.63)	58.5 (10.12)	57.9 (9.85)
Median	58.1	58.1	58.1
Min, Max	31, 76	39, 80	31, 80
Duration since onset of motor fluctuation (years)			
n	132	111	243
Mean (SD)	6.84 (4.877)	6.30 (4.488)	6.59 (4.701)
Median	5.88	5.05	5.25
Min, Max	0.1, 31.4	0.4, 22.9	0.1, 31.4

Note: Percentages calculated on non-missing or non-unknown values.

Program Source Code: [redacted]

TABLE 14.1__3.1.1

Parkinson's Disease History by Dose Category
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
MDS-UPDRS - Part III score during 'Off' state			
n	131	111	242
Mean (SD)	46.6 (14.25)	49.0 (15.20)	47.7 (14.71)
Median	45.0	49.0	47.0
Min, Max	7, 87	19, 95	7, 95

Note: Percentages calculated on non-missing or non-unknown values.

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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 6.1

Daily Prescribed Dose
(Safety Analysis Set)

	N	Mean	SD	25% Quantile	Median	75% Quantile	Min / Max
Oral loading dose on day 1 - levodopa (mg LD)	233	149.0	55.68	100.0	125.0	200.0	100.0 / 300.0
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	244	66.3	27.75	46.1	63.2	80.3	29.0 / 152.0
End of optimization	203	76.8	29.37	56.3	71.7	95.6	29.0 / 170.8
Final prescription in 48-week maintenance period	204	80.5	31.64	56.3	76.8	99.0	29.0 / 174.2
Final prescription in study	244	79.5	31.08	56.3	76.8	98.2	29.0 / 174.2
Change from initial to end of optimization	203	10.3	16.66	0.0	6.8	18.8	-29.0 / 88.8
Change from initial to end of maintenance	204	14.1	22.24	0.0	12.0	23.9	-71.7 / 88.8
Change from initial to final	244	13.2	22.22	0.0	12.0	23.9	-73.4 / 88.8
Change from end of optimization to final	203	3.9	15.05	0.0	1.7	10.2	-56.3 / 49.5
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	198	74.7	30.84	51.2	68.3	88.8	30.7 / 177.6
End of optimization	177	84.2	31.82	59.8	78.5	102.5	30.7 / 177.6
Final prescription in 48-week maintenance period	182	88.1	33.32	63.2	84.5	107.6	34.2 / 177.6
Final prescription in study	214	87.7	32.59	63.2	85.4	107.6	34.2 / 177.6
Change from initial to end of optimization	166	10.1	18.88	0.0	6.8	20.5	-35.9 / 97.3
Change from initial to end of maintenance	163	13.6	23.23	0.0	10.2	25.6	-47.8 / 97.3
Change from initial to final	192	12.8	23.65	0.0	8.5	25.6	-83.7 / 97.3
Change from end of optimization to final	172	3.7	15.43	0.0	1.7	10.2	-52.9 / 58.1

& 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]

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 ('low') & - LD mg/HR							
Initial CSCI prescription	188	56.4	23.36	37.6	51.2	71.7	22.2 / 128.1
End of optimization	177	68.9	28.34	44.4	64.9	85.4	27.3 / 162.2
Final prescription in 48-week maintenance period	182	72.0	29.96	47.8	67.4	92.2	25.6 / 170.8
Final prescription in study	213	71.2	29.08	47.8	66.6	90.5	25.6 / 170.8
Change from initial to end of optimization	157	12.2	16.88	0.0	10.2	20.5	-47.8 / 80.3
Change from initial to end of maintenance	155	15.5	20.66	3.4	13.7	27.3	-52.9 / 80.3
Change from initial to final	184	14.3	20.94	0.9	12.0	24.8	-63.2 / 80.3
Change from end of optimization to final	175	3.2	17.13	0.0	0.0	12.0	-70.0 / 68.3
Extra dose $ - LD mg/use							
Initial CSCI prescription	227	29.79	11.128	18.78	25.61	32.44	18.78 / 51.23
End of optimization	193	33.39	11.769	25.61	32.44	40.98	18.78 / 51.23
Final prescription in 48-week maintenance period	192	33.58	11.716	25.61	32.44	40.98	18.78 / 51.23
Final prescription in study	230	33.42	11.713	25.61	32.44	40.98	18.78 / 51.23
Change from initial to end of optimization	188	3.55	9.148	0.00	0.00	6.83	-25.61 / 32.44
Change from initial to end of maintenance	187	3.86	10.463	0.00	0.00	8.54	-32.44 / 32.44
Change from initial to final	224	3.87	10.054	0.00	0.00	8.54	-32.44 / 32.44
Change from end of optimization to final	190	0.54	7.923	0.00	0.00	0.00	-32.44 / 25.61
Total daily dose # - LD mg/day							
Initial CSCI prescription	244	1591.5	666.06	1106.5	1516.3	1926.1	696.7 / 3647.2
End of optimization	203	1844.1	704.93	1352.3	1721.2	2294.9	696.7 / 4098.0
Final prescription in 48-week maintenance period	204	1931.7	759.28	1352.3	1844.1	2376.8	696.7 / 4180.0
Final prescription in study	244	1909.1	745.96	1352.3	1844.1	2356.4	696.7 / 4180.0
Change from initial to end of optimization	203	246.1	399.87	0.0	163.9	450.8	-696.7 / 2131.0
Change from initial to end of maintenance	204	338.1	533.74	0.0	286.9	573.7	-1721.2 / 2131.0
Change from initial to final	244	317.6	533.38	0.0	286.9	573.7	-1762.1 / 2131.0
Change from end of optimization to final	203	93.7	361.25	0.0	41.0	245.9	-1352.3 / 1188.4

& 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　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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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
Oral loading dose on day 1 - levodopa (mg LD)	27	114.8	29.63	100.0	100.0	125.0	100.0 / 200.0
ABBV-951 continuous infusion rate ('base') - LD mg/HR							
Initial CSCI prescription	27	45.0	12.26	34.2	44.4	51.2	29.0 / 71.7
End of optimization	19	55.4	16.96	42.7	51.2	68.3	29.0 / 85.4
Final prescription in 48-week maintenance period	20	55.9	18.06	46.1	50.4	70.0	29.0 / 88.8
Final prescription in study	27	56.9	18.35	46.1	51.2	76.8	29.0 / 88.8
Change from initial to end of optimization	19	7.6	14.05	0.0	5.1	15.4	-27.3 / 39.3
Change from initial to end of maintenance	20	9.0	17.89	0.0	6.0	16.2	-34.2 / 42.7
Change from initial to final	27	11.8	18.21	0.0	6.8	22.2	-34.2 / 46.1
Change from end of optimization to final	19	1.9	14.09	-5.1	0.0	6.8	-22.2 / 37.6
ABBV-951 continuous infusion rate ('high') & - LD mg/HR							
Initial CSCI prescription	25	54.3	14.58	46.1	52.9	61.5	34.2 / 82.0
End of optimization	19	63.5	19.99	47.8	54.6	75.1	34.2 / 102.5
Final prescription in 48-week maintenance period	20	61.9	18.94	51.2	54.6	76.0	34.2 / 95.6
Final prescription in study	25	63.7	21.26	51.2	54.6	83.7	34.2 / 102.5
Change from initial to end of optimization	19	6.7	16.48	0.0	0.0	13.7	-34.1 / 47.8
Change from initial to end of maintenance	20	6.2	19.76	-0.9	3.4	10.2	-41.0 / 42.7
Change from initial to final	25	9.4	21.42	0.0	3.4	13.7	-41.0 / 56.3
Change from end of optimization to final	19	-0.2	16.49	-8.5	-1.7	6.8	-27.3 / 41.0

& 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]

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 ('low') & - LD mg/HR							
Initial CSCI prescription	24	38.2	8.63	31.6	37.6	41.0	23.9 / 54.6
End of optimization	18	47.5	13.59	37.6	42.7	56.3	29.0 / 73.4
Final prescription in 48-week maintenance period	18	46.8	14.61	35.9	41.8	58.1	29.0 / 80.3
Final prescription in study	24	47.7	14.27	37.6	41.8	59.8	29.0 / 80.3
Change from initial to end of optimization	18	8.1	11.08	0.0	5.1	18.8	-13.7 / 30.7
Change from initial to end of maintenance	18	7.3	14.56	-3.4	6.0	15.4	-20.5 / 34.2
Change from initial to final	23	9.4	14.77	0.0	8.5	18.8	-20.5 / 35.9
Change from end of optimization to final	18	-0.8	10.05	-5.1	-1.7	6.8	-20.5 / 17.1
Extra dose $ - LD mg/use							
Initial CSCI prescription	25	26.16	6.515	18.78	25.61	32.44	18.78 / 32.44
End of optimization	18	28.93	7.579	25.61	29.03	32.44	18.78 / 40.98
Final prescription in 48-week maintenance period	20	29.63	9.439	25.61	25.61	32.44	18.78 / 51.23
Final prescription in study	25	30.26	8.783	25.61	32.44	32.44	18.78 / 51.23
Change from initial to end of optimization	18	2.94	3.832	0.00	0.00	6.83	0.00 / 8.54
Change from initial to end of maintenance	20	4.01	6.025	0.00	0.00	6.83	0.00 / 18.78
Change from initial to final	25	4.10	5.956	0.00	0.00	6.83	0.00 / 18.78
Change from end of optimization to final	18	1.52	4.259	0.00	0.00	0.00	-6.83 / 10.25
Total daily dose # - LD mg/day							
Initial CSCI prescription	27	1080.7	294.23	819.6	1065.5	1229.4	696.7 / 1721.2
End of optimization	19	1330.8	407.14	1024.5	1229.4	1639.2	696.7 / 2049.0
Final prescription in 48-week maintenance period	20	1342.1	433.46	1106.5	1208.9	1680.2	696.7 / 2131.0
Final prescription in study	27	1364.5	440.32	1106.5	1229.4	1844.1	696.7 / 2131.0
Change from initial to end of optimization	19	183.3	337.20	0.0	122.9	368.8	-655.7 / 942.5
Change from initial to end of maintenance	20	217.2	429.41	0.0	143.4	389.3	-819.6 / 1024.5
Change from initial to final	27	283.8	436.94	0.0	163.9	532.7	-819.6 / 1106.5
Change from end of optimization to final	19	45.3	338.18	-122.9	0.0	163.9	-532.7 / 901.6

& 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11　規定注入速度（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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=244	N=215	N=213
FLOW RATE < 0.17 mL/hr	0	0	0
0.17 <= FLOW RATE < 0.20 mL/hr	8 (3.3)	1 (0.5)	13 (6.1)
0.20 <= FLOW RATE < 0.23 mL/hr	10 (4.1)	8 (3.7)	14 (6.6)
0.23 <= FLOW RATE < 0.26 mL/hr	8 (3.3)	5 (2.3)	14 (6.6)
0.26 <= FLOW RATE < 0.29 mL/hr	17 (7.0)	9 (4.2)	14 (6.6)
0.29 <= FLOW RATE < 0.32 mL/hr	11 (4.5)	9 (4.2)	18 (8.5)
0.32 <= FLOW RATE < 0.35 mL/hr	17 (7.0)	11 (5.1)	22 (10.3)
0.35 <= FLOW RATE < 0.38 mL/hr	23 (9.4)	16 (7.4)	12 (5.6)
0.38 <= FLOW RATE < 0.41 mL/hr	14 (5.7)	17 (7.9)	15 (7.0)
0.41 <= FLOW RATE < 0.44 mL/hr	23 (9.4)	12 (5.6)	11 (5.2)
0.44 <= FLOW RATE < 0.47 mL/hr	11 (4.5)	17 (7.9)	15 (7.0)
0.47 <= FLOW RATE < 0.50 mL/hr	11 (4.5)	11 (5.1)	7 (3.3)
0.50 <= FLOW RATE < 0.53 mL/hr	13 (5.3)	12 (5.6)	9 (4.2)
0.53 <= FLOW RATE < 0.56 mL/hr	10 (4.1)	11 (5.1)	10 (4.7)

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	14 (5.7)	8 (3.7)	9 (4.2)
0.59 <= FLOW RATE < 0.62 mL/hr	13 (5.3)	15 (7.0)	3 (1.4)
0.62 <= FLOW RATE < 0.65 mL/hr	5 (2.0)	9 (4.2)	6 (2.8)
0.65 <= FLOW RATE < 0.68 mL/hr	9 (3.7)	3 (1.4)	3 (1.4)
0.68 <= FLOW RATE < 0.71 mL/hr	7 (2.9)	10 (4.7)	7 (3.3)
0.71 <= FLOW RATE < 0.74 mL/hr	1 (0.4)	7 (3.3)	2 (0.9)
0.74 <= FLOW RATE < 0.77 mL/hr	2 (0.8)	2 (0.9)	1 (0.5)
0.77 <= FLOW RATE < 0.80 mL/hr	3 (1.2)	2 (0.9)	1 (0.5)
0.80 <= FLOW RATE < 0.83 mL/hr	4 (1.6)	3 (1.4)	4 (1.9)
0.83 <= FLOW RATE < 0.86 mL/hr	5 (2.0)	5 (2.3)	1 (0.5)
0.86 <= FLOW RATE < 0.89 mL/hr	2 (0.8)	2 (0.9)	0
0.89 <= FLOW RATE < 0.92 mL/hr	1 (0.4)	5 (2.3)	1 (0.5)
0.92 <= FLOW RATE < 0.95 mL/hr	0	1 (0.5)	0
0.95 <= FLOW RATE < 0.98 mL/hr	1 (0.4)	1 (0.5)	1 (0.5)
0.98 <= FLOW RATE < 1.01 mL/hr	1 (0.4)	2 (0.9)	0
FLOW RATE >= 1.01 mL/hr	0	1 (0.5)	0

Note: High and low columns only contain subjects whose high/low prescription is not 0.

Program Source Code: [redacted]

表12　レボドパの1日あたりの投与量（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1								
WEEK 1	n	141	84	141	19	3	20	141
	Mean	1662.5	83.0	1711.9	128.9	133.3	142.5	1732.1
	SD	671.01	66.86	676.53	60.82	57.74	63.40	687.97
	Median	1507.7	56.3	1579.4	100.0	100.0	100.0	1579.4
	Min	682.1	18.8	682.1	100.0	100.0	100.0	682.1
	Max	3524.3	327.8	3562.7	300.0	200.0	300.0	3710.4
WEEK 2	n	142	94	142	19	3	21	142
	Mean	1753.1	82.9	1808.0	163.2	133.3	166.7	1832.6
	SD	673.97	65.24	676.79	107.81	57.74	102.88	687.42
	Median	1608.5	64.0	1646.2	100.0	100.0	100.0	1648.4
	Min	696.7	18.8	696.7	100.0	100.0	100.0	696.7
	Max	4072.4	368.8	4136.4	450.0	200.0	450.0	4136.4
WEEK 3	n	124	81	124	15	2	17	124
	Mean	1824.6	72.3	1871.8	126.7	100.0	123.5	1888.7
	SD	689.78	57.33	695.35	41.69	0.00	39.99	697.95
	Median	1669.0	51.2	1723.3	100.0	100.0	100.0	1741.7
	Min	696.7	18.8	696.7	100.0	100.0	100.0	696.7
	Max	4021.2	333.0	4059.6	200.0	100.0	200.0	4059.6
WEEK 4	n	117	79	117	13	0	13	117
	Mean	1883.3	66.0	1927.8	134.6		134.6	1942.8
	SD	716.71	54.18	719.31	89.87		89.87	727.83
	Median	1762.1	48.7	1794.6	100.0		100.0	1803.1
	Min	696.7	18.8	696.7	100.0		100.0	696.7
	Max	4080.9	281.7	4106.5	400.0		400.0	4106.5

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample / Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1 (Cont.)								
WEEK 6	n	113	77	113	18	3	21	113
	Mean	1879.3	61.5	1921.2	144.4	200.0	152.4	1949.5
	SD	711.17	39.35	719.94	118.68	86.60	114.54	728.05
	Median	1762.1	48.7	1791.2	100.0	250.0	100.0	1872.3
	Min	800.8	18.8	800.8	100.0	100.0	100.0	800.8
	Max	4055.3	204.9	4119.3	600.0	250.0	600.0	4119.3
WEEK 13	n	103	68	103	20	4	23	103
	Mean	1911.1	60.4	1951.0	155.0	187.5	167.4	1988.4
	SD	746.85	52.44	751.01	190.50	62.92	178.13	758.65
	Median	1797.1	46.1	1844.1	100.0	200.0	100.0	1862.9
	Min	898.1	18.8	973.3	100.0	100.0	100.0	973.3
	Max	4098.0	307.4	4098.0	950.0	250.0	950.0	4098.0
WEEK 26	n	91	55	91	16	9	21	91
	Mean	1874.6	56.3	1908.6	146.9	161.1	181.0	1950.4
	SD	745.34	39.88	754.00	118.98	74.07	123.97	779.93
	Median	1691.2	41.0	1732.2	100.0	100.0	100.0	1769.8
	Min	851.4	18.8	898.3	100.0	100.0	100.0	898.3
	Max	4098.0	230.5	4116.8	550.0	250.0	550.0	4316.8
WEEK 39	n	79	50	79	15	7	17	79
	Mean	1896.3	67.0	1938.6	150.0	164.3	200.0	1981.7
	SD	704.01	61.38	709.80	114.95	85.22	126.24	736.35
	Median	1747.6	49.9	1769.0	100.0	100.0	150.0	1828.0
	Min	837.5	18.8	888.5	100.0	100.0	100.0	888.5
	Max	3961.4	307.4	3987.0	550.0	300.0	550.0	3987.0

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample Week		ABBV-951 CSCI			Oral			
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
Sample 1 (Cont.)								
WEEK 52	n	70	41	70	14	4	17	70
	Mean	1922.9	67.1	1962.2	100.0	162.5	120.6	1991.5
	SD	685.08	57.15	686.16	0.00	75.00	58.79	692.49
	Median	1829.2	51.2	1854.8	100.0	150.0	100.0	1910.6
	Min	856.8	18.8	945.1	100.0	100.0	100.0	954.2
	Max	3682.7	266.4	3721.2	100.0	250.0	300.0	3721.2

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2								
WEEK 1	n	79	54	79	9	1	10	79
	Mean	1415.2	67.1	1461.1	138.9	150.0	140.0	1478.8
	SD	593.58	53.82	592.24	69.72	NA	65.83	598.97
	Median	1352.3	44.8	1393.3	100.0	150.0	100.0	1393.3
	Min	430.3	18.8	486.6	100.0	150.0	100.0	486.6
	Max	3279.8	256.1	3279.8	300.0	150.0	300.0	3379.8
WEEK 2	n	78	61	78	14	2	15	78
	Mean	1508.9	77.3	1569.4	182.1	137.5	188.3	1605.6
	SD	597.64	59.61	604.60	72.34	17.68	67.39	617.16
	Median	1506.0	51.2	1522.2	200.0	137.5	200.0	1594.0
	Min	630.1	18.8	668.5	100.0	125.0	100.0	668.5
	Max	3606.2	281.7	3606.2	300.0	150.0	300.0	3606.2
WEEK 3	n	76	58	76	8	1	9	76
	Mean	1527.1	75.7	1584.9	150.0	100.0	144.4	1602.0
	SD	575.97	51.23	587.08	88.64	NA	84.57	594.64
	Median	1527.2	62.8	1560.4	100.0	100.0	100.0	1593.3
	Min	686.5	18.8	686.5	100.0	100.0	100.0	686.5
	Max	3016.4	225.4	3053.9	350.0	100.0	350.0	3053.9
WEEK 4	n	75	57	75	7	0	7	75
	Mean	1594.1	66.7	1644.7	192.9		192.9	1662.7
	SD	589.95	44.28	597.67	101.77		101.77	598.38
	Median	1615.3	51.2	1650.5	200.0		200.0	1694.4
	Min	672.0	18.8	703.8	100.0		100.0	703.8
	Max	2932.2	204.9	3096.1	350.0		350.0	3096.1

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample / Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2 (Cont.)								
WEEK 6	n	70	52	70	8	1	8	70
	Mean	1642.4	62.4	1688.8	175.0	100.0	187.5	1710.2
	SD	609.50	43.53	616.01	125.36	NA	121.74	615.80
	Median	1689.2	44.8	1725.8	100.0	100.0	150.0	1762.6
	Min	672.0	18.8	686.5	100.0	100.0	100.0	686.5
	Max	2984.7	204.9	3107.7	450.0	100.0	450.0	3107.7
WEEK 13	n	69	47	69	10	0	10	69
	Mean	1632.6	68.3	1679.1	135.0		135.0	1698.7
	SD	632.04	41.73	634.88	52.97		52.97	642.76
	Median	1634.1	51.2	1699.5	100.0		100.0	1714.9
	Min	682.1	18.8	697.3	100.0		100.0	697.3
	Max	3269.9	204.9	3392.8	250.0		250.0	3392.8
WEEK 26	n	63	46	63	15	2	16	63
	Mean	1612.3	62.6	1658.0	120.0	100.0	125.0	1689.7
	SD	660.22	43.32	660.03	36.84	0.00	54.77	665.05
	Median	1591.6	49.9	1624.0	100.0	100.0	100.0	1705.6
	Min	669.1	18.8	705.3	100.0	100.0	100.0	705.3
	Max	3385.1	179.3	3462.0	200.0	100.0	300.0	3462.0
WEEK 39	n	58	43	58	17	0	17	58
	Mean	1578.8	75.3	1634.7	132.4		132.4	1673.5
	SD	681.99	47.69	682.02	58.47		58.47	693.99
	Median	1573.2	64.9	1591.8	100.0		100.0	1630.2
	Min	657.0	18.8	657.0	100.0		100.0	657.0
	Max	3439.8	192.1	3439.8	300.0		300.0	3439.8

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample Week		ABBV-951 CSCI			Oral			
		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
Sample 2 (Cont.)								
WEEK 52	n	48	33	48	10	2	12	48
	Mean	1634.4	66.7	1680.3	110.0	187.5	122.9	1711.0
	SD	695.08	50.59	694.24	31.62	88.39	49.38	706.19
	Median	1573.4	51.2	1585.7	100.0	187.5	100.0	1604.0
	Min	669.1	18.8	669.1	100.0	125.0	100.0	709.6
	Max	3385.4	230.5	3404.2	200.0	250.0	250.0	3404.2

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples								
	WEEK 1 n	220	138	220	28	4	30	220
	Mean	1573.7	76.8	1621.9	132.1	137.5	141.7	1641.2
	SD	653.80	62.36	657.31	62.68	47.87	63.09	667.22
	Median	1440.8	56.3	1501.4	100.0	125.0	100.0	1521.0
	Min	430.3	18.8	486.6	100.0	100.0	100.0	486.6
	Max	3524.3	327.8	3562.7	300.0	200.0	300.0	3710.4
	WEEK 2 n	220	155	220	33	5	36	220
	Mean	1666.6	80.7	1723.4	171.2	135.0	175.7	1752.1
	SD	657.07	62.94	660.70	93.57	41.83	89.34	670.83
	Median	1572.8	61.5	1629.4	100.0	125.0	175.0	1646.2
	Min	630.1	18.8	668.5	100.0	100.0	100.0	668.5
	Max	4072.4	368.8	4136.4	450.0	200.0	450.0	4136.4
	WEEK 3 n	200	139	200	23	3	26	200
	Mean	1711.5	73.7	1762.8	134.8	100.0	130.8	1779.8
	SD	663.38	54.70	669.51	61.12	0.00	58.44	673.67
	Median	1595.9	51.2	1657.6	100.0	100.0	100.0	1665.9
	Min	686.5	18.8	686.5	100.0	100.0	100.0	686.5
	Max	4021.2	333.0	4059.6	350.0	100.0	350.0	4059.6
	WEEK 4 n	192	136	192	20	0	20	192
	Mean	1770.3	66.2	1817.3	155.0		155.0	1833.4
	SD	683.25	50.10	686.89	95.83		95.83	692.26
	Median	1687.1	51.2	1740.2	100.0		100.0	1752.0
	Min	672.0	18.8	696.7	100.0		100.0	696.7
	Max	4080.9	281.7	4106.5	400.0		400.0	4106.5

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample / Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples (Cont.)								
WEEK 6	n	183	129	183	26	4	29	183
	Mean	1788.7	61.9	1832.3	153.8	175.0	162.1	1858.0
	SD	682.20	40.92	689.68	119.10	86.60	115.46	695.38
	Median	1721.2	48.7	1762.1	100.0	175.0	100.0	1831.5
	Min	672.0	18.8	686.5	100.0	100.0	100.0	686.5
	Max	4055.3	204.9	4119.3	600.0	250.0	600.0	4119.3
WEEK 13	n	172	115	172	30	4	33	172
	Mean	1799.4	63.6	1841.9	148.3	187.5	157.6	1872.2
	SD	714.36	48.31	717.34	157.28	62.92	151.10	726.55
	Median	1720.2	51.2	1783.0	100.0	200.0	100.0	1820.3
	Min	682.1	18.8	697.3	100.0	100.0	100.0	697.3
	Max	4098.0	307.4	4098.0	950.0	250.0	950.0	4098.0
WEEK 26	n	154	101	154	31	11	37	154
	Mean	1767.3	59.1	1806.1	133.9	150.0	156.8	1843.8
	SD	721.22	41.39	725.43	88.87	70.71	102.85	744.02
	Median	1645.2	41.0	1716.5	100.0	100.0	100.0	1760.0
	Min	669.1	18.8	705.3	100.0	100.0	100.0	705.3
	Max	4098.0	230.5	4116.8	550.0	250.0	550.0	4316.8
WEEK 39	n	137	93	137	32	7	34	137
	Mean	1761.9	70.8	1810.0	140.6	164.3	166.2	1851.2
	SD	709.91	55.34	711.78	88.39	85.22	102.78	732.25
	Median	1669.7	51.2	1713.6	100.0	100.0	100.0	1747.6
	Min	657.0	18.8	657.0	100.0	100.0	100.0	657.0
	Max	3961.4	307.4	3987.0	550.0	300.0	550.0	3987.0

Program Source Code: [redacted]

TABLE 14.1__8.1

Daily Levodopa Dose (mg LD)
(Safety Analysis Set)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples (Cont.)								
	WEEK 52 n	118	74	118	24	6	29	118
	Mean	1805.6	67.0	1847.5	104.2	170.8	121.6	1877.4
	SD	700.81	53.96	700.45	20.41	71.44	54.17	708.73
	Median	1708.7	51.2	1779.9	100.0	162.5	100.0	1807.6
	Min	669.1	18.8	669.1	100.0	100.0	100.0	709.6
	Max	3682.7	266.4	3721.2	200.0	250.0	300.0	3721.2

Program Source Code: [redacted]

表13　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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample		ABBV-951 CSCI			Oral			
Week		Continuous Infusion	Extra Dose	Total	Rescue Dose	Loading Dose	Total	Overall Total
Sample 1								
WEEK 1	n	18	8	18	1	0	1	18
	Mean	1255.4	77.9	1290.0	100.0		100.0	1295.5
	SD	363.89	42.18	380.69	NA		NA	380.06
	Median	1195.4	81.1	1227.9	100.0		100.0	1253.5
	Min	682.1	28.2	682.1	100.0		100.0	682.1
	Max	2213.3	153.7	2294.5	100.0		100.0	2294.5
WEEK 2	n	17	9	17	2	1	2	17
	Mean	1438.9	94.1	1488.7	100.0	100.0	150.0	1506.3
	SD	276.36	64.54	310.25	0.00	NA	70.71	311.71
	Median	1354.7	81.1	1494.9	100.0	100.0	150.0	1494.9
	Min	1030.5	32.4	1030.5	100.0	100.0	100.0	1030.5
	Max	1977.8	210.9	2162.2	100.0	100.0	200.0	2262.2
WEEK 3	n	15	9	15	3	1	4	15
	Mean	1467.0	63.4	1505.0	150.0	100.0	137.5	1541.7
	SD	379.74	23.74	392.72	50.00	NA	47.87	403.15
	Median	1338.0	61.5	1370.4	150.0	100.0	125.0	1520.4
	Min	1024.5	32.4	1056.6	100.0	100.0	100.0	1056.6
	Max	2345.3	97.3	2426.4	200.0	100.0	200.0	2426.4
WEEK 4	n	11	6	11	0	0	0	11
	Mean	1483.6	78.5	1526.5				1526.5
	SD	380.31	28.87	388.68				388.68
	Median	1423.7	81.1	1423.7				1423.7
	Min	1001.1	32.4	1001.1				1001.1
	Max	2099.9	112.7	2099.9				2099.9

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 1 (Cont.)								
WEEK 6	n	10	6	10	2	0	2	10
	Mean	1533.5	77.8	1580.2	350.0		350.0	1650.2
	SD	450.68	22.61	457.00	353.55		353.55	532.52
	Median	1716.7	81.1	1759.1	350.0		350.0	1809.0
	Min	800.8	41.0	800.8	100.0		100.0	800.8
	Max	2179.6	102.5	2179.6	600.0		600.0	2446.7
WEEK 13	n	10	8	10	2	1	3	10
	Mean	1523.6	68.5	1578.5	525.0	200.0	416.7	1703.5
	SD	411.33	28.98	411.65	601.04	NA	464.58	466.37
	Median	1654.6	62.8	1725.0	525.0	200.0	200.0	1913.6
	Min	937.2	32.4	1034.6	100.0	200.0	100.0	1034.6
	Max	1992.7	113.5	1993.4	950.0	200.0	950.0	2221.2
WEEK 26	n	9	7	9	1	0	1	9
	Mean	1426.6	55.0	1469.4	100.0		100.0	1480.5
	SD	386.50	31.97	389.38	NA		NA	390.74
	Median	1401.5	41.0	1467.3	100.0		100.0	1567.3
	Min	932.8	25.6	997.4	100.0		100.0	997.4
	Max	1919.0	97.3	1951.4	100.0		100.0	1951.4
WEEK 39	n	6	4	6	1	0	1	6
	Mean	1450.2	81.1	1504.2	150.0		150.0	1529.2
	SD	479.65	22.95	452.92	NA		NA	488.69
	Median	1539.8	73.4	1572.7	150.0		150.0	1572.7
	Min	837.5	64.0	951.1	150.0		150.0	951.1
	Max	1930.6	113.5	2003.1	150.0		150.0	2153.1

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI Continuous Infusion	ABBV-951 CSCI Extra Dose	ABBV-951 CSCI Total	Oral Rescue Dose	Oral Loading Dose	Oral Total	Overall Total
Sample 1 (Cont.)								
WEEK 52	n	5	4	5	1	0	1	5
	Mean	1558.2	82.6	1624.3	100.0		100.0	1644.3
	SD	419.36	33.56	407.70	NA		NA	423.80
	Median	1627.5	97.3	1660.2	100.0		100.0	1660.2
	Min	856.8	32.4	954.2	100.0		100.0	954.2
	Max	1930.2	103.3	2027.5	100.0		100.0	2027.5

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2								
WEEK 1	n	9	7	9	1	0	1	9
	Mean	945.1	57.4	989.8	200.0		200.0	1012.0
	SD	196.29	25.89	198.52	NA		NA	221.28
	Median	1007.4	65.7	1078.6	200.0		200.0	1078.6
	Min	644.1	18.8	702.3	200.0		200.0	702.3
	Max	1183.3	84.5	1220.9	200.0		200.0	1291.9
WEEK 2	n	8	8	8	0	0	0	8
	Mean	1023.9	53.7	1077.6				1077.6
	SD	205.34	26.60	219.36				219.36
	Median	1068.1	49.5	1101.0				1101.0
	Min	683.6	18.8	721.2				721.2
	Max	1311.4	89.6	1386.5				1386.5
WEEK 3	n	8	7	8	1	1	2	8
	Mean	1070.6	67.9	1130.1	100.0	100.0	100.0	1155.1
	SD	258.37	32.71	274.68	NA	NA	0.00	291.86
	Median	1093.9	61.5	1122.0	100.0	100.0	100.0	1172.0
	Min	686.5	18.8	737.7	100.0	100.0	100.0	737.7
	Max	1413.8	122.9	1488.9	100.0	100.0	100.0	1488.9
WEEK 4	n	8	8	8	0	0	0	8
	Mean	1121.5	57.1	1178.6				1178.6
	SD	334.86	31.82	342.97				342.97
	Median	1179.8	53.8	1198.5				1198.5
	Min	672.0	18.8	709.6				709.6
	Max	1638.0	102.5	1694.4				1694.4

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2 (Cont.)								
WEEK 6	n	8	7	8	1	0	1	8
	Mean	1133.9	55.9	1182.8	100.0		100.0	1195.3
	SD	349.28	39.18	357.13	NA		NA	338.73
	Median	1106.5	51.2	1148.2	100.0		100.0	1148.2
	Min	672.0	18.8	690.8	100.0		100.0	779.6
	Max	1617.9	122.9	1646.0	100.0		100.0	1646.0
WEEK 13	n	8	8	8	1	0	1	8
	Mean	1058.5	66.4	1124.9	100.0		100.0	1137.4
	SD	200.18	28.24	221.80	NA		NA	197.15
	Median	1083.1	64.0	1145.1	100.0		100.0	1145.1
	Min	682.1	37.6	719.7	100.0		100.0	819.7
	Max	1324.2	102.5	1426.6	100.0		100.0	1426.6
WEEK 26	n	8	7	8	3	0	3	8
	Mean	1083.3	91.2	1163.1	100.0		100.0	1200.6
	SD	290.92	56.78	343.02	0.00		0.00	383.06
	Median	1038.5	76.8	1102.5	100.0		100.0	1140.2
	Min	669.1	37.6	706.6	100.0		100.0	706.6
	Max	1610.5	179.3	1764.2	100.0		100.0	1864.2
WEEK 39	n	8	7	8	0	0	0	8
	Mean	1120.3	78.9	1189.4				1189.4
	SD	325.58	46.71	365.02				365.02
	Median	1053.4	64.0	1091.8				1091.8
	Min	672.0	18.8	690.8				690.8
	Max	1788.9	153.7	1917.0				1917.0

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Sample 2 (Cont.)								
WEEK 52	n	7	5	7	0	0	0	7
	Mean	1150.5	111.3	1230.0				1230.0
	SD	302.62	82.57	364.10				364.10
	Median	1099.5	89.6	1099.5				1099.5
	Min	690.9	18.8	709.6				709.6
	Max	1686.0	230.5	1839.7				1839.7

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples								
	WEEK 1 n	27	15	27	2	0	2	27
	Mean	1151.9	68.4	1189.9	150.0		150.0	1201.0
	SD	347.35	35.90	357.33	70.71		70.71	357.86
	Median	1121.1	76.8	1162.2	150.0		150.0	1220.9
	Min	644.1	18.8	682.1	100.0		100.0	682.1
	Max	2213.3	153.7	2294.5	200.0		200.0	2294.5
	WEEK 2 n	25	17	25	2	1	2	25
	Mean	1306.1	75.1	1357.1	100.0	100.0	150.0	1369.1
	SD	319.75	53.15	341.33	0.00	NA	70.71	347.09
	Median	1292.2	64.9	1343.5	100.0	100.0	150.0	1343.5
	Min	683.6	18.8	721.2	100.0	100.0	100.0	721.2
	Max	1977.8	210.9	2162.2	100.0	100.0	200.0	2262.2
	WEEK 3 n	23	16	23	4	2	6	23
	Mean	1329.1	65.4	1374.6	137.5	100.0	125.0	1407.2
	SD	387.65	27.09	394.34	47.87	0.00	41.83	407.41
	Median	1221.7	61.5	1303.9	125.0	100.0	100.0	1403.9
	Min	686.5	18.8	737.7	100.0	100.0	100.0	737.7
	Max	2345.3	122.9	2426.4	200.0	100.0	200.0	2426.4
	WEEK 4 n	19	14	19	0	0	0	19
	Mean	1331.2	66.3	1380.0				1380.0
	SD	397.12	31.42	401.02				401.02
	Median	1258.6	71.3	1357.2				1357.2
	Min	672.0	18.8	709.6				709.6
	Max	2099.9	112.7	2099.9				2099.9

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample / Week		ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples (Cont.)								
WEEK 6	n	18	13	18	3	0	3	18
	Mean	1355.9	66.0	1403.6	266.7		266.7	1448.0
	SD	446.68	33.32	452.09	288.68		288.68	501.49
	Median	1391.4	64.0	1468.8	100.0		100.0	1468.8
	Min	672.0	18.8	690.8	100.0		100.0	779.6
	Max	2179.6	122.9	2179.6	600.0		600.0	2446.7
WEEK 13	n	18	16	18	3	1	4	18
	Mean	1316.9	67.4	1376.9	383.3	200.0	337.5	1451.9
	SD	403.29	27.66	404.67	490.75	NA	411.05	463.61
	Median	1160.0	62.8	1235.8	100.0	200.0	150.0	1277.6
	Min	682.1	32.4	719.7	100.0	200.0	100.0	819.7
	Max	1992.7	113.5	1993.4	950.0	200.0	950.0	2221.2
WEEK 26	n	17	14	17	4	0	4	17
	Mean	1265.0	73.1	1325.3	100.0		100.0	1348.8
	SD	378.05	48.09	390.02	0.00		0.00	401.58
	Median	1065.5	58.5	1167.4	100.0		100.0	1192.1
	Min	669.1	25.6	706.6	100.0		100.0	706.6
	Max	1919.0	179.3	1951.4	100.0		100.0	1951.4
WEEK 39	n	14	11	14	1	0	1	14
	Mean	1261.7	79.7	1324.3	150.0		150.0	1335.0
	SD	417.44	38.32	420.46	NA		NA	440.52
	Median	1082.3	65.7	1144.2	150.0		150.0	1144.2
	Min	672.0	18.8	690.8	150.0		150.0	690.8
	Max	1930.6	153.7	2003.1	150.0		150.0	2153.1

Program Source Code: [redacted]

TABLE 14.1__8.1.J

Daily Levodopa Dose (mg LD)
(Safety Analysis Set - Japan Subjects)

Enrollment Sample	Week	ABBV-951 CSCI: Continuous Infusion	ABBV-951 CSCI: Extra Dose	ABBV-951 CSCI: Total	Oral: Rescue Dose	Oral: Loading Dose	Oral: Total	Overall Total
Both Enrollment Samples (Cont.)								
	WEEK 52 n	12	9	12	1	0	1	12
	Mean	1320.4	98.6	1394.3	100.0		100.0	1402.6
	SD	397.48	63.72	417.11	NA		NA	427.94
	Median	1245.9	97.3	1406.0	100.0		100.0	1406.0
	Min	690.9	18.8	709.6	100.0		100.0	709.6
	Max	1930.2	230.5	2027.5	100.0		100.0	2027.5

Program Source Code: [redacted]

表14　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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Sample 1	N=157	N=157
< 500	0	0
500 - < 600	0	0
600 - < 700	4 (2.5)	4 (2.5)
700 - < 800	0	0
800 - < 900	3 (1.9)	3 (1.9)
900 - < 1000	2 (1.3)	2 (1.3)
1000 - < 1100	5 (3.2)	5 (3.2)
1100 - < 1200	9 (5.7)	8 (5.1)
1200 - < 1300	8 (5.1)	8 (5.1)
1300 - < 1400	12 (7.6)	12 (7.6)
1400 - < 1500	9 (5.7)	8 (5.1)
1500 - < 1600	7 (4.5)	9 (5.7)
1600 - < 1700	14 (8.9)	14 (8.9)
1700 - < 1800	6 (3.8)	6 (3.8)
1800 - < 1900	10 (6.4)	10 (6.4)
1900 - < 2000	9 (5.7)	6 (3.8)
2000 - < 2100	4 (2.5)	7 (4.5)
2100 - < 2200	8 (5.1)	8 (5.1)
2200 - < 2300	5 (3.2)	4 (2.5)
2300 - < 2400	4 (2.5)	5 (3.2)
2400 - < 2500	5 (3.2)	5 (3.2)
2500 - < 2600	4 (2.5)	4 (2.5)
2600 - < 2700	4 (2.5)	4 (2.5)
2700 - < 2800	7 (4.5)	7 (4.5)
2800 - < 2900	4 (2.5)	4 (2.5)
2900 - < 3000	1 (0.6)	1 (0.6)
3000 - < 3100	1 (0.6)	1 (0.6)
3100 - < 3200	3 (1.9)	3 (1.9)

Program Source Code: [redacted]

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Sample 1 (Cont.)	N=157	N=157
3200 - < 3300	3 (1.9)	3 (1.9)
3300 - < 3400	1 (0.6)	1 (0.6)
3400 - < 3500	1 (0.6)	1 (0.6)
3500 - < 3600	1 (0.6)	1 (0.6)
3600 - < 3700	1 (0.6)	1 (0.6)
3700 - < 3800	0	0
3800 - < 3900	0	0
3900 - < 4000	1 (0.6)	1 (0.6)
4000 - < 4100	1 (0.6)	1 (0.6)
4100 - < 4200	0	0
4200 - < 4300	0	0
>= 4300	0	0

Program Source Code: [redacted]

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Sample 2	N=87	N=87
< 500	0	0
500 - < 600	0	0
600 - < 700	3 (3.4)	3 (3.4)
700 - < 800	4 (4.6)	4 (4.6)
800 - < 900	4 (4.6)	4 (4.6)
900 - < 1000	9 (10.3)	9 (10.3)
1000 - < 1100	3 (3.4)	3 (3.4)
1100 - < 1200	5 (5.7)	5 (5.7)
1200 - < 1300	3 (3.4)	3 (3.4)
1300 - < 1400	5 (5.7)	5 (5.7)
1400 - < 1500	3 (3.4)	2 (2.3)
1500 - < 1600	7 (8.0)	8 (9.2)
1600 - < 1700	1 (1.1)	1 (1.1)
1700 - < 1800	6 (6.9)	6 (6.9)
1800 - < 1900	5 (5.7)	5 (5.7)
1900 - < 2000	2 (2.3)	2 (2.3)
2000 - < 2100	5 (5.7)	5 (5.7)
2100 - < 2200	3 (3.4)	3 (3.4)
2200 - < 2300	4 (4.6)	4 (4.6)
2300 - < 2400	2 (2.3)	2 (2.3)
2400 - < 2500	4 (4.6)	4 (4.6)
2500 - < 2600	2 (2.3)	2 (2.3)
2600 - < 2700	2 (2.3)	2 (2.3)
2700 - < 2800	0	0
2800 - < 2900	1 (1.1)	1 (1.1)
2900 - < 3000	0	0
3000 - < 3100	0	0
3100 - < 3200	0	0

Program Source Code: [redacted]

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Sample 2 (Cont.)	N=87	N=87
3200 - < 3300	1 (1.1)	1 (1.1)
3300 - < 3400	1 (1.1)	1 (1.1)
3400 - < 3500	1 (1.1)	1 (1.1)
3500 - < 3600	0	0
3600 - < 3700	1 (1.1)	1 (1.1)
3700 - < 3800	0	0
3800 - < 3900	0	0
3900 - < 4000	0	0
4000 - < 4100	0	0
4100 - < 4200	0	0
4200 - < 4300	0	0
>= 4300	0	0

Program Source Code: [redacted]

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Both Enrollment Samples	N=244	N=244
< 500	0	0
500 - < 600	0	0
600 - < 700	7 (2.9)	7 (2.9)
700 - < 800	4 (1.6)	4 (1.6)
800 - < 900	7 (2.9)	7 (2.9)
900 - < 1000	11 (4.5)	11 (4.5)
1000 - < 1100	8 (3.3)	8 (3.3)
1100 - < 1200	14 (5.7)	13 (5.3)
1200 - < 1300	11 (4.5)	11 (4.5)
1300 - < 1400	17 (7.0)	17 (7.0)
1400 - < 1500	12 (4.9)	10 (4.1)
1500 - < 1600	14 (5.7)	17 (7.0)
1600 - < 1700	15 (6.1)	15 (6.1)
1700 - < 1800	12 (4.9)	12 (4.9)
1800 - < 1900	15 (6.1)	15 (6.1)
1900 - < 2000	11 (4.5)	8 (3.3)
2000 - < 2100	9 (3.7)	12 (4.9)
2100 - < 2200	11 (4.5)	11 (4.5)
2200 - < 2300	9 (3.7)	8 (3.3)
2300 - < 2400	6 (2.5)	7 (2.9)
2400 - < 2500	9 (3.7)	9 (3.7)
2500 - < 2600	6 (2.5)	6 (2.5)
2600 - < 2700	6 (2.5)	6 (2.5)
2700 - < 2800	7 (2.9)	7 (2.9)
2800 - < 2900	5 (2.0)	5 (2.0)
2900 - < 3000	1 (0.4)	1 (0.4)
3000 - < 3100	1 (0.4)	1 (0.4)
3100 - < 3200	3 (1.2)	3 (1.2)

Program Source Code: [redacted]

TABLE 14.1__8.2

Modal Daily Levodopa Dose by Dose Range Category
(Safety Analysis Set)

Enrollment Sample Categories (mg LD)	CSCI + Extra n (%)	CSCI + Extra + Rescue + Loading Oral n (%)
Both Enrollment Samples (Cont.)	N=244	N=244
3200 - < 3300	4 (1.6)	4 (1.6)
3300 - < 3400	2 (0.8)	2 (0.8)
3400 - < 3500	2 (0.8)	2 (0.8)
3500 - < 3600	1 (0.4)	1 (0.4)
3600 - < 3700	2 (0.8)	2 (0.8)
3700 - < 3800	0	0
3800 - < 3900	0	0
3900 - < 4000	1 (0.4)	1 (0.4)
4000 - < 4100	1 (0.4)	1 (0.4)
4100 - < 4200	0	0
4200 - < 4300	0	0
>= 4300	0	0

Program Source Code: [redacted]

表15　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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 1	n	220	119	220
	Mean	1621.9	810.7	2060.4
	SD	657.31	877.63	1065.82
	Median	1501.4	578.0	1839.0
	Min	486.6	4.0	682.1
	Max	3562.7	5101.6	8346.9
WEEK 2	n	220	71	220
	Mean	1723.4	375.9	1844.7
	SD	660.70	311.93	693.00
	Median	1629.4	250.0	1765.8
	Min	668.5	2.0	668.5
	Max	4136.4	1620.0	4136.4
WEEK 3	n	200	56	200
	Mean	1762.8	413.0	1878.4
	SD	669.51	389.01	722.51
	Median	1657.6	300.0	1813.0
	Min	686.5	2.0	686.5
	Max	4059.6	2200.0	4308.2
WEEK 4	n	192	52	192
	Mean	1817.3	434.2	1934.9
	SD	686.89	434.52	743.24
	Median	1740.2	280.0	1865.1
	Min	696.7	2.0	696.7
	Max	4106.5	2200.0	4109.2

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 6	n	183	50	183
	Mean	1832.3	461.3	1958.3
	SD	689.68	432.53	742.44
	Median	1762.1	255.0	1916.0
	Min	686.5	80.0	686.5
	Max	4119.3	1720.0	4468.3
WEEK 13	n	172	45	172
	Mean	1841.9	722.4	2031.0
	SD	717.34	757.53	898.07
	Median	1783.0	340.0	1933.7
	Min	697.3	80.0	697.3
	Max	4098.0	3250.0	7348.0
WEEK 26	n	154	38	154
	Mean	1806.1	970.7	2045.6
	SD	725.43	1627.10	1214.17
	Median	1716.5	332.5	1823.5
	Min	705.3	26.0	705.3
	Max	4116.8	6745.0	10616.8
WEEK 39	n	137	23	137
	Mean	1810.0	837.6	1950.6
	SD	711.78	1317.97	958.92
	Median	1713.6	240.0	1772.2
	Min	657.0	100.0	657.0
	Max	3987.0	5320.0	7491.9

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 52	n	118	20	118
	Mean	1847.5	558.6	1942.2
	SD	700.45	559.67	788.44
	Median	1779.9	330.0	1848.5
	Min	669.1	40.0	669.1
	Max	3721.2	2150.0	4537.1

Program Source Code: [redacted]

表16　治験薬曝露期間（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 10

Duration of Study Drug Exposure
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Duration of ABBV-951 exposure (days) &			
n	132	112	244
Mean (SD)	239.1 (151.76)	237.2 (147.89)	238.2 (149.69)
Median	360.0	348.0	357.5
Min, Max	3, 450	4, 389	3, 450
By time intervals - n(%) &			
1 - 7 Days	5 (3.8)	2 (1.8)	7 (2.9)
8 - 14 Days	3 (2.3)	7 (6.3)	10 (4.1)
15 - 21 Days	10 (7.6)	3 (2.7)	13 (5.3)
22 - 28 Days	3 (2.3)	5 (4.5)	8 (3.3)
29 - 42 Days	7 (5.3)	4 (3.6)	11 (4.5)
43 - 91 Days	8 (6.1)	10 (8.9)	18 (7.4)
92 - 182 Days	14 (10.6)	12 (10.7)	26 (10.7)
183 - 273 Days	7 (5.3)	7 (6.3)	14 (5.7)
>= 274 Days	75 (56.8)	62 (55.4)	137 (56.1)
At least 6 months (>= 180 days)	83 (62.9)	70 (62.5)	153 (62.7)
At least 1 year (>= 360 days)	66 (50.0)	53 (47.3)	119 (48.8)
Patient-years of exposure &	86.4	72.7	159.1

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=132)	High Dose (N=112)	All Subjects (N=244)
Duration of ABBV-951 exposure (days) without interruption *			
n	132	112	244
Mean (SD)	231.4 (152.65)	232.7 (148.54)	232.0 (150.47)
Median	336.5	313.0	333.0
Min, Max	3, 450	4, 389	3, 450
By time intervals - n(%) *			
1 - 7 Days	7 (5.3)	2 (1.8)	9 (3.7)
8 - 14 Days	2 (1.5)	7 (6.3)	9 (3.7)
15 - 21 Days	9 (6.8)	4 (3.6)	13 (5.3)
22 - 28 Days	4 (3.0)	4 (3.6)	8 (3.3)
29 - 42 Days	9 (6.8)	4 (3.6)	13 (5.3)
43 - 91 Days	8 (6.1)	11 (9.8)	19 (7.8)
92 - 182 Days	15 (11.4)	15 (13.4)	30 (12.3)
183 - 273 Days	5 (3.8)	4 (3.6)	9 (3.7)
>= 274 Days	73 (55.3)	61 (54.5)	134 (54.9)
At least 6 months (>= 180 days)	79 (59.8)	66 (58.9)	145 (59.4)
At least 1 year (>= 360 days)	55 (41.7)	50 (44.6)	105 (43.0)
Patient-years of exposure *	83.6	71.3	155.0

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　治験薬曝露期間（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 10.J

Duration of Study Drug Exposure
(Safety Analysis Set - Japan Subjects)

	Dose Category		
	Low Dose (N=22)	High Dose (N=5)	All Subjects (N=27)
Duration of ABBV-951 exposure (days) &			
n	22	5	27
Mean (SD)	194.8 (156.90)	226.4 (189.34)	200.7 (159.86)
Median	178.5	364.0	190.0
Min, Max	3, 366	17, 365	3, 366
By time intervals - n(%) &			
1 - 7 Days	1 (4.5)	0	1 (3.7)
8 - 14 Days	1 (4.5)	0	1 (3.7)
15 - 21 Days	2 (9.1)	2 (40.0)	4 (14.8)
22 - 28 Days	1 (4.5)	0	1 (3.7)
29 - 42 Days	2 (9.1)	0	2 (7.4)
43 - 91 Days	1 (4.5)	0	1 (3.7)
92 - 182 Days	3 (13.6)	0	3 (11.1)
183 - 273 Days	2 (9.1)	0	2 (7.4)
>= 274 Days	9 (40.9)	3 (60.0)	12 (44.4)
At least 6 months (>= 180 days)	11 (50.0)	3 (60.0)	14 (51.9)
At least 1 year (>= 360 days)	9 (40.9)	3 (60.0)	12 (44.4)
Patient-years of exposure &	11.7	3.1	14.8

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=22)	High Dose (N=5)	All Subjects (N=27)
Duration of ABBV-951 exposure (days) without interruption *			
n	22	5	27
Mean (SD)	181.5 (154.12)	226.0 (188.97)	189.8 (158.08)
Median	143.0	363.0	167.0
Min, Max	3, 366	17, 365	3, 366
By time intervals - n(%) *			
1 - 7 Days	1 (4.5)	0	1 (3.7)
8 - 14 Days	1 (4.5)	0	1 (3.7)
15 - 21 Days	2 (9.1)	2 (40.0)	4 (14.8)
22 - 28 Days	1 (4.5)	0	1 (3.7)
29 - 42 Days	3 (13.6)	0	3 (11.1)
43 - 91 Days	1 (4.5)	0	1 (3.7)
92 - 182 Days	4 (18.2)	0	4 (14.8)
183 - 273 Days	0	0	0
>= 274 Days	9 (40.9)	3 (60.0)	12 (44.4)
At least 6 months (>= 180 days)	9 (40.9)	3 (60.0)	12 (44.4)
At least 1 year (>= 360 days)	7 (31.8)	3 (60.0)	10 (37.0)
Patient-years of exposure *	10.9	3.1	14.0

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18　治験薬投与中断理由（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 12.1

All Reasons for Infusion Interruption
(Safety Analysis Set)

	Total
Total number of subjects with any interruptions	91
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	3
Pump malfunction	20
Adverse event (not COVID-19 infection)	39
Other	49

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表19　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）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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	9
By all reasons	
COVID-19 infection	0
COVID-19 logistical restrictions	0
Pump malfunction	1
Adverse event (not COVID-19 infection)	3
Other	6

Note: One subject can be counted multiple times.

Program Source Code: [redacted]

表20　治験薬投与中断期間（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:41 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.1 12.2

Duration of Infusion Interruption
(Safety Analysis Set)

	Dose Category		
	Low Dose (N=132)	High Dose (N=112)	All Subjects (N=244)
Duration of ABBV-951 interruption (days)			
n	60	34	94
Mean (SD)	15.01 (36.784)	12.35 (28.875)	14.05 (33.998)
Median	1.20	0.84	1.00
Min, Max	0.0, 246.9	0.0, 121.0	0.0, 246.9
By time intervals - n(%)			
< 1 day	27 (45.0)	18 (52.9)	45 (47.9)
1 - < 2 days	8 (13.3)	6 (17.6)	14 (14.9)
2 - < 3 days	1 (1.7)	1 (2.9)	2 (2.1)
3 - < 4 days	1 (1.7)	2 (5.9)	3 (3.2)
4 - < 5 days	3 (5.0)	0	3 (3.2)
5 - < 10 days	4 (6.7)	1 (2.9)	5 (5.3)
10 - < 20 days	4 (6.7)	0	4 (4.3)
20 - < 30 days	4 (6.7)	1 (2.9)	5 (5.3)
>= 30 days	8 (13.3)	5 (14.7)	13 (13.8)

Program Source Code: [redacted]

表21　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）：M15-741試験

[redacted]20[redacted] 10:49 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

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 (SD)	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	236		5.90 (2.24)	5.9	0.0, 12.6				
Low Dose	127		5.68 (2.19)	5.8	0.0, 10.3				
High Dose	109		6.16 (2.28)	6.4	0.0, 12.6				
WEEK 1	225	5.91 (2.25)	3.97 (3.43)	3.1	0.0, 16.0	-1.94 (3.68)	-2.2	-10.2, 10.4	<=0.001***
Low Dose	121	5.73 (2.21)	3.69 (3.19)	2.9	0.0, 13.8	-2.04 (3.49)	-2.2	-10.2, 5.9	<=0.001***
High Dose	104	6.12 (2.29)	4.29 (3.67)	3.6	0.0, 16.0	-1.83 (3.89)	-2.1	-8.9, 10.4	<=0.001***
WEEK 6	205	5.94 (2.24)	3.55 (3.26)	3.1	0.0, 16.0	-2.39 (3.60)	-2.9	-10.6, 9.9	<=0.001***
Low Dose	111	5.73 (2.12)	3.32 (3.33)	3.1	0.0, 16.0	-2.41 (3.65)	-2.9	-10.2, 9.9	<=0.001***
High Dose	94	6.19 (2.35)	3.82 (3.16)	3.1	0.0, 12.5	-2.37 (3.57)	-2.9	-10.6, 6.8	<=0.001***
WEEK 13	114	5.52 (2.28)	3.09 (3.46)	1.8	0.0, 13.4	-2.43 (3.70)	-3.2	-9.9, 8.1	<=0.001***
Low Dose	64	5.41 (2.22)	2.88 (3.53)	1.6	0.0, 13.4	-2.52 (3.80)	-3.3	-9.9, 8.1	<=0.001***
High Dose	50	5.66 (2.36)	3.35 (3.40)	2.1	0.0, 10.7	-2.31 (3.60)	-2.8	-9.2, 6.3	<=0.001***
WEEK 26	131	5.95 (2.23)	2.61 (3.02)	1.4	0.0, 14.3	-3.34 (3.25)	-3.4	-10.6, 7.1	<=0.001***
Low Dose	69	5.77 (1.96)	2.45 (3.17)	0.9	0.0, 14.3	-3.31 (3.36)	-3.8	-10.2, 7.1	<=0.001***
High Dose	62	6.15 (2.50)	2.79 (2.86)	1.8	0.0, 9.8	-3.36 (3.15)	-2.9	-10.6, 5.5	<=0.001***

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 (SD)	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 39	119	5.89 (2.22)	2.65 (2.78)	2.0	0.0, 13.3	-3.24 (3.14)	-3.2	-9.9, 9.6	<=0.001***
Low Dose	67	5.63 (1.95)	2.54 (2.91)	1.7	0.0, 13.3	-3.08 (3.29)	-3.1	-9.9, 9.6	<=0.001***
High Dose	52	6.23 (2.49)	2.79 (2.63)	2.4	0.0, 7.7	-3.44 (2.94)	-3.4	-9.2, 4.0	<=0.001***
WEEK 52	104	5.88 (2.27)	2.52 (2.88)	1.3	0.0, 11.5	-3.36 (3.12)	-3.5	-11.2, 5.9	<=0.001***
Low Dose	56	5.80 (2.02)	2.63 (2.81)	2.2	0.0, 10.9	-3.18 (3.12)	-3.4	-10.2, 5.9	<=0.001***
High Dose	48	5.96 (2.55)	2.39 (2.98)	0.7	0.0, 11.5	-3.57 (3.15)	-3.6	-11.2, 2.8	<=0.001***
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	236		6.51 (3.35)	6.6	0.0, 15.4				
Low Dose	127		6.35 (3.47)	6.4	0.0, 15.4				
High Dose	109		6.70 (3.22)	6.7	0.0, 13.8				
WEEK 1	225	6.48 (3.31)	8.43 (4.52)	8.3	0.0, 16.0	1.94 (4.09)	1.6	-8.9, 12.0	<=0.001***
Low Dose	121	6.21 (3.38)	7.99 (4.53)	8.3	0.0, 16.0	1.78 (3.93)	1.6	-8.9, 10.7	<=0.001***
High Dose	104	6.80 (3.21)	8.94 (4.47)	9.0	0.0, 16.0	2.14 (4.27)	1.9	-8.1, 12.0	<=0.001***
WEEK 6	205	6.54 (3.36)	9.92 (4.48)	10.6	0.0, 16.0	3.38 (4.39)	3.5	-9.1, 13.8	<=0.001***
Low Dose	111	6.37 (3.45)	9.86 (4.55)	10.5	0.0, 16.0	3.49 (4.50)	3.9	-9.1, 13.8	<=0.001***
High Dose	94	6.74 (3.26)	9.99 (4.43)	10.7	0.0, 16.0	3.25 (4.28)	3.2	-6.7, 12.0	<=0.001***

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 (SD)	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 13	114	6.67 (3.42)	10.80 (4.61)	11.5	0.0, 16.0	4.12 (4.36)	4.3	-9.0, 15.2	<=0.001***
Low Dose	64	6.66 (3.46)	10.66 (4.92)	12.4	0.0, 16.0	4.00 (4.41)	4.0	-9.0, 15.2	<=0.001***
High Dose	50	6.70 (3.41)	10.98 (4.23)	11.1	0.9, 16.0	4.28 (4.34)	4.5	-6.3, 14.1	<=0.001***
WEEK 26	131	6.85 (3.37)	11.29 (4.33)	12.6	0.0, 16.0	4.44 (4.47)	4.9	-11.0, 14.1	<=0.001***
Low Dose	69	6.78 (3.46)	11.69 (4.18)	12.8	0.0, 16.0	4.91 (3.99)	5.4	-10.1, 11.5	<=0.001***
High Dose	62	6.93 (3.28)	10.84 (4.48)	11.6	0.0, 16.0	3.92 (4.93)	4.6	-11.0, 14.1	<=0.001***
WEEK 39	119	6.96 (3.28)	10.97 (4.37)	11.3	0.0, 16.0	4.00 (4.10)	4.2	-10.6, 13.5	<=0.001***
Low Dose	67	6.90 (3.28)	11.24 (4.45)	11.8	0.3, 16.0	4.35 (4.23)	4.9	-10.6, 11.4	<=0.001***
High Dose	52	7.05 (3.32)	10.61 (4.29)	11.3	0.0, 16.0	3.56 (3.92)	3.1	-3.8, 13.5	<=0.001***
WEEK 52	104	7.03 (3.30)	10.83 (4.67)	11.8	0.0, 16.0	3.79 (4.21)	4.1	-12.0, 13.8	<=0.001***
Low Dose	56	6.77 (3.29)	11.32 (4.33)	12.7	0.0, 16.0	4.55 (3.85)	4.8	-6.5, 11.3	<=0.001***
High Dose	48	7.34 (3.32)	10.25 (5.02)	11.2	0.0, 16.0	2.91 (4.48)	2.4	-12.0, 13.8	<=0.001***
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	236		2.63 (2.55)	2.4	0.0, 12.2				
Low Dose	127		2.69 (2.39)	2.6	0.0, 10.3				
High Dose	109		2.55 (2.73)	1.9	0.0, 12.2				

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__1.1

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 (SD)	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 1	225	2.66 (2.56)	2.61 (3.16)	1.5	0.0, 14.9	-0.05 (3.04)	0.0	-8.5, 13.6	0.8070
Low Dose	121	2.77 (2.40)	3.04 (3.28)	2.2	0.0, 14.9	0.27 (3.29)	0.0	-8.5, 13.6	0.3612
High Dose	104	2.54 (2.74)	2.12 (2.95)	0.7	0.0, 12.8	-0.43 (2.68)	0.0	-8.2, 8.8	0.1075
WEEK 6	205	2.67 (2.62)	2.09 (3.29)	0.5	0.0, 15.4	-0.58 (3.01)	-0.3	-7.8, 11.6	0.0064**
Low Dose	111	2.75 (2.42)	2.23 (3.17)	0.8	0.0, 15.4	-0.51 (3.05)	-0.2	-7.6, 11.6	0.0785
High Dose	94	2.58 (2.85)	1.93 (3.43)	0.0	0.0, 14.6	-0.66 (2.97)	-0.3	-7.8, 9.6	0.0352*
WEEK 13	114	2.98 (2.75)	1.78 (3.31)	0.0	0.0, 16.0	-1.19 (3.51)	-0.9	-12.2, 13.2	<=0.001***
Low Dose	64	2.94 (2.58)	2.07 (3.69)	0.2	0.0, 16.0	-0.87 (3.58)	-1.1	-8.0, 13.2	0.0571
High Dose	50	3.03 (2.98)	1.42 (2.72)	0.0	0.0, 14.4	-1.61 (3.40)	-0.7	-12.2, 7.2	0.0016**
WEEK 26	131	2.43 (2.47)	1.78 (2.93)	0.3	0.0, 15.2	-0.65 (3.24)	-0.1	-12.2, 12.0	0.0227*
Low Dose	69	2.54 (2.27)	1.56 (2.39)	0.6	0.0, 12.1	-0.99 (2.76)	-0.6	-6.8, 5.4	0.0042**
High Dose	62	2.31 (2.69)	2.03 (3.43)	0.0	0.0, 15.2	-0.28 (3.69)	0.0	-12.2, 12.0	0.5507
WEEK 39	119	2.43 (2.54)	2.03 (3.53)	0.0	0.0, 16.0	-0.40 (3.48)	0.0	-7.8, 15.4	0.2135
Low Dose	67	2.68 (2.38)	1.94 (3.47)	0.0	0.0, 15.4	-0.74 (3.56)	-0.2	-7.8, 15.4	0.0954
High Dose	52	2.11 (2.72)	2.15 (3.63)	0.0	0.0, 16.0	0.04 (3.35)	0.0	-7.8, 9.9	0.9391

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 (SD)	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 52	104	2.49 (2.71)	2.16 (3.85)	0.2	0.0, 16.0	-0.33 (3.38)	0.0	-7.3, 12.9	0.3224
Low Dose	56	2.72 (2.52)	1.85 (3.52)	0.1	0.0, 16.0	-0.86 (3.38)	-0.5	-6.8, 9.2	0.0609
High Dose	48	2.22 (2.91)	2.52 (4.21)	0.4	0.0, 16.0	0.29 (3.30)	0.0	-7.3, 12.9	0.5392
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	236		0.96 (1.73)	0.0	0.0, 10.5				
Low Dose	127		1.27 (2.02)	0.0	0.0, 10.5				
High Dose	109		0.59 (1.20)	0.0	0.0, 5.3				
WEEK 1	225	0.94 (1.71)	0.99 (2.09)	0.0	0.0, 11.7	0.05 (1.89)	0.0	-6.0, 10.5	0.6962
Low Dose	121	1.29 (2.03)	1.28 (2.35)	0.0	0.0, 11.7	-0.01 (2.09)	0.0	-6.0, 10.5	0.9647
High Dose	104	0.53 (1.11)	0.65 (1.68)	0.0	0.0, 9.8	0.12 (1.65)	0.0	-4.9, 7.0	0.4714
WEEK 6	205	0.85 (1.61)	0.44 (1.30)	0.0	0.0, 9.0	-0.41 (1.60)	0.0	-9.2, 6.9	<=0.001***
Low Dose	111	1.15 (1.92)	0.59 (1.59)	0.0	0.0, 9.0	-0.56 (1.94)	0.0	-9.2, 6.9	0.0030**
High Dose	94	0.49 (1.05)	0.26 (0.81)	0.0	0.0, 4.4	-0.23 (1.06)	0.0	-4.9, 4.4	0.0402*
WEEK 13	114	0.83 (1.43)	0.33 (1.12)	0.0	0.0, 8.0	-0.50 (1.45)	0.0	-7.2, 6.0	<=0.001***
Low Dose	64	1.00 (1.57)	0.39 (1.32)	0.0	0.0, 8.0	-0.61 (1.70)	0.0	-7.2, 6.0	0.0059**
High Dose	50	0.62 (1.22)	0.25 (0.81)	0.0	0.0, 3.7	-0.36 (1.05)	0.0	-4.9, 2.6	0.0178*

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 (SD)	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 Troublesome Dyskinesia (Cont.)									
WEEK 26	131	0.77 (1.51)	0.32 (1.38)	0.0	0.0, 12.1	-0.45 (1.85)	0.0	-9.2, 8.8	0.0063**
Low Dose	69	0.91 (1.65)	0.30 (1.53)	0.0	0.0, 12.1	-0.61 (1.95)	0.0	-9.2, 7.2	0.0119*
High Dose	62	0.61 (1.32)	0.34 (1.21)	0.0	0.0, 8.8	-0.27 (1.73)	0.0	-4.9, 8.8	0.2200
WEEK 39	119	0.72 (1.30)	0.35 (1.06)	0.0	0.0, 8.1	-0.37 (1.34)	0.0	-5.1, 7.3	0.0033**
Low Dose	67	0.80 (1.31)	0.27 (0.78)	0.0	0.0, 3.8	-0.53 (1.06)	0.0	-5.1, 0.8	<=0.001***
High Dose	52	0.61 (1.29)	0.46 (1.34)	0.0	0.0, 8.1	-0.16 (1.61)	0.0	-5.0, 7.3	0.4835
WEEK 52	104	0.60 (1.17)	0.50 (1.67)	0.0	0.0, 13.5	-0.10 (1.99)	0.0	-5.1, 13.0	0.5986
Low Dose	56	0.70 (1.21)	0.20 (0.63)	0.0	0.0, 3.3	-0.50 (1.29)	0.0	-5.1, 3.3	0.0050**
High Dose	48	0.48 (1.12)	0.84 (2.33)	0.0	0.0, 13.5	0.36 (2.52)	0.0	-5.0, 13.0	0.3230
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	236		9.14 (2.50)	9.4	0.3, 16.0				
Low Dose	127		9.05 (2.67)	9.7	0.3, 16.0				
High Dose	109		9.25 (2.30)	9.4	2.6, 16.0				
WEEK 1	225	9.15 (2.50)	11.04 (3.68)	11.2	0.0, 16.0	1.89 (3.77)	1.8	-10.4, 11.3	<=0.001***
Low Dose	121	8.98 (2.66)	11.03 (3.64)	11.2	1.6, 16.0	2.05 (3.53)	2.2	-5.9, 11.3	<=0.001***
High Dose	104	9.35 (2.31)	11.06 (3.75)	11.5	0.0, 16.0	1.71 (4.05)	1.6	-10.4, 8.9	<=0.001***

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 (SD)	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 6	205	9.21 (2.44)	12.01 (3.36)	12.4	0.0, 16.0	2.80 (3.59)	3.2	-9.9, 10.6	<=0.001***
Low Dose	111	9.12 (2.54)	12.09 (3.52)	12.6	0.0, 16.0	2.97 (3.58)	3.3	-9.9, 10.5	<=0.001***
High Dose	94	9.32 (2.32)	11.92 (3.18)	12.3	3.5, 16.0	2.60 (3.60)	3.2	-6.8, 10.6	<=0.001***
WEEK 13	114	9.65 (2.35)	12.58 (3.61)	13.9	2.6, 16.0	2.93 (3.48)	3.3	-6.3, 9.9	<=0.001***
Low Dose	64	9.59 (2.37)	12.72 (3.71)	14.2	2.6, 16.0	3.13 (3.31)	3.7	-5.0, 9.9	<=0.001***
High Dose	50	9.73 (2.33)	12.40 (3.50)	13.6	5.3, 16.0	2.67 (3.70)	3.1	-6.3, 9.2	<=0.001***
WEEK 26	131	9.28 (2.60)	13.07 (3.24)	14.3	1.5, 16.0	3.79 (3.54)	3.9	-5.5, 12.5	<=0.001***
Low Dose	69	9.33 (2.66)	13.25 (3.51)	14.9	1.5, 16.0	3.92 (3.76)	4.1	-5.5, 12.5	<=0.001***
High Dose	62	9.24 (2.55)	12.87 (2.93)	14.0	6.2, 16.0	3.64 (3.30)	3.0	-5.5, 10.6	<=0.001***
WEEK 39	119	9.39 (2.47)	13.00 (3.01)	13.5	2.4, 16.0	3.60 (3.32)	3.4	-9.2, 9.9	<=0.001***
Low Dose	67	9.57 (2.42)	13.19 (2.95)	13.7	2.7, 16.0	3.61 (3.32)	3.1	-9.1, 9.9	<=0.001***
High Dose	52	9.16 (2.55)	12.75 (3.09)	13.1	2.4, 16.0	3.60 (3.35)	3.4	-9.2, 9.7	<=0.001***
WEEK 52	104	9.52 (2.43)	12.99 (3.14)	13.7	2.5, 16.0	3.46 (3.11)	3.5	-5.4, 11.2	<=0.001***
Low Dose	56	9.49 (2.44)	13.17 (2.81)	13.7	5.1, 16.0	3.68 (3.07)	3.5	-5.4, 10.2	<=0.001***
High Dose	48	9.56 (2.46)	12.77 (3.51)	14.0	2.5, 16.0	3.21 (3.17)	3.2	-3.8, 11.2	<=0.001***

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22　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）：M15-741試験

TABLE 14.2 1.4

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 (SD)	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									
Average Daily Normalized 'Off' Time									
BASELINE	95		5.99 (2.28)	6.1	0.0, 10.3				
Low Dose	64		6.02 (2.32)	6.2	0.0, 10.3				
High Dose	31		5.93 (2.23)	5.7	1.5, 9.5				
WEEK 1	92	5.96 (2.29)	4.44 (3.75)	3.8	0.0, 14.8	-1.52 (4.10)	-1.7	-10.2, 10.4	<=0.001***
Low Dose	62	6.03 (2.35)	3.83 (3.54)	2.9	0.0, 13.8	-2.20 (3.89)	-2.3	-10.2, 5.9	<=0.001***
High Dose	30	5.82 (2.19)	5.71 (3.91)	5.5	0.0, 14.8	-0.11 (4.24)	-0.3	-7.5, 10.4	0.8888
WEEK 6	83	5.90 (2.30)	4.20 (3.40)	3.8	0.0, 14.9	-1.70 (3.91)	-2.0	-10.2, 8.1	<=0.001***
Low Dose	55	5.87 (2.32)	3.67 (3.34)	3.3	0.0, 14.9	-2.21 (3.75)	-2.7	-10.2, 8.1	<=0.001***
High Dose	28	5.96 (2.31)	5.25 (3.34)	5.2	0.0, 12.5	-0.71 (4.09)	-1.1	-7.5, 6.8	0.3659
WEEK 13	45	5.68 (2.47)	3.38 (3.34)	2.0	0.0, 12.1	-2.30 (4.20)	-3.3	-9.9, 8.1	<=0.001***
Low Dose	32	5.68 (2.54)	3.06 (3.39)	1.6	0.0, 12.1	-2.62 (4.31)	-3.3	-9.9, 8.1	0.0017**
High Dose	13	5.68 (2.40)	4.15 (3.20)	4.2	0.0, 10.3	-1.53 (3.99)	-2.4	-7.5, 6.3	0.1930

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__1.4

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 (SD)	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 26	51	6.14 (2.13)	2.22 (2.66)	1.0	0.0, 9.8	-3.92 (3.32)	-4.0	-10.2, 5.5	<=0.001***
Low Dose	35	6.06 (2.09)	1.74 (2.25)	0.8	0.0, 7.9	-4.32 (3.04)	-4.0	-10.2, 2.7	<=0.001***
High Dose	16	6.30 (2.28)	3.26 (3.22)	2.2	0.0, 9.8	-3.04 (3.83)	-3.4	-9.2, 5.5	0.0062**
WEEK 39	49	6.09 (2.15)	2.54 (2.32)	1.8	0.0, 7.7	-3.55 (3.16)	-2.9	-9.9, 2.9	<=0.001***
Low Dose	34	5.91 (2.07)	2.05 (1.95)	1.4	0.0, 6.2	-3.87 (2.83)	-3.1	-9.9, 1.1	<=0.001***
High Dose	15	6.49 (2.34)	3.65 (2.76)	4.2	0.0, 7.7	-2.84 (3.82)	-2.3	-9.2, 2.9	0.0121*
WEEK 52	38	6.27 (1.96)	1.84 (2.23)	1.0	0.0, 8.8	-4.43 (3.05)	-4.3	-10.2, 3.1	<=0.001***
Low Dose	29	6.29 (1.96)	2.03 (2.43)	1.1	0.0, 8.8	-4.26 (3.02)	-4.1	-10.2, 3.1	<=0.001***
High Dose	9	6.21 (2.07)	1.21 (1.35)	0.8	0.0, 3.6	-4.99 (3.27)	-4.8	-9.2, -0.3	0.0018**
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	95		6.26 (3.20)	6.5	0.0, 14.0				
Low Dose	64		5.95 (3.11)	5.8	0.0, 14.0				
High Dose	31		6.90 (3.32)	6.9	0.9, 12.0				

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__1.4

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 (SD)	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 1	92	6.17 (3.19)	8.03 (4.47)	7.8	0.0, 16.0	1.86 (4.29)	1.9	-8.9, 10.4	<=0.001***
Low Dose	62	5.82 (3.06)	7.75 (4.68)	7.3	0.0, 16.0	1.93 (4.17)	1.9	-8.9, 10.4	<=0.001***
High Dose	30	6.89 (3.38)	8.61 (4.01)	8.2	0.5, 16.0	1.72 (4.59)	1.9	-8.1, 8.7	0.0497*
WEEK 6	83	6.31 (3.15)	9.75 (4.05)	9.9	0.0, 16.0	3.45 (4.32)	4.1	-8.3, 12.7	<=0.001***
Low Dose	55	6.00 (3.10)	9.91 (4.20)	10.2	0.0, 16.0	3.91 (4.11)	4.3	-8.3, 12.7	<=0.001***
High Dose	28	6.91 (3.20)	9.45 (3.80)	9.8	2.4, 16.0	2.54 (4.65)	2.7	-6.7, 9.5	0.0074**
WEEK 13	45	6.64 (3.14)	11.16 (4.42)	13.1	0.0, 16.0	4.52 (4.27)	5.6	-9.0, 11.0	<=0.001***
Low Dose	32	6.43 (2.94)	11.35 (4.66)	13.2	0.0, 16.0	4.92 (4.17)	5.6	-9.0, 11.0	<=0.001***
High Dose	13	7.17 (3.66)	10.69 (3.88)	10.6	3.8, 16.0	3.52 (4.53)	4.3	-6.3, 9.5	0.0159*
WEEK 26	51	6.38 (3.40)	12.11 (3.58)	13.1	0.6, 16.0	5.73 (4.34)	6.6	-11.0, 11.5	<=0.001***
Low Dose	35	6.29 (3.28)	12.97 (2.64)	13.5	7.5, 16.0	6.68 (2.95)	6.8	-1.2, 11.5	<=0.001***
High Dose	16	6.58 (3.74)	10.23 (4.63)	9.9	0.6, 16.0	3.65 (6.03)	5.2	-11.0, 9.5	0.0286*
WEEK 39	49	6.53 (3.27)	11.37 (3.93)	11.8	1.2, 16.0	4.84 (3.91)	5.2	-5.0, 12.4	<=0.001***
Low Dose	34	6.49 (3.04)	11.93 (3.65)	13.0	5.0, 16.0	5.43 (3.67)	5.7	-5.0, 11.4	<=0.001***
High Dose	15	6.60 (3.86)	10.10 (4.36)	11.3	1.2, 16.0	3.50 (4.22)	2.7	-2.9, 12.4	0.0063**

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__1.4

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 (SD)	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 52	38	6.67 (3.06)	11.59 (4.70)	13.2	0.0, 16.0	4.91 (4.81)	6.0	-12.0, 11.3	<=0.001***
Low Dose	29	6.13 (2.95)	11.97 (4.34)	13.3	1.3, 16.0	5.84 (3.97)	6.7	-6.5, 11.3	<=0.001***
High Dose	9	8.44 (2.84)	10.35 (5.81)	12.4	0.0, 16.0	1.91 (6.20)	2.2	-12.0, 9.5	0.3817
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	95		2.52 (2.11)	2.6	0.0, 8.5				
Low Dose	64		2.55 (2.18)	2.6	0.0, 8.5				
High Dose	31		2.44 (1.98)	2.4	0.0, 7.6				
WEEK 1	92	2.59 (2.10)	2.45 (3.11)	1.1	0.0, 13.6	-0.15 (3.39)	-0.3	-8.5, 13.6	0.6809
Low Dose	62	2.63 (2.17)	3.01 (3.35)	2.2	0.0, 13.6	0.38 (3.77)	0.0	-8.5, 13.6	0.4338
High Dose	30	2.52 (1.96)	1.29 (2.15)	0.4	0.0, 8.1	-1.23 (2.09)	-0.7	-5.1, 5.0	0.0032**
WEEK 6	83	2.60 (2.16)	1.58 (2.67)	0.5	0.0, 15.4	-1.02 (2.73)	-0.8	-7.6, 11.6	0.0010**
Low Dose	55	2.67 (2.25)	1.90 (2.99)	0.8	0.0, 15.4	-0.76 (2.90)	-0.8	-7.6, 11.6	0.0562
High Dose	28	2.48 (2.02)	0.95 (1.80)	0.0	0.0, 6.2	-1.53 (2.33)	-0.8	-7.6, 4.0	0.0018**

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__1.4

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 (SD)	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 (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 13	45	2.79 (2.35)	1.10 (2.41)	0.0	0.0, 14.0	-1.70 (2.65)	-2.0	-6.5, 7.9	<=0.001***
Low Dose	32	2.79 (2.35)	1.18 (2.60)	0.0	0.0, 14.0	-1.61 (2.83)	-1.6	-6.5, 7.9	0.0031**
High Dose	13	2.81 (2.47)	0.90 (1.93)	0.0	0.0, 6.4	-1.92 (2.22)	-2.0	-5.3, 1.9	0.0091**
WEEK 26	51	2.55 (2.22)	1.54 (2.62)	0.0	0.0, 15.2	-1.01 (3.24)	-1.0	-6.7, 12.0	0.0304*
Low Dose	35	2.61 (2.29)	1.24 (1.71)	0.0	0.0, 7.3	-1.37 (2.79)	-1.0	-6.7, 4.3	0.0063**
High Dose	16	2.43 (2.13)	2.20 (3.94)	0.0	0.0, 15.2	-0.23 (4.06)	-1.0	-5.3, 12.0	0.8255
WEEK 39	49	2.61 (2.42)	1.64 (2.57)	0.0	0.0, 8.8	-0.96 (3.16)	-0.6	-7.8, 7.2	0.0377*
Low Dose	34	2.76 (2.50)	1.73 (2.58)	0.0	0.0, 7.7	-1.03 (2.95)	0.0	-7.8, 5.0	0.0505
High Dose	15	2.25 (2.27)	1.43 (2.62)	0.0	0.0, 8.8	-0.82 (3.69)	-2.0	-6.4, 7.2	0.4039
WEEK 52	38	2.31 (2.14)	1.92 (3.55)	0.0	0.0, 12.9	-0.40 (3.94)	-0.4	-6.7, 12.9	0.5374
Low Dose	29	2.65 (2.26)	1.83 (3.32)	0.0	0.0, 12.0	-0.82 (3.63)	-0.4	-6.7, 9.2	0.2332
High Dose	9	1.24 (1.28)	2.21 (4.42)	0.0	0.0, 12.9	0.97 (4.76)	-0.4	-2.7, 12.9	0.5572

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__1.4

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 (SD)	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	95		1.24 (2.06)	0.0	0.0, 10.5				
Low Dose	64		1.48 (2.30)	0.0	0.0, 10.5				
High Dose	31		0.74 (1.33)	0.0	0.0, 5.3				
WEEK 1	92	1.28 (2.08)	1.08 (2.15)	0.0	0.0, 10.5	-0.20 (1.99)	0.0	-6.0, 10.5	0.3434
Low Dose	62	1.52 (2.32)	1.41 (2.49)	0.2	0.0, 10.5	-0.11 (2.25)	0.0	-6.0, 10.5	0.7022
High Dose	30	0.77 (1.34)	0.39 (0.89)	0.0	0.0, 4.2	-0.38 (1.33)	0.0	-4.9, 3.4	0.1286
WEEK 6	83	1.19 (2.10)	0.46 (1.30)	0.0	0.0, 5.8	-0.72 (1.79)	0.0	-9.2, 4.1	<=0.001***
Low Dose	55	1.46 (2.39)	0.52 (1.43)	0.0	0.0, 5.8	-0.94 (2.10)	0.0	-9.2, 4.1	0.0016**
High Dose	28	0.66 (1.24)	0.35 (1.01)	0.0	0.0, 4.3	-0.30 (0.82)	0.0	-2.5, 1.4	0.0583
WEEK 13	45	0.88 (1.57)	0.36 (1.37)	0.0	0.0, 8.0	-0.52 (1.90)	0.0	-7.2, 6.0	0.0735
Low Dose	32	1.10 (1.78)	0.41 (1.53)	0.0	0.0, 8.0	-0.70 (2.14)	0.0	-7.2, 6.0	0.0757
High Dose	13	0.34 (0.64)	0.26 (0.93)	0.0	0.0, 3.4	-0.08 (1.02)	0.0	-2.2, 2.6	0.7786

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__1.4

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 (SD)	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 26	51	0.93 (1.77)	0.13 (0.45)	0.0	0.0, 2.4	-0.80 (1.83)	0.0	-9.2, 1.6	0.0032**
Low Dose	35	1.04 (1.93)	0.05 (0.22)	0.0	0.0, 1.3	-0.99 (1.97)	0.0	-9.2, 1.3	0.0056**
High Dose	16	0.69 (1.37)	0.31 (0.73)	0.0	0.0, 2.4	-0.38 (1.46)	0.0	-4.9, 1.6	0.3172
WEEK 39	49	0.78 (1.36)	0.45 (1.43)	0.0	0.0, 8.1	-0.33 (1.50)	0.0	-5.1, 7.3	0.1339
Low Dose	34	0.83 (1.36)	0.29 (0.91)	0.0	0.0, 3.8	-0.54 (1.10)	0.0	-5.1, 0.5	0.0070**
High Dose	15	0.67 (1.41)	0.82 (2.20)	0.0	0.0, 8.1	0.16 (2.13)	0.0	-2.2, 7.3	0.7770
WEEK 52	38	0.74 (1.31)	0.66 (2.41)	0.0	0.0, 13.5	-0.08 (2.74)	0.0	-5.1, 13.0	0.8508
Low Dose	29	0.94 (1.44)	0.18 (0.56)	0.0	0.0, 2.7	-0.76 (1.38)	0.0	-5.1, 1.8	0.0059**
High Dose	9	0.11 (0.23)	2.22 (4.71)	0.0	0.0, 13.5	2.11 (4.59)	0.0	-0.5, 13.0	0.2053
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	95		8.78 (2.72)	8.9	0.3, 15.0				
Low Dose	64		8.51 (2.70)	8.8	0.3, 15.0				
High Dose	31		9.33 (2.70)	9.8	2.6, 14.5				

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__1.4

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 (SD)	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 1	92	8.76 (2.74)	10.48 (3.82)	10.5	1.2, 16.0	1.71 (4.08)	1.5	-10.4, 11.3	<=0.001***
Low Dose	62	8.45 (2.72)	10.76 (3.81)	11.0	2.2, 16.0	2.31 (3.68)	2.1	-5.9, 11.3	<=0.001***
High Dose	30	9.41 (2.71)	9.90 (3.84)	9.9	1.2, 16.0	0.49 (4.64)	0.8	-10.4, 8.3	0.5679
WEEK 6	83	8.91 (2.65)	11.34 (3.49)	11.7	1.1, 16.0	2.43 (3.99)	2.8	-6.8, 10.5	<=0.001***
Low Dose	55	8.67 (2.64)	11.81 (3.50)	12.3	1.1, 16.0	3.15 (3.69)	3.0	-5.7, 10.5	<=0.001***
High Dose	28	9.38 (2.66)	10.40 (3.35)	10.2	3.5, 16.0	1.02 (4.26)	1.2	-6.8, 8.4	0.2180
WEEK 13	45	9.44 (2.42)	12.26 (3.63)	14.0	3.9, 16.0	2.82 (3.88)	3.5	-6.3, 9.9	<=0.001***
Low Dose	32	9.22 (2.36)	12.53 (3.73)	14.4	3.9, 16.0	3.32 (3.63)	3.6	-5.0, 9.9	<=0.001***
High Dose	13	9.98 (2.57)	11.59 (3.43)	11.8	5.7, 16.0	1.61 (4.33)	2.4	-6.3, 7.5	0.2057
WEEK 26	51	8.93 (2.85)	13.65 (2.68)	14.8	6.2, 16.0	4.71 (3.83)	5.2	-5.5, 12.5	<=0.001***
Low Dose	35	8.90 (2.88)	14.21 (2.30)	15.2	8.1, 16.0	5.31 (3.47)	5.2	-2.7, 12.5	<=0.001***
High Dose	16	9.01 (2.88)	12.43 (3.11)	12.9	6.2, 16.0	3.42 (4.36)	4.1	-5.5, 10.2	0.0067**
WEEK 39	49	9.13 (2.63)	13.01 (2.79)	13.7	2.4, 16.0	3.88 (3.75)	3.1	-9.2, 9.9	<=0.001***
Low Dose	34	9.26 (2.49)	13.66 (2.04)	14.1	9.8, 16.0	4.41 (3.00)	3.4	-1.1, 9.9	<=0.001***
High Dose	15	8.85 (2.98)	11.53 (3.68)	11.8	2.4, 16.0	2.68 (4.98)	2.6	-9.2, 9.7	0.0560

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__1.4

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 (SD)	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 52	38	8.99 (2.38)	13.50 (3.00)	14.7	2.5, 16.0	4.52 (3.22)	4.7	-3.8, 10.2	<=0.001***
Low Dose	29	8.77 (2.44)	13.80 (2.48)	14.7	7.2, 16.0	5.02 (3.00)	5.0	-3.1, 10.2	<=0.001***
High Dose	9	9.68 (2.15)	12.56 (4.34)	13.8	2.5, 16.0	2.88 (3.54)	2.3	-3.8, 7.5	0.0404*
Gender:Male									
Average Daily Normalized 'Off' Time									
BASELINE	141		5.85 (2.22)	5.8	0.0, 12.6				
Low Dose	63		5.34 (2.01)	5.4	0.0, 10.0				
High Dose	78		6.26 (2.31)	6.4	0.0, 12.6				
WEEK 1	133	5.88 (2.23)	3.64 (3.16)	2.7	0.0, 16.0	-2.24 (3.34)	-2.7	-9.7, 8.0	<=0.001***
Low Dose	59	5.42 (2.02)	3.54 (2.81)	2.8	0.0, 11.2	-1.88 (3.05)	-2.2	-9.7, 5.6	<=0.001***
High Dose	74	6.24 (2.33)	3.72 (3.43)	2.7	0.0, 16.0	-2.53 (3.54)	-3.4	-8.9, 8.0	<=0.001***
WEEK 6	122	5.97 (2.20)	3.10 (3.09)	2.5	0.0, 16.0	-2.86 (3.32)	-3.4	-10.6, 9.9	<=0.001***
Low Dose	56	5.59 (1.92)	2.98 (3.33)	2.3	0.0, 16.0	-2.62 (3.57)	-3.4	-8.6, 9.9	<=0.001***
High Dose	66	6.29 (2.39)	3.21 (2.90)	2.7	0.0, 11.3	-3.07 (3.09)	-3.3	-10.6, 5.6	<=0.001***

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__1.4

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 (SD)	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 13	69	5.41 (2.15)	2.90 (3.55)	1.7	0.0, 13.4	-2.51 (3.36)	-3.2	-9.2, 7.8	<=0.001***
Low Dose	32	5.13 (1.85)	2.71 (3.70)	1.2	0.0, 13.4	-2.43 (3.29)	-3.4	-6.6, 7.8	<=0.001***
High Dose	37	5.65 (2.38)	3.07 (3.46)	1.7	0.0, 10.7	-2.59 (3.46)	-3.2	-9.2, 5.2	<=0.001***
WEEK 26	80	5.83 (2.30)	2.86 (3.22)	1.7	0.0, 14.3	-2.97 (3.17)	-2.9	-10.6, 7.1	<=0.001***
Low Dose	34	5.46 (1.79)	3.19 (3.79)	1.5	0.0, 14.3	-2.28 (3.40)	-3.0	-6.6, 7.1	<=0.001***
High Dose	46	6.10 (2.60)	2.62 (2.75)	1.8	0.0, 8.9	-3.48 (2.92)	-2.9	-10.6, 4.4	<=0.001***
WEEK 39	70	5.75 (2.26)	2.73 (3.08)	2.1	0.0, 13.3	-3.02 (3.12)	-3.4	-8.1, 9.6	<=0.001***
Low Dose	33	5.33 (1.80)	3.06 (3.61)	2.5	0.0, 13.3	-2.27 (3.58)	-2.9	-7.1, 9.6	<=0.001***
High Dose	37	6.12 (2.57)	2.44 (2.53)	2.1	0.0, 7.2	-3.68 (2.52)	-3.6	-8.1, 4.0	<=0.001***
WEEK 52	66	5.65 (2.41)	2.91 (3.14)	2.2	0.0, 11.5	-2.74 (3.02)	-2.9	-11.2, 5.9	<=0.001***
Low Dose	27	5.28 (1.99)	3.27 (3.09)	2.6	0.0, 10.9	-2.02 (2.84)	-2.4	-5.9, 5.9	0.0010**
High Dose	39	5.90 (2.66)	2.66 (3.19)	0.7	0.0, 11.5	-3.24 (3.07)	-3.4	-11.2, 2.8	<=0.001***

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__1.4

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 (SD)	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	141		6.68 (3.45)	6.7	0.0, 15.4				
Low Dose	63		6.76 (3.77)	7.5	0.0, 15.4				
High Dose	78		6.62 (3.20)	6.6	0.0, 13.8				
WEEK 1	133	6.70 (3.39)	8.70 (4.55)	8.9	0.0, 16.0	2.00 (3.96)	1.2	-6.1, 12.0	<=0.001***
Low Dose	59	6.62 (3.67)	8.24 (4.40)	8.6	0.0, 16.0	1.62 (3.70)	1.0	-6.0, 10.7	0.0014**
High Dose	74	6.77 (3.17)	9.08 (4.66)	9.1	0.0, 16.0	2.31 (4.16)	1.8	-6.1, 12.0	<=0.001***
WEEK 6	122	6.70 (3.50)	10.03 (4.77)	11.4	0.0, 16.0	3.33 (4.45)	3.0	-9.1, 13.8	<=0.001***
Low Dose	56	6.74 (3.75)	9.81 (4.90)	11.3	0.0, 16.0	3.07 (4.85)	2.9	-9.1, 13.8	<=0.001***
High Dose	66	6.67 (3.30)	10.22 (4.68)	11.6	0.0, 16.0	3.55 (4.11)	3.4	-6.4, 12.0	<=0.001***
WEEK 13	69	6.69 (3.61)	10.56 (4.75)	10.9	0.0, 16.0	3.87 (4.43)	3.7	-6.5, 15.2	<=0.001***
Low Dose	32	6.88 (3.94)	9.96 (5.15)	10.1	0.0, 16.0	3.08 (4.51)	2.5	-6.5, 15.2	<=0.001***
High Dose	37	6.53 (3.35)	11.08 (4.39)	11.3	0.9, 16.0	4.55 (4.30)	4.7	-4.7, 14.1	<=0.001***

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__1.4

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 (SD)	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 26	80	7.15 (3.33)	10.77 (4.69)	11.4	0.0, 16.0	3.62 (4.38)	4.0	-10.1, 14.1	<=0.001***
Low Dose	34	7.29 (3.61)	10.38 (5.03)	10.8	0.0, 16.0	3.09 (4.14)	3.6	-10.1, 11.2	<=0.001***
High Dose	46	7.05 (3.15)	11.06 (4.45)	12.4	0.0, 16.0	4.01 (4.56)	4.3	-9.6, 14.1	<=0.001***
WEEK 39	70	7.27 (3.28)	10.68 (4.67)	11.3	0.0, 16.0	3.42 (4.15)	3.1	-10.6, 13.5	<=0.001***
Low Dose	33	7.31 (3.51)	10.54 (5.11)	11.3	0.3, 16.0	3.23 (4.52)	3.1	-10.6, 11.2	<=0.001***
High Dose	37	7.23 (3.11)	10.81 (4.30)	11.3	0.0, 16.0	3.58 (3.85)	3.3	-3.8, 13.5	<=0.001***
WEEK 52	66	7.24 (3.43)	10.39 (4.64)	11.2	0.0, 16.0	3.15 (3.71)	3.2	-3.1, 13.8	<=0.001***
Low Dose	27	7.47 (3.53)	10.62 (4.29)	11.8	0.0, 16.0	3.15 (3.23)	3.4	-2.9, 8.1	<=0.001***
High Dose	39	7.08 (3.40)	10.23 (4.91)	11.2	0.0, 16.0	3.14 (4.05)	2.5	-3.1, 13.8	<=0.001***
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	141		2.70 (2.82)	2.1	0.0, 12.2				
Low Dose	63		2.83 (2.60)	2.7	0.0, 10.3				
High Dose	78		2.60 (2.99)	1.4	0.0, 12.2				

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__1.4

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 (SD)	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 1	133	2.71 (2.84)	2.73 (3.20)	1.5	0.0, 14.9	0.02 (2.78)	0.0	-8.2, 8.8	0.9435
Low Dose	59	2.91 (2.64)	3.07 (3.22)	2.4	0.0, 14.9	0.17 (2.73)	0.0	-5.3, 8.6	0.6419
High Dose	74	2.55 (3.01)	2.45 (3.17)	1.0	0.0, 12.8	-0.10 (2.83)	0.0	-8.2, 8.8	0.7582
WEEK 6	122	2.72 (2.89)	2.44 (3.62)	0.5	0.0, 14.6	-0.28 (3.16)	0.0	-7.8, 9.6	0.3320
Low Dose	56	2.82 (2.59)	2.55 (3.34)	0.9	0.0, 12.2	-0.27 (3.20)	0.0	-6.8, 9.6	0.5296
High Dose	66	2.63 (3.14)	2.34 (3.86)	0.1	0.0, 14.6	-0.29 (3.15)	-0.1	-7.8, 9.6	0.4642
WEEK 13	69	3.10 (2.99)	2.23 (3.73)	0.0	0.0, 16.0	-0.87 (3.96)	-0.5	-12.2, 13.2	0.0733
Low Dose	32	3.09 (2.82)	2.96 (4.40)	0.5	0.0, 16.0	-0.13 (4.12)	-0.5	-8.0, 13.2	0.8590
High Dose	37	3.11 (3.17)	1.60 (2.95)	0.0	0.0, 14.4	-1.50 (3.75)	-0.5	-12.2, 7.2	0.0198*
WEEK 26	80	2.36 (2.63)	1.93 (3.11)	0.6	0.0, 14.9	-0.42 (3.24)	0.0	-12.2, 7.8	0.2457
Low Dose	34	2.47 (2.27)	1.88 (2.91)	0.7	0.0, 12.1	-0.59 (2.72)	0.0	-6.8, 5.4	0.2141
High Dose	46	2.27 (2.88)	1.97 (3.28)	0.2	0.0, 14.9	-0.30 (3.60)	0.0	-12.2, 7.8	0.5750
WEEK 39	70	2.31 (2.63)	2.31 (4.06)	0.0	0.0, 16.0	-0.00 (3.65)	0.0	-7.8, 15.4	0.9959
Low Dose	33	2.59 (2.29)	2.16 (4.23)	0.0	0.0, 15.4	-0.43 (4.12)	-0.6	-6.8, 15.4	0.5491
High Dose	37	2.06 (2.90)	2.44 (3.97)	0.0	0.0, 16.0	0.38 (3.19)	0.0	-7.8, 9.9	0.4699

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__1.4

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 (SD)	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 52	66	2.59 (3.00)	2.30 (4.03)	0.3	0.0, 16.0	-0.29 (3.04)	0.0	-7.3, 7.5	0.4414
Low Dose	27	2.79 (2.82)	1.89 (3.79)	0.3	0.0, 16.0	-0.91 (3.15)	-0.6	-6.8, 6.0	0.1458
High Dose	39	2.45 (3.14)	2.59 (4.21)	0.5	0.0, 16.0	0.14 (2.93)	0.0	-7.3, 7.5	0.7694
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	141		0.77 (1.44)	0.0	0.0, 8.8				
Low Dose	63		1.07 (1.69)	0.2	0.0, 8.8				
High Dose	78		0.52 (1.16)	0.0	0.0, 5.0				
WEEK 1	133	0.71 (1.36)	0.93 (2.05)	0.0	0.0, 11.7	0.22 (1.81)	0.0	-5.7, 7.9	0.1624
Low Dose	59	1.05 (1.66)	1.14 (2.20)	0.0	0.0, 11.7	0.10 (1.92)	0.0	-5.7, 7.9	0.6962
High Dose	74	0.44 (1.00)	0.75 (1.91)	0.0	0.0, 9.8	0.32 (1.72)	0.0	-3.7, 7.0	0.1167
WEEK 6	122	0.61 (1.12)	0.42 (1.31)	0.0	0.0, 9.0	-0.19 (1.43)	0.0	-4.9, 6.9	0.1425
Low Dose	56	0.85 (1.26)	0.66 (1.75)	0.0	0.0, 9.0	-0.19 (1.71)	0.0	-3.4, 6.9	0.4157
High Dose	66	0.41 (0.96)	0.22 (0.71)	0.0	0.0, 4.4	-0.19 (1.15)	0.0	-4.9, 4.4	0.1753

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__1.4

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 (SD)	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 13	69	0.80 (1.35)	0.31 (0.93)	0.0	0.0, 5.5	-0.49 (1.08)	0.0	-4.9, 1.7	<=0.001***
Low Dose	32	0.90 (1.35)	0.38 (1.09)	0.0	0.0, 5.5	-0.52 (1.14)	0.0	-3.4, 1.7	0.0148*
High Dose	37	0.71 (1.36)	0.25 (0.78)	0.0	0.0, 3.7	-0.46 (1.05)	0.0	-4.9, 0.9	0.0112*
WEEK 26	80	0.66 (1.32)	0.44 (1.73)	0.0	0.0, 12.1	-0.23 (1.84)	0.0	-4.9, 8.8	0.2712
Low Dose	34	0.77 (1.32)	0.55 (2.15)	0.0	0.0, 12.1	-0.22 (1.88)	0.0	-3.6, 7.2	0.5054
High Dose	46	0.58 (1.32)	0.35 (1.35)	0.0	0.0, 8.8	-0.24 (1.83)	0.0	-4.9, 8.8	0.3868
WEEK 39	70	0.67 (1.26)	0.28 (0.71)	0.0	0.0, 2.9	-0.40 (1.22)	0.0	-5.0, 2.7	0.0084**
Low Dose	33	0.77 (1.29)	0.25 (0.64)	0.0	0.0, 2.6	-0.52 (1.03)	0.0	-3.6, 0.8	0.0069**
High Dose	37	0.59 (1.26)	0.31 (0.78)	0.0	0.0, 2.9	-0.29 (1.37)	0.0	-5.0, 2.7	0.2118
WEEK 52	66	0.52 (1.08)	0.40 (1.04)	0.0	0.0, 5.3	-0.11 (1.42)	0.0	-5.0, 5.3	0.5157
Low Dose	27	0.45 (0.85)	0.23 (0.70)	0.0	0.0, 3.3	-0.22 (1.13)	0.0	-3.4, 3.3	0.3177
High Dose	39	0.56 (1.23)	0.52 (1.21)	0.0	0.0, 5.3	-0.04 (1.60)	0.0	-5.0, 5.3	0.8792

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__1.4

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 (SD)	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	141		9.39 (2.33)	9.6	3.1, 16.0				
Low Dose	63		9.59 (2.54)	10.1	3.1, 16.0				
High Dose	78		9.22 (2.14)	9.3	3.4, 16.0				
WEEK 1	133	9.41 (2.30)	11.43 (3.55)	11.7	0.0, 16.0	2.02 (3.56)	2.5	-8.0, 9.7	<=0.001***
Low Dose	59	9.53 (2.50)	11.31 (3.46)	11.2	1.6, 16.0	1.78 (3.39)	2.2	-5.6, 9.7	<=0.001***
High Dose	74	9.32 (2.14)	11.53 (3.63)	11.9	0.0, 16.0	2.21 (3.70)	2.6	-8.0, 8.9	<=0.001***
WEEK 6	122	9.42 (2.27)	12.47 (3.21)	13.0	0.0, 16.0	3.05 (3.27)	3.5	-9.9, 10.6	<=0.001***
Low Dose	56	9.56 (2.37)	12.37 (3.56)	12.9	0.0, 16.0	2.80 (3.50)	3.7	-9.9, 9.2	<=0.001***
High Dose	66	9.30 (2.19)	12.57 (2.90)	13.1	4.7, 16.0	3.27 (3.07)	3.5	-2.6, 10.6	<=0.001***
WEEK 13	69	9.79 (2.31)	12.79 (3.61)	13.9	2.6, 16.0	3.00 (3.22)	3.2	-5.2, 9.2	<=0.001***
Low Dose	32	9.97 (2.37)	12.92 (3.75)	13.9	2.6, 16.0	2.95 (2.99)	3.7	-4.9, 7.2	<=0.001***
High Dose	37	9.63 (2.27)	12.68 (3.53)	13.9	5.3, 16.0	3.05 (3.44)	3.2	-5.2, 9.2	<=0.001***

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__1.4

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 (SD)	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 26	80	9.51 (2.41)	12.70 (3.51)	14.1	1.5, 16.0	3.20 (3.24)	2.9	-5.5, 10.6	<=0.001***
Low Dose	34	9.77 (2.37)	12.26 (4.23)	13.8	1.5, 16.0	2.50 (3.56)	3.0	-5.5, 9.4	<=0.001***
High Dose	46	9.32 (2.45)	13.03 (2.88)	14.1	7.1, 16.0	3.71 (2.91)	2.9	-2.5, 10.6	<=0.001***
WEEK 39	70	9.58 (2.36)	12.99 (3.17)	13.2	2.7, 16.0	3.41 (2.99)	3.4	-9.1, 9.4	<=0.001***
Low Dose	33	9.90 (2.33)	12.69 (3.64)	12.9	2.7, 16.0	2.79 (3.48)	3.0	-9.1, 9.4	<=0.001***
High Dose	37	9.28 (2.38)	13.25 (2.71)	13.8	6.6, 16.0	3.97 (2.39)	4.1	-1.3, 8.9	<=0.001***
WEEK 52	66	9.83 (2.43)	12.69 (3.20)	13.4	4.5, 16.0	2.86 (2.90)	2.9	-5.4, 11.2	<=0.001***
Low Dose	27	10.27 (2.23)	12.51 (3.03)	13.4	5.1, 16.0	2.24 (2.46)	2.8	-5.4, 5.9	<=0.001***
High Dose	39	9.53 (2.54)	12.82 (3.35)	14.2	4.5, 16.0	3.28 (3.13)	3.4	-2.8, 11.2	<=0.001***
Race:WHITE									
Average Daily Normalized 'Off' Time									
BASELINE	199		5.75 (2.25)	5.8	0.0, 12.6				
Low Dose	98		5.46 (2.16)	5.6	0.0, 10.2				
High Dose	101		6.04 (2.30)	6.1	0.0, 12.6				

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__1.4

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 (SD)	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 1	190	5.76 (2.25)	3.86 (3.46)	2.9	0.0, 16.0	-1.91 (3.68)	-2.1	-10.2, 10.4	<=0.001***
Low Dose	93	5.53 (2.18)	3.45 (3.17)	2.7	0.0, 11.2	-2.08 (3.45)	-2.4	-10.2, 5.9	<=0.001***
High Dose	97	5.99 (2.29)	4.24 (3.70)	3.1	0.0, 16.0	-1.75 (3.90)	-2.0	-8.9, 10.4	<=0.001***
WEEK 6	173	5.82 (2.27)	3.25 (3.08)	2.9	0.0, 16.0	-2.57 (3.52)	-2.9	-10.6, 9.9	<=0.001***
Low Dose	86	5.59 (2.15)	2.93 (3.16)	2.6	0.0, 16.0	-2.66 (3.54)	-2.9	-10.2, 9.9	<=0.001***
High Dose	87	6.05 (2.37)	3.57 (2.98)	3.0	0.0, 10.7	-2.48 (3.51)	-2.9	-10.6, 6.8	<=0.001***
WEEK 13	99	5.45 (2.30)	2.69 (3.11)	1.7	0.0, 12.6	-2.76 (3.45)	-3.2	-9.9, 7.8	<=0.001***
Low Dose	51	5.31 (2.24)	2.22 (2.81)	1.1	0.0, 12.6	-3.09 (3.26)	-3.4	-9.9, 7.8	<=0.001***
High Dose	48	5.60 (2.38)	3.18 (3.36)	2.0	0.0, 10.7	-2.41 (3.64)	-3.2	-9.2, 6.3	<=0.001***
WEEK 26	112	5.86 (2.33)	2.17 (2.53)	1.2	0.0, 9.8	-3.69 (2.91)	-3.9	-10.6, 5.5	<=0.001***
Low Dose	54	5.68 (2.11)	1.69 (2.21)	0.6	0.0, 7.4	-3.99 (2.64)	-4.2	-10.2, 3.3	<=0.001***
High Dose	58	6.03 (2.51)	2.61 (2.74)	1.7	0.0, 9.8	-3.41 (3.14)	-3.1	-10.6, 5.5	<=0.001***
WEEK 39	100	5.75 (2.29)	2.29 (2.46)	1.5	0.0, 11.4	-3.46 (2.81)	-3.3	-9.9, 6.4	<=0.001***
Low Dose	52	5.44 (2.04)	1.92 (2.28)	1.0	0.0, 11.4	-3.52 (2.72)	-3.1	-9.9, 6.4	<=0.001***
High Dose	48	6.08 (2.51)	2.69 (2.61)	2.1	0.0, 7.7	-3.40 (2.92)	-3.4	-9.2, 4.0	<=0.001***

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__1.4

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 (SD)	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 52	88	5.70 (2.34)	2.18 (2.77)	0.9	0.0, 11.5	-3.51 (3.04)	-3.7	-11.2, 5.9	<=0.001***
Low Dose	44	5.62 (2.13)	2.16 (2.61)	1.2	0.0, 10.9	-3.46 (2.93)	-3.7	-10.2, 5.9	<=0.001***
High Dose	44	5.78 (2.55)	2.20 (2.94)	0.6	0.0, 11.5	-3.57 (3.18)	-3.7	-11.2, 2.8	<=0.001***
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	199		6.63 (3.42)	6.7	0.0, 15.4				
Low Dose	98		6.52 (3.59)	6.6	0.0, 15.4				
High Dose	101		6.74 (3.27)	6.7	0.0, 13.8				
WEEK 1	190	6.61 (3.37)	8.80 (4.52)	8.8	0.0, 16.0	2.19 (4.09)	1.9	-8.8, 12.0	<=0.001***
Low Dose	93	6.37 (3.49)	8.61 (4.59)	8.6	0.0, 16.0	2.24 (3.85)	1.9	-8.8, 10.7	<=0.001***
High Dose	97	6.83 (3.26)	8.98 (4.47)	9.0	0.0, 16.0	2.14 (4.34)	2.1	-8.1, 12.0	<=0.001***
WEEK 6	173	6.62 (3.43)	10.28 (4.42)	11.2	0.0, 16.0	3.67 (4.16)	3.9	-8.3, 12.7	<=0.001***
Low Dose	86	6.46 (3.56)	10.22 (4.60)	10.9	0.0, 16.0	3.75 (4.20)	4.0	-8.3, 12.7	<=0.001***
High Dose	87	6.77 (3.31)	10.34 (4.25)	11.2	0.0, 16.0	3.58 (4.14)	3.5	-6.7, 12.0	<=0.001***

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__1.4

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 (SD)	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 13	99	6.80 (3.52)	11.41 (4.26)	12.6	0.0, 16.0	4.61 (4.10)	4.9	-6.3, 15.2	<=0.001***
Low Dose	51	6.86 (3.61)	11.62 (4.38)	13.2	0.0, 16.0	4.76 (3.90)	4.9	-3.9, 15.2	<=0.001***
High Dose	48	6.73 (3.46)	11.19 (4.16)	11.5	0.9, 16.0	4.46 (4.34)	5.1	-6.3, 14.1	<=0.001***
WEEK 26	112	6.98 (3.46)	11.74 (4.04)	13.1	0.0, 16.0	4.76 (4.38)	5.3	-11.0, 14.1	<=0.001***
Low Dose	54	7.01 (3.58)	12.58 (3.36)	13.4	0.5, 16.0	5.57 (3.44)	5.6	-2.4, 11.5	<=0.001***
High Dose	58	6.95 (3.37)	10.95 (4.48)	11.9	0.0, 16.0	4.00 (5.02)	4.6	-11.0, 14.1	<=0.001***
WEEK 39	100	7.18 (3.32)	11.29 (4.33)	11.8	0.0, 16.0	4.11 (4.17)	4.2	-10.6, 13.5	<=0.001***
Low Dose	52	7.26 (3.26)	11.86 (4.32)	13.1	0.6, 16.0	4.60 (4.30)	5.1	-10.6, 11.4	<=0.001***
High Dose	48	7.09 (3.42)	10.67 (4.30)	11.3	0.0, 16.0	3.58 (4.00)	3.2	-3.8, 13.5	<=0.001***
WEEK 52	88	7.24 (3.34)	11.00 (4.78)	12.4	0.0, 16.0	3.75 (4.45)	4.3	-12.0, 13.8	<=0.001***
Low Dose	44	7.08 (3.28)	11.67 (4.42)	13.3	0.0, 16.0	4.59 (4.20)	5.0	-6.5, 11.3	<=0.001***
High Dose	44	7.41 (3.43)	10.33 (5.08)	11.5	0.0, 16.0	2.91 (4.58)	2.6	-12.0, 13.8	<=0.001***

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__1.4

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 (SD)	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	199		2.64 (2.52)	2.4	0.0, 12.2				
Low Dose	98		2.64 (2.31)	2.6	0.0, 10.3				
High Dose	101		2.64 (2.71)	2.0	0.0, 12.2				
WEEK 1	190	2.67 (2.52)	2.37 (2.90)	1.1	0.0, 13.6	-0.29 (2.89)	0.0	-8.5, 13.6	0.1648
Low Dose	93	2.71 (2.33)	2.67 (2.96)	2.0	0.0, 13.6	-0.04 (3.06)	0.0	-8.5, 13.6	0.9055
High Dose	97	2.63 (2.70)	2.09 (2.83)	0.7	0.0, 11.9	-0.54 (2.71)	0.0	-8.2, 8.8	0.0541
WEEK 6	173	2.69 (2.60)	2.03 (3.21)	0.5	0.0, 15.4	-0.66 (2.85)	-0.4	-7.8, 11.6	0.0026**
Low Dose	86	2.71 (2.37)	2.26 (3.18)	1.0	0.0, 15.4	-0.45 (2.89)	-0.3	-7.6, 11.6	0.1497
High Dose	87	2.68 (2.82)	1.81 (3.25)	0.0	0.0, 14.6	-0.87 (2.82)	-0.6	-7.8, 7.5	0.0051**
WEEK 13	99	2.99 (2.78)	1.56 (2.99)	0.0	0.0, 15.5	-1.43 (3.25)	-1.1	-12.2, 7.9	<=0.001***
Low Dose	51	2.88 (2.56)	1.70 (3.21)	0.2	0.0, 15.5	-1.18 (3.07)	-1.2	-8.0, 7.9	0.0083**
High Dose	48	3.10 (3.01)	1.42 (2.77)	0.0	0.0, 14.4	-1.68 (3.45)	-0.9	-12.2, 7.2	0.0015**

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__1.4

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 (SD)	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 26	112	2.36 (2.41)	1.76 (2.93)	0.4	0.0, 15.2	-0.61 (3.31)	-0.2	-12.2, 12.0	0.0550
Low Dose	54	2.29 (2.04)	1.39 (2.10)	0.7	0.0, 10.8	-0.91 (2.68)	-0.6	-6.8, 5.4	0.0159*
High Dose	58	2.43 (2.73)	2.10 (3.52)	0.0	0.0, 15.2	-0.33 (3.81)	-0.1	-12.2, 12.0	0.5172
WEEK 39	100	2.37 (2.48)	2.07 (3.59)	0.0	0.0, 16.0	-0.31 (3.54)	0.0	-7.8, 15.4	0.3869
Low Dose	52	2.50 (2.20)	1.96 (3.48)	0.0	0.0, 15.4	-0.54 (3.62)	-0.1	-7.8, 15.4	0.2854
High Dose	48	2.23 (2.78)	2.18 (3.75)	0.0	0.0, 16.0	-0.05 (3.46)	0.0	-7.8, 9.9	0.9163
WEEK 52	88	2.49 (2.67)	2.29 (4.08)	0.1	0.0, 16.0	-0.20 (3.46)	-0.2	-7.3, 12.9	0.5836
Low Dose	44	2.61 (2.33)	1.97 (3.82)	0.0	0.0, 16.0	-0.64 (3.48)	-0.5	-6.8, 9.2	0.2302
High Dose	44	2.37 (2.99)	2.60 (4.35)	0.4	0.0, 16.0	0.23 (3.43)	0.0	-7.3, 12.9	0.6552
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	199		0.97 (1.73)	0.0	0.0, 10.5				
Low Dose	98		1.38 (2.08)	0.2	0.0, 10.5				
High Dose	101		0.58 (1.21)	0.0	0.0, 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__1.4

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 (SD)	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 1	190	0.96 (1.72)	0.97 (2.05)	0.0	0.0, 11.7	0.01 (1.78)	0.0	-5.7, 10.5	0.9551
Low Dose	93	1.39 (2.08)	1.26 (2.31)	0.0	0.0, 11.7	-0.13 (1.86)	0.0	-5.7, 10.5	0.5025
High Dose	97	0.55 (1.14)	0.69 (1.73)	0.0	0.0, 9.8	0.14 (1.70)	0.0	-4.9, 7.0	0.4237
WEEK 6	173	0.87 (1.61)	0.44 (1.28)	0.0	0.0, 9.0	-0.43 (1.48)	0.0	-9.2, 5.3	<=0.001***
Low Dose	86	1.23 (1.95)	0.60 (1.60)	0.0	0.0, 9.0	-0.64 (1.77)	0.0	-9.2, 5.3	0.0012**
High Dose	87	0.51 (1.08)	0.28 (0.84)	0.0	0.0, 4.4	-0.23 (1.09)	0.0	-4.9, 4.4	0.0564
WEEK 13	99	0.76 (1.27)	0.34 (1.17)	0.0	0.0, 8.0	-0.43 (1.30)	0.0	-5.2, 6.0	0.0015**
Low Dose	51	0.95 (1.35)	0.46 (1.45)	0.0	0.0, 8.0	-0.49 (1.49)	0.0	-5.2, 6.0	0.0236*
High Dose	48	0.57 (1.17)	0.20 (0.74)	0.0	0.0, 3.7	-0.36 (1.07)	0.0	-4.9, 2.6	0.0229*
WEEK 26	112	0.79 (1.55)	0.33 (1.48)	0.0	0.0, 12.1	-0.46 (1.95)	0.0	-9.2, 8.8	0.0140*
Low Dose	54	1.01 (1.77)	0.34 (1.72)	0.0	0.0, 12.1	-0.67 (2.12)	0.0	-9.2, 7.2	0.0231*
High Dose	58	0.59 (1.30)	0.33 (1.24)	0.0	0.0, 8.8	-0.26 (1.78)	0.0	-4.9, 8.8	0.2683
WEEK 39	100	0.70 (1.27)	0.35 (1.10)	0.0	0.0, 8.1	-0.34 (1.40)	0.0	-5.1, 7.3	0.0163*
Low Dose	52	0.79 (1.27)	0.26 (0.76)	0.0	0.0, 3.8	-0.53 (1.08)	0.0	-5.1, 0.8	<=0.001***
High Dose	48	0.59 (1.26)	0.46 (1.38)	0.0	0.0, 8.1	-0.13 (1.66)	0.0	-5.0, 7.3	0.5842

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__1.4

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 (SD)	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 52	88	0.57 (1.10)	0.53 (1.79)	0.0	0.0, 13.5	-0.03 (2.11)	0.0	-5.1, 13.0	0.8798
Low Dose	44	0.69 (1.13)	0.20 (0.67)	0.0	0.0, 3.3	-0.49 (1.31)	0.0	-5.1, 3.3	0.0159*
High Dose	44	0.44 (1.07)	0.87 (2.41)	0.0	0.0, 13.5	0.43 (2.62)	0.0	-5.0, 13.0	0.2867
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	199		9.27 (2.55)	9.6	0.3, 16.0				
Low Dose	98		9.16 (2.77)	9.8	0.3, 16.0				
High Dose	101		9.38 (2.33)	9.5	2.6, 16.0				
WEEK 1	190	9.27 (2.55)	11.17 (3.73)	11.7	0.0, 16.0	1.90 (3.81)	2.0	-10.4, 11.3	<=0.001***
Low Dose	93	9.08 (2.76)	11.29 (3.69)	12.0	1.6, 16.0	2.21 (3.52)	2.6	-5.9, 11.3	<=0.001***
High Dose	97	9.46 (2.33)	11.06 (3.78)	11.7	0.0, 16.0	1.61 (4.07)	1.5	-10.4, 8.9	<=0.001***
WEEK 6	173	9.31 (2.53)	12.31 (3.23)	12.8	0.0, 16.0	3.00 (3.54)	3.3	-9.9, 10.6	<=0.001***
Low Dose	86	9.17 (2.70)	12.47 (3.43)	12.8	0.0, 16.0	3.30 (3.49)	3.3	-9.9, 10.5	<=0.001***
High Dose	87	9.45 (2.35)	12.15 (3.04)	12.6	5.1, 16.0	2.71 (3.57)	3.3	-6.8, 10.6	<=0.001***

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__1.4

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 (SD)	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 13	99	9.79 (2.36)	12.98 (3.30)	14.1	3.4, 16.0	3.19 (3.41)	3.5	-6.3, 9.9	<=0.001***
Low Dose	51	9.74 (2.43)	13.32 (3.19)	14.5	3.4, 16.0	3.58 (3.05)	4.0	-4.9, 9.9	<=0.001***
High Dose	48	9.84 (2.31)	12.61 (3.41)	13.7	5.3, 16.0	2.78 (3.75)	3.2	-6.3, 9.2	<=0.001***
WEEK 26	112	9.35 (2.71)	13.50 (2.84)	14.5	1.5, 16.0	4.15 (3.35)	4.1	-5.5, 12.5	<=0.001***
Low Dose	54	9.31 (2.88)	13.97 (2.84)	15.3	1.5, 16.0	4.66 (3.34)	4.7	-4.5, 12.5	<=0.001***
High Dose	58	9.38 (2.57)	13.06 (2.80)	14.0	6.2, 16.0	3.67 (3.33)	3.4	-5.5, 10.6	<=0.001***
WEEK 39	100	9.55 (2.47)	13.36 (2.78)	14.0	2.4, 16.0	3.80 (3.12)	3.4	-9.2, 9.9	<=0.001***
Low Dose	52	9.76 (2.38)	13.82 (2.41)	14.6	4.6, 16.0	4.06 (2.86)	3.2	-5.9, 9.9	<=0.001***
High Dose	48	9.33 (2.57)	12.86 (3.08)	13.2	2.4, 16.0	3.53 (3.39)	3.4	-9.2, 9.7	<=0.001***
WEEK 52	88	9.73 (2.42)	13.28 (3.08)	14.1	2.5, 16.0	3.55 (3.09)	3.6	-5.4, 11.2	<=0.001***
Low Dose	44	9.69 (2.42)	13.64 (2.57)	14.0	5.1, 16.0	3.95 (2.93)	3.9	-5.4, 10.2	<=0.001***
High Dose	44	9.78 (2.44)	12.93 (3.51)	14.4	2.5, 16.0	3.15 (3.22)	3.2	-3.8, 11.2	<=0.001***

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__1.4

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 (SD)	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									
Average Daily Normalized 'Off' Time									
BASELINE	34		6.68 (2.04)	6.8	0.0, 10.3				
Low Dose	27		6.45 (2.13)	6.6	0.0, 10.3				
High Dose	7		7.60 (1.44)	8.1	5.7, 9.6				
WEEK 1	32	6.70 (2.10)	4.78 (3.25)	4.7	0.0, 13.8	-1.92 (3.79)	-2.2	-9.7, 4.7	0.0074**
Low Dose	26	6.43 (2.17)	4.72 (3.18)	4.6	0.0, 13.8	-1.71 (3.75)	-2.0	-9.7, 4.7	0.0283*
High Dose	6	7.89 (1.34)	5.05 (3.84)	5.1	0.0, 10.9	-2.83 (4.22)	-3.9	-8.3, 2.8	0.1613
WEEK 6	29	6.56 (1.96)	5.41 (3.69)	4.3	0.0, 13.4	-1.15 (3.98)	-2.7	-7.5, 6.8	0.1319
Low Dose	23	6.21 (1.97)	5.00 (3.55)	3.8	0.0, 13.4	-1.21 (3.90)	-2.4	-7.5, 6.2	0.1520
High Dose	6	7.89 (1.34)	6.96 (4.16)	5.8	1.6, 12.5	-0.92 (4.67)	-3.1	-5.4, 6.8	0.6493
WEEK 13	13	5.95 (2.10)	5.96 (4.52)	6.2	0.0, 13.4	0.01 (4.89)	0.3	-7.0, 8.1	0.9927
Low Dose	12	5.96 (2.19)	5.94 (4.72)	5.0	0.0, 13.4	-0.01 (5.10)	-0.3	-7.0, 8.1	0.9930
High Dose	1	5.87 (N/A)	6.20 (N/A)	6.2	6.2, 6.2	0.32 (N/A)	0.3	0.3, 0.3	

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__1.4

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 (SD)	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 26	18	6.63 (1.39)	5.50 (4.17)	5.4	0.0, 14.3	-1.13 (4.40)	-0.7	-8.1, 7.1	0.2919
Low Dose	14	6.25 (1.12)	5.56 (4.41)	5.4	0.0, 14.3	-0.69 (4.62)	-0.4	-7.8, 7.1	0.5870
High Dose	4	7.98 (1.56)	5.31 (3.81)	6.2	0.0, 8.9	-2.67 (3.64)	-1.1	-8.1, -0.4	0.2388
WEEK 39	18	6.78 (1.52)	4.08 (2.97)	4.2	0.0, 12.3	-2.70 (3.48)	-1.7	-8.1, 5.1	0.0043**
Low Dose	14	6.44 (1.38)	4.09 (3.09)	4.2	0.0, 12.3	-2.35 (3.51)	-1.6	-8.1, 5.1	0.0266*
High Dose	4	7.98 (1.56)	4.03 (2.93)	4.6	0.0, 6.8	-3.95 (3.53)	-3.6	-8.1, -0.6	0.1110
WEEK 52	16	6.85 (1.56)	4.34 (2.88)	5.2	0.0, 10.1	-2.51 (3.54)	-2.7	-8.7, 4.1	0.0126*
Low Dose	12	6.47 (1.43)	4.32 (2.97)	4.5	0.0, 10.1	-2.16 (3.70)	-2.7	-8.7, 4.1	0.0688
High Dose	4	7.98 (1.56)	4.41 (2.99)	5.6	0.0, 6.4	-3.57 (3.23)	-2.7	-8.1, -0.7	0.1143
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	34		5.67 (2.94)	5.8	0.0, 11.8				
Low Dose	27		5.61 (3.03)	5.1	0.0, 11.8				
High Dose	7		5.91 (2.79)	6.5	0.5, 8.4				

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__1.4

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 (SD)	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 1	32	5.62 (2.96)	6.34 (4.03)	6.8	0.3, 16.0	0.72 (3.85)	0.7	-8.9, 10.2	0.2970
Low Dose	26	5.48 (3.01)	5.96 (3.81)	6.4	0.3, 14.9	0.48 (3.90)	0.6	-8.9, 10.2	0.5371
High Dose	6	6.22 (2.93)	8.00 (4.92)	8.0	1.2, 16.0	1.78 (3.78)	1.0	-2.8, 8.3	0.3018
WEEK 6	29	5.95 (3.05)	8.38 (4.29)	8.6	0.0, 14.4	2.43 (4.98)	3.5	-6.4, 13.8	0.0137*
Low Dose	23	5.88 (3.14)	9.25 (3.81)	9.3	2.1, 14.4	3.37 (4.78)	3.9	-6.1, 13.8	0.0027**
High Dose	6	6.22 (2.93)	5.06 (4.74)	3.1	0.0, 11.2	-1.16 (4.33)	-1.0	-6.4, 3.5	0.5391
WEEK 13	13	5.47 (2.59)	6.53 (5.28)	5.9	0.0, 14.7	1.06 (5.15)	1.1	-9.0, 9.6	0.4744
Low Dose	12	5.59 (2.67)	6.72 (5.47)	6.1	0.0, 14.7	1.13 (5.38)	1.4	-9.0, 9.6	0.4812
High Dose	1	4.05 (N/A)	4.20 (N/A)	4.2	4.2, 4.2	0.15 (N/A)	0.1	0.1, 0.1	
WEEK 26	18	5.90 (2.66)	8.42 (5.13)	7.8	0.0, 16.0	2.52 (4.76)	2.3	-10.1, 9.5	0.0385*
Low Dose	14	5.73 (2.90)	8.18 (5.36)	7.8	0.0, 16.0	2.45 (5.16)	3.2	-10.1, 9.5	0.0986
High Dose	4	6.50 (1.77)	9.24 (4.80)	7.9	5.1, 16.0	2.74 (3.60)	1.2	0.4, 8.1	0.2257
WEEK 39	18	5.64 (2.83)	9.62 (4.13)	10.3	0.3, 16.0	3.98 (3.01)	4.7	-1.9, 8.1	<=0.001***
Low Dose	14	5.39 (3.08)	9.56 (4.16)	10.5	0.3, 16.0	4.17 (3.02)	4.9	-1.9, 8.0	<=0.001***
High Dose	4	6.50 (1.77)	9.82 (4.67)	9.3	4.7, 16.0	3.32 (3.35)	2.3	0.6, 8.1	0.1414

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__1.4

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 (SD)	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 52	16	5.88 (2.89)	9.89 (4.02)	9.4	4.0, 16.0	4.01 (2.56)	3.1	-0.1, 8.7	<=0.001***
Low Dose	12	5.67 (3.21)	10.05 (3.89)	10.0	4.2, 16.0	4.38 (2.21)	3.8	1.9, 8.7	<=0.001***
High Dose	4	6.50 (1.77)	9.42 (4.99)	8.8	4.0, 16.0	2.91 (3.57)	1.8	-0.1, 8.1	0.2009
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	34		2.72 (2.80)	2.4	0.0, 8.5				
Low Dose	27		2.97 (2.73)	2.8	0.0, 8.0				
High Dose	7		1.75 (3.10)	0.3	0.0, 8.5				
WEEK 1	32	2.81 (2.85)	3.85 (4.13)	2.5	0.0, 14.9	1.04 (3.49)	0.1	-5.4, 13.2	0.1021
Low Dose	26	3.08 (2.71)	4.07 (4.00)	2.7	0.0, 14.9	0.99 (3.80)	0.1	-5.4, 13.2	0.1978
High Dose	6	1.63 (3.38)	2.90 (4.95)	1.0	0.0, 12.8	1.27 (1.81)	0.7	-0.4, 4.3	0.1459
WEEK 6	29	2.72 (2.83)	2.09 (3.35)	0.5	0.0, 12.3	-0.63 (3.34)	0.0	-6.7, 9.6	0.3169
Low Dose	23	3.01 (2.68)	1.60 (2.46)	0.5	0.0, 9.0	-1.41 (2.76)	0.0	-6.7, 4.4	0.0227*
High Dose	6	1.63 (3.38)	3.98 (5.53)	1.0	0.0, 12.3	2.35 (3.95)	0.8	-1.0, 9.6	0.2048

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__1.4

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 (SD)	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 13	13	3.15 (2.75)	3.18 (4.95)	1.2	0.0, 16.0	0.03 (4.96)	0.0	-6.5, 13.2	0.9809
Low Dose	12	3.20 (2.86)	3.21 (5.17)	0.7	0.0, 16.0	0.01 (5.18)	-0.3	-6.5, 13.2	0.9947
High Dose	1	2.48 (N/A)	2.80 (N/A)	2.8	2.8, 2.8	0.32 (N/A)	0.3	0.3, 0.3	
WEEK 26	18	2.86 (2.90)	1.84 (3.04)	0.2	0.0, 12.1	-1.01 (2.90)	0.0	-6.7, 4.6	0.1559
Low Dose	14	3.50 (2.95)	2.09 (3.33)	0.2	0.0, 12.1	-1.41 (3.19)	-2.3	-6.7, 4.6	0.1218
High Dose	4	0.62 (1.24)	0.99 (1.76)	0.2	0.0, 3.6	0.37 (0.54)	0.2	0.0, 1.1	0.2625
WEEK 39	18	2.73 (2.96)	1.95 (3.32)	0.0	0.0, 13.2	-0.78 (3.26)	0.0	-6.7, 5.2	0.3235
Low Dose	14	3.33 (3.05)	2.01 (3.65)	0.0	0.0, 13.2	-1.32 (3.48)	-0.9	-6.7, 5.2	0.1800
High Dose	4	0.62 (1.24)	1.72 (2.12)	1.3	0.0, 4.3	1.10 (1.30)	0.9	0.0, 2.5	0.1889
WEEK 52	16	2.49 (3.02)	1.47 (2.08)	0.5	0.0, 6.7	-1.02 (2.84)	0.0	-6.7, 3.9	0.1707
Low Dose	12	3.12 (3.22)	1.43 (2.15)	0.5	0.0, 6.7	-1.69 (2.95)	-0.6	-6.7, 3.9	0.0731
High Dose	4	0.62 (1.24)	1.60 (2.16)	0.9	0.0, 4.6	0.98 (1.13)	0.9	0.0, 2.1	0.1832

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__1.4

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 (SD)	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									
BASELINE	34		0.93 (1.77)	0.0	0.0, 7.2				
Low Dose	27		0.98 (1.89)	0.0	0.0, 7.2				
High Dose	7		0.74 (1.31)	0.0	0.0, 3.6				
WEEK 1	32	0.87 (1.75)	1.03 (2.27)	0.0	0.0, 10.3	0.16 (2.39)	0.0	-6.0, 7.9	0.7122
Low Dose	26	1.01 (1.91)	1.26 (2.47)	0.1	0.0, 10.3	0.24 (2.65)	0.0	-6.0, 7.9	0.6420
High Dose	6	0.26 (0.41)	0.04 (0.10)	0.0	0.0, 0.3	-0.22 (0.35)	0.0	-0.8, 0.0	0.1861
WEEK 6	29	0.77 (1.70)	0.12 (0.52)	0.0	0.0, 2.7	-0.65 (1.69)	0.0	-7.2, 1.0	0.0473*
Low Dose	23	0.91 (1.88)	0.16 (0.58)	0.0	0.0, 2.7	-0.75 (1.88)	0.0	-7.2, 1.0	0.0684
High Dose	6	0.26 (0.41)	0.00 (0.00)	0.0	0.0, 0.0	-0.26 (0.41)	0.0	-0.8, 0.0	0.1748
WEEK 13	13	1.43 (2.39)	0.33 (0.85)	0.0	0.0, 2.8	-1.10 (2.39)	0.0	-7.2, 1.3	0.1220
Low Dose	12	1.25 (2.40)	0.13 (0.43)	0.0	0.0, 1.5	-1.13 (2.49)	0.0	-7.2, 1.3	0.1451
High Dose	1	3.59 (N/A)	2.81 (N/A)	2.8	2.8, 2.8	-0.79 (N/A)	-0.8	-0.8, -0.8	

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__1.4

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 (SD)	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 With Troublesome Dyskinesia (Cont.)									
WEEK 26	18	0.61 (1.26)	0.23 (0.52)	0.0	0.0, 1.8	-0.37 (1.16)	0.0	-3.4, 1.3	0.1884
Low Dose	14	0.52 (1.14)	0.17 (0.38)	0.0	0.0, 1.3	-0.36 (1.25)	0.0	-3.4, 1.3	0.3082
High Dose	4	0.90 (1.80)	0.46 (0.92)	0.0	0.0, 1.8	-0.44 (0.87)	0.0	-1.7, 0.0	0.3910
WEEK 39	18	0.86 (1.55)	0.36 (0.89)	0.0	0.0, 3.5	-0.50 (0.99)	0.0	-3.0, 0.0	0.0481*
Low Dose	14	0.85 (1.55)	0.34 (0.93)	0.0	0.0, 3.5	-0.51 (1.04)	0.0	-3.0, 0.0	0.0918
High Dose	4	0.90 (1.80)	0.43 (0.86)	0.0	0.0, 1.7	-0.47 (0.94)	0.0	-1.9, 0.0	0.3910
WEEK 52	16	0.78 (1.54)	0.29 (0.66)	0.0	0.0, 2.3	-0.48 (1.13)	0.0	-3.4, 0.5	0.1067
Low Dose	12	0.74 (1.53)	0.20 (0.45)	0.0	0.0, 1.5	-0.54 (1.27)	0.0	-3.4, 0.5	0.1708
High Dose	4	0.90 (1.80)	0.57 (1.14)	0.0	0.0, 2.3	-0.33 (0.65)	0.0	-1.3, 0.0	0.3910
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	34		8.39 (2.10)	8.7	2.2, 11.8				
Low Dose	27		8.57 (2.26)	9.0	2.2, 11.8				
High Dose	7		7.66 (1.21)	7.7	6.4, 9.5				

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__1.4

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 (SD)	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 1	32	8.43 (2.14)	10.19 (3.33)	10.2	2.2, 16.0	1.76 (3.75)	1.1	-4.0, 9.7	0.0123*
Low Dose	26	8.56 (2.30)	10.03 (3.27)	9.9	2.2, 16.0	1.47 (3.69)	1.0	-4.0, 9.7	0.0538
High Dose	6	7.85 (1.21)	10.90 (3.85)	10.8	5.1, 16.0	3.05 (4.08)	4.2	-2.8, 8.3	0.1261
WEEK 6	29	8.67 (1.77)	10.47 (3.78)	11.5	2.6, 16.0	1.80 (3.90)	3.1	-6.0, 7.5	0.0193*
Low Dose	23	8.88 (1.85)	10.84 (3.69)	12.2	2.6, 16.0	1.96 (3.88)	3.1	-5.7, 7.5	0.0242*
High Dose	6	7.85 (1.21)	9.04 (4.16)	10.2	3.5, 14.4	1.18 (4.29)	3.1	-6.0, 5.4	0.5288
WEEK 13	13	8.62 (2.05)	9.70 (4.53)	9.4	2.6, 16.0	1.09 (3.71)	0.5	-5.0, 7.0	0.3109
Low Dose	12	8.79 (2.03)	9.93 (4.66)	10.5	2.6, 16.0	1.14 (3.87)	0.8	-5.0, 7.0	0.3291
High Dose	1	6.53 (N/A)	7.00 (N/A)	7.0	7.0, 7.0	0.46 (N/A)	0.5	0.5, 0.5	
WEEK 26	18	8.76 (1.72)	10.26 (4.16)	10.0	1.7, 16.0	1.50 (4.02)	0.7	-5.5, 8.1	0.1315
Low Dose	14	9.23 (1.64)	10.27 (4.37)	10.5	1.7, 16.0	1.04 (4.18)	0.5	-5.5, 7.8	0.3678
High Dose	4	7.12 (0.78)	10.23 (3.94)	8.9	7.1, 16.0	3.11 (3.38)	1.8	0.7, 8.1	0.1633
WEEK 39	18	8.36 (2.30)	11.57 (2.90)	11.6	3.7, 16.0	3.20 (3.15)	2.6	-2.1, 9.1	<=0.001***
Low Dose	14	8.72 (2.49)	11.57 (2.92)	11.6	3.7, 16.0	2.86 (3.20)	2.3	-2.1, 9.1	0.0053**
High Dose	4	7.12 (0.78)	11.54 (3.28)	10.6	9.0, 16.0	4.42 (3.02)	4.0	1.5, 8.1	0.0614

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__1.4

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 (SD)	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 52	16	8.37 (2.27)	11.36 (3.08)	10.3	5.9, 16.0	2.99 (3.31)	2.7	-2.2, 8.7	0.0025**
Low Dose	12	8.79 (2.47)	11.48 (3.13)	11.5	5.9, 16.0	2.69 (3.50)	2.7	-2.2, 8.7	0.0220*
High Dose	4	7.12 (0.78)	11.01 (3.37)	9.7	8.6, 16.0	3.89 (2.90)	2.8	1.9, 8.1	0.0745
Race:OTHER									
Average Daily Normalized 'Off' Time									
BASELINE	3		6.91 (2.75)	8.5	3.7, 8.5				
Low Dose	2		6.13 (3.39)	6.1	3.7, 8.5				
High Dose	1		8.46 (N/A)	8.5	8.5, 8.5				
WEEK 1	3	6.91 (2.75)	2.44 (2.29)	2.8	0.0, 4.5	-4.47 (1.12)	-3.9	-5.8, -3.7	0.0201*
Low Dose	2	6.13 (3.39)	1.39 (1.96)	1.4	0.0, 2.8	-4.74 (1.43)	-4.7	-5.8, -3.7	0.1335
High Dose	1	8.46 (N/A)	4.53 (N/A)	4.5	4.5, 4.5	-3.92 (N/A)	-3.9	-3.9, -3.9	
WEEK 6	3	6.91 (2.75)	2.71 (3.86)	1.0	0.0, 7.1	-4.19 (3.13)	-3.7	-7.5, -1.3	0.1460
Low Dose	2	6.13 (3.39)	0.50 (0.71)	0.5	0.0, 1.0	-5.63 (2.68)	-5.6	-7.5, -3.7	0.2070
High Dose	1	8.46 (N/A)	7.14 (N/A)	7.1	7.1, 7.1	-1.32 (N/A)	-1.3	-1.3, -1.3	

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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'Off' Time (Cont.)									
WEEK 13	2	6.10 (3.34)	4.24 (5.99)	4.2	0.0, 8.5	-1.86 (2.65)	-1.9	-3.7, 0.0	0.5035
Low Dose	1	3.73 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-3.73 (N/A)	-3.7	-3.7, -3.7	
High Dose	1	8.46 (N/A)	8.48 (N/A)	8.5	8.5, 8.5	0.02 (N/A)	0.0	0.0, 0.0	
WEEK 26	1	3.73 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-3.73 (N/A)	-3.7	-3.7, -3.7	
Low Dose	1	3.73 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-3.73 (N/A)	-3.7	-3.7, -3.7	
High Dose	0								
WEEK 39	1	3.73 (N/A)	13.33 (N/A)	13.3	13.3, 13.3	9.60 (N/A)	9.6	9.6, 9.6	
Low Dose	1	3.73 (N/A)	13.33 (N/A)	13.3	13.3, 13.3	9.60 (N/A)	9.6	9.6, 9.6	
High Dose	0								
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	3		8.03 (0.90)	7.5	7.5, 9.1				
Low Dose	2		8.27 (1.13)	8.3	7.5, 9.1				
High Dose	1		7.54 (N/A)	7.5	7.5, 7.5				

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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 1	3	8.03 (0.90)	7.25 (4.01)	6.8	3.5, 11.5	-0.78 (4.16)	-2.3	-4.0, 3.9	0.7761
Low Dose	2	8.27 (1.13)	5.14 (2.34)	5.1	3.5, 6.8	-3.13 (1.21)	-3.1	-4.0, -2.3	0.1695
High Dose	1	7.54 (N/A)	11.47 (N/A)	11.5	11.5, 11.5	3.92 (N/A)	3.9	3.9, 3.9	
WEEK 6	3	8.03 (0.90)	4.09 (4.47)	3.4	0.0, 8.9	-3.94 (5.20)	-4.1	-9.1, 1.3	0.3194
Low Dose	2	8.27 (1.13)	1.70 (2.40)	1.7	0.0, 3.4	-6.57 (3.53)	-6.6	-9.1, -4.1	0.2310
High Dose	1	7.54 (N/A)	8.86 (N/A)	8.9	8.9, 8.9	1.32 (N/A)	1.3	1.3, 1.3	
WEEK 13	2	8.30 (1.08)	8.15 (0.89)	8.1	7.5, 8.8	-0.16 (0.19)	-0.2	-0.3, -0.0	0.4548
Low Dose	1	9.07 (N/A)	8.77 (N/A)	8.8	8.8, 8.8	-0.29 (N/A)	-0.3	-0.3, -0.3	
High Dose	1	7.54 (N/A)	7.52 (N/A)	7.5	7.5, 7.5	-0.02 (N/A)	-0.0	-0.0, -0.0	
WEEK 26	1	9.07 (N/A)	12.58 (N/A)	12.6	12.6, 12.6	3.52 (N/A)	3.5	3.5, 3.5	
Low Dose	1	9.07 (N/A)	12.58 (N/A)	12.6	12.6, 12.6	3.52 (N/A)	3.5	3.5, 3.5	
High Dose	0								
WEEK 39	1	9.07 (N/A)	2.67 (N/A)	2.7	2.7, 2.7	-6.40 (N/A)	-6.4	-6.4, -6.4	
Low Dose	1	9.07 (N/A)	2.67 (N/A)	2.7	2.7, 2.7	-6.40 (N/A)	-6.4	-6.4, -6.4	
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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	3		0.89 (1.54)	0.0	0.0, 2.7				
Low Dose	2		1.33 (1.89)	1.3	0.0, 2.7				
High Dose	1		0.00 (N/A)	0.0	0.0, 0.0				
WEEK 1	3	0.89 (1.54)	4.58 (4.61)	4.5	0.0, 9.2	3.69 (3.35)	4.5	0.0, 6.5	0.1969
Low Dose	2	1.33 (1.89)	6.86 (3.32)	6.9	4.5, 9.2	5.53 (1.43)	5.5	4.5, 6.5	0.1154
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 6	3	0.89 (1.54)	5.65 (6.18)	4.7	0.0, 12.2	4.76 (4.79)	4.7	0.0, 9.6	0.2274
Low Dose	2	1.33 (1.89)	8.47 (5.33)	8.5	4.7, 12.2	7.14 (3.45)	7.1	4.7, 9.6	0.2097
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 13	2	1.33 (1.89)	3.61 (5.11)	3.6	0.0, 7.2	2.28 (3.22)	2.3	0.0, 4.6	0.5000
Low Dose	1	2.67 (N/A)	7.23 (N/A)	7.2	7.2, 7.2	4.56 (N/A)	4.6	4.6, 4.6	
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia (Cont.)									
WEEK 26	1	2.67 (N/A)	3.42 (N/A)	3.4	3.4, 3.4	0.75 (N/A)	0.7	0.7, 0.7	
Low Dose	1	2.67 (N/A)	3.42 (N/A)	3.4	3.4, 3.4	0.75 (N/A)	0.7	0.7, 0.7	
High Dose	0								
WEEK 39	1	2.67 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-2.67 (N/A)	-2.7	-2.7, -2.7	
Low Dose	1	2.67 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-2.67 (N/A)	-2.7	-2.7, -2.7	
High Dose	0								
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	3		0.18 (0.31)	0.0	0.0, 0.5				
Low Dose	2		0.27 (0.38)	0.3	0.0, 0.5				
High Dose	1		0.00 (N/A)	0.0	0.0, 0.0				
WEEK 1	3	0.18 (0.31)	1.74 (3.02)	0.0	0.0, 5.2	1.56 (3.18)	0.0	-0.5, 5.2	0.4843
Low Dose	2	0.27 (0.38)	2.61 (3.69)	2.6	0.0, 5.2	2.35 (4.07)	2.3	-0.5, 5.2	0.5648
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time With Troublesome Dyskinesia (Cont.)									
WEEK 6	3	0.18 (0.31)	3.56 (3.46)	3.8	0.0, 6.9	3.38 (3.46)	3.2	0.0, 6.9	0.2326
Low Dose	2	0.27 (0.38)	5.33 (2.23)	5.3	3.8, 6.9	5.07 (2.60)	5.1	3.2, 6.9	0.2220
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 13	2	0.27 (0.38)	0.00 (0.00)	0.0	0.0, 0.0	-0.27 (0.38)	-0.3	-0.5, 0.0	0.5000
Low Dose	1	0.53 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.53 (N/A)	-0.5	-0.5, -0.5	
High Dose	1	0.00 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	0.00 (N/A)	0.0	0.0, 0.0	
WEEK 26	1	0.53 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.53 (N/A)	-0.5	-0.5, -0.5	
Low Dose	1	0.53 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.53 (N/A)	-0.5	-0.5, -0.5	
High Dose	0								
WEEK 39	1	0.53 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.53 (N/A)	-0.5	-0.5, -0.5	
Low Dose	1	0.53 (N/A)	0.00 (N/A)	0.0	0.0, 0.0	-0.53 (N/A)	-0.5	-0.5, -0.5	
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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	3		8.92 (2.44)	7.5	7.5, 11.7				
Low Dose	2		9.60 (3.01)	9.6	7.5, 11.7				
High Dose	1		7.54 (N/A)	7.5	7.5, 7.5				
WEEK 1	3	8.92 (2.44)	11.82 (4.01)	11.5	8.0, 16.0	2.91 (2.07)	3.9	0.5, 4.3	0.1351
Low Dose	2	9.60 (3.01)	12.00 (5.66)	12.0	8.0, 16.0	2.40 (2.64)	2.4	0.5, 4.3	0.4214
High Dose	1	7.54 (N/A)	11.47 (N/A)	11.5	11.5, 11.5	3.92 (N/A)	3.9	3.9, 3.9	
WEEK 6	3	8.92 (2.44)	9.73 (2.21)	8.9	8.1, 12.2	0.82 (0.44)	0.6	0.5, 1.3	0.0850
Low Dose	2	9.60 (3.01)	10.17 (2.93)	10.2	8.1, 12.2	0.56 (0.08)	0.6	0.5, 0.6	0.0631
High Dose	1	7.54 (N/A)	8.86 (N/A)	8.9	8.9, 8.9	1.32 (N/A)	1.3	1.3, 1.3	
WEEK 13	2	9.64 (2.96)	11.76 (5.99)	11.8	7.5, 16.0	2.12 (3.03)	2.1	-0.0, 4.3	0.5031
Low Dose	1	11.73 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	4.27 (N/A)	4.3	4.3, 4.3	
High Dose	1	7.54 (N/A)	7.52 (N/A)	7.5	7.5, 7.5	-0.02 (N/A)	-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__1.4

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 (SD)	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:OTHER (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 26	1	11.73 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	4.27 (N/A)	4.3	4.3, 4.3	
Low Dose	1	11.73 (N/A)	16.00 (N/A)	16.0	16.0, 16.0	4.27 (N/A)	4.3	4.3, 4.3	
High Dose	0								
WEEK 39	1	11.73 (N/A)	2.67 (N/A)	2.7	2.7, 2.7	-9.07 (N/A)	-9.1	-9.1, -9.1	
Low Dose	1	11.73 (N/A)	2.67 (N/A)	2.7	2.7, 2.7	-9.07 (N/A)	-9.1	-9.1, -9.1	
High Dose	0								
Age category:< 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	117		5.78 (2.19)	5.8	0.0, 10.3				
Low Dose	61		5.81 (2.06)	5.8	0.0, 10.3				
High Dose	56		5.74 (2.34)	5.8	0.0, 9.6				
WEEK 1	112	5.80 (2.22)	3.62 (3.29)	2.7	0.0, 14.8	-2.18 (3.35)	-2.4	-10.2, 5.9	<=0.001***
Low Dose	57	5.86 (2.09)	3.92 (3.22)	2.9	0.0, 13.8	-1.94 (3.12)	-1.9	-10.2, 5.2	<=0.001***
High Dose	55	5.74 (2.36)	3.31 (3.37)	2.1	0.0, 14.8	-2.42 (3.59)	-3.3	-8.9, 5.9	<=0.001***

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__1.4

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 (SD)	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 6	99	5.79 (2.18)	3.06 (3.03)	2.6	0.0, 12.3	-2.73 (3.27)	-3.1	-10.2, 6.7	<=0.001***
Low Dose	52	5.84 (1.94)	3.21 (2.97)	3.1	0.0, 12.3	-2.63 (3.37)	-2.9	-10.2, 5.7	<=0.001***
High Dose	47	5.73 (2.44)	2.90 (3.12)	1.9	0.0, 10.7	-2.83 (3.19)	-3.3	-8.2, 6.7	<=0.001***
WEEK 13	57	5.48 (2.32)	3.09 (3.62)	1.7	0.0, 12.1	-2.39 (3.60)	-3.2	-9.9, 6.3	<=0.001***
Low Dose	29	5.83 (2.24)	2.65 (3.44)	1.5	0.0, 12.1	-3.18 (3.41)	-3.4	-9.9, 5.0	<=0.001***
High Dose	28	5.12 (2.38)	3.55 (3.81)	1.8	0.0, 10.7	-1.57 (3.67)	-1.5	-7.5, 6.3	0.0321*
WEEK 26	66	5.62 (2.28)	2.55 (2.94)	1.4	0.0, 11.2	-3.06 (3.18)	-3.2	-10.2, 5.5	<=0.001***
Low Dose	32	5.67 (2.04)	2.51 (3.18)	1.1	0.0, 11.2	-3.15 (3.48)	-3.8	-10.2, 5.5	<=0.001***
High Dose	34	5.57 (2.52)	2.59 (2.75)	1.6	0.0, 8.9	-2.98 (2.93)	-2.7	-9.2, 4.4	<=0.001***
WEEK 39	59	5.62 (2.24)	2.31 (2.55)	1.3	0.0, 11.4	-3.31 (2.92)	-3.2	-9.9, 6.4	<=0.001***
Low Dose	31	5.63 (2.08)	2.21 (2.56)	1.2	0.0, 11.4	-3.42 (3.19)	-2.9	-9.9, 6.4	<=0.001***
High Dose	28	5.61 (2.45)	2.43 (2.59)	1.4	0.0, 7.2	-3.19 (2.64)	-3.4	-9.2, 4.0	<=0.001***
WEEK 52	60	5.60 (2.40)	2.62 (3.19)	1.1	0.0, 11.5	-2.98 (3.22)	-3.4	-10.2, 5.9	<=0.001***
Low Dose	31	5.71 (2.22)	2.81 (3.22)	1.7	0.0, 10.9	-2.90 (3.55)	-3.1	-10.2, 5.9	<=0.001***
High Dose	29	5.49 (2.61)	2.42 (3.20)	0.5	0.0, 11.5	-3.07 (2.89)	-3.4	-9.2, 2.6	<=0.001***

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__1.4

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 (SD)	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	117		6.82 (3.42)	6.7	0.0, 15.4				
Low Dose	61		6.64 (3.49)	6.7	0.0, 15.4				
High Dose	56		7.01 (3.35)	6.7	0.0, 13.8				
WEEK 1	112	6.78 (3.39)	8.85 (4.57)	8.7	0.0, 16.0	2.07 (3.69)	1.7	-5.4, 12.0	<=0.001***
Low Dose	57	6.51 (3.42)	8.63 (4.42)	8.6	0.0, 16.0	2.13 (3.12)	2.0	-4.0, 10.2	<=0.001***
High Dose	55	7.06 (3.36)	9.07 (4.74)	9.1	0.0, 16.0	2.01 (4.23)	1.5	-5.4, 12.0	<=0.001***
WEEK 6	99	6.93 (3.39)	10.49 (4.57)	11.6	0.0, 16.0	3.56 (4.33)	4.0	-6.7, 12.7	<=0.001***
Low Dose	52	6.75 (3.46)	10.38 (4.45)	11.4	0.0, 16.0	3.63 (4.07)	4.0	-6.1, 12.7	<=0.001***
High Dose	47	7.14 (3.34)	10.62 (4.74)	12.8	0.0, 16.0	3.48 (4.63)	4.2	-6.7, 12.0	<=0.001***
WEEK 13	57	6.97 (3.74)	10.78 (4.80)	12.3	0.0, 16.0	3.82 (4.30)	3.7	-9.0, 14.1	<=0.001***
Low Dose	29	7.12 (3.93)	10.63 (5.25)	12.3	0.0, 16.0	3.51 (4.21)	3.7	-9.0, 9.9	<=0.001***
High Dose	28	6.81 (3.60)	10.94 (4.37)	11.9	2.7, 16.0	4.13 (4.45)	4.1	-6.3, 14.1	<=0.001***

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__1.4

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 (SD)	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 26	66	7.30 (3.39)	11.26 (4.51)	12.9	0.0, 16.0	3.95 (4.44)	4.3	-10.1, 14.1	<=0.001***
Low Dose	32	7.17 (3.59)	11.45 (4.94)	13.5	0.0, 16.0	4.28 (4.44)	4.8	-10.1, 11.0	<=0.001***
High Dose	34	7.42 (3.24)	11.07 (4.14)	11.7	0.0, 16.0	3.65 (4.49)	3.8	-9.6, 14.1	<=0.001***
WEEK 39	59	7.26 (3.37)	10.96 (4.60)	11.3	0.0, 16.0	3.70 (4.03)	3.3	-10.6, 12.4	<=0.001***
Low Dose	31	7.27 (3.37)	11.57 (4.74)	12.4	0.3, 16.0	4.30 (4.42)	4.9	-10.6, 10.9	<=0.001***
High Dose	28	7.25 (3.42)	10.29 (4.42)	11.0	0.0, 16.0	3.04 (3.52)	2.8	-2.8, 12.4	<=0.001***
WEEK 52	60	7.22 (3.44)	10.37 (5.27)	11.9	0.0, 16.0	3.15 (4.31)	3.4	-12.0, 11.3	<=0.001***
Low Dose	31	6.79 (3.64)	11.01 (4.86)	12.4	0.0, 16.0	4.22 (4.10)	4.3	-6.5, 11.3	<=0.001***
High Dose	29	7.68 (3.22)	9.68 (5.68)	9.6	0.0, 16.0	2.00 (4.30)	2.2	-12.0, 9.5	0.0183*
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	117		2.56 (2.71)	2.1	0.0, 12.2				
Low Dose	61		2.49 (2.48)	2.1	0.0, 10.3				
High Dose	56		2.64 (2.96)	2.2	0.0, 12.2				

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__1.4

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 (SD)	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 1	112	2.61 (2.74)	2.59 (2.88)	1.7	0.0, 11.9	-0.02 (2.53)	0.0	-8.2, 8.8	0.9198
Low Dose	57	2.58 (2.50)	2.54 (2.72)	2.1	0.0, 10.7	-0.04 (2.30)	0.0	-5.3, 6.9	0.8870
High Dose	55	2.65 (2.99)	2.64 (3.07)	1.5	0.0, 11.9	-0.00 (2.77)	0.0	-8.2, 8.8	0.9913
WEEK 6	99	2.62 (2.81)	1.98 (3.13)	0.5	0.0, 13.9	-0.64 (2.74)	-0.4	-7.6, 9.6	0.0220*
Low Dose	52	2.56 (2.51)	1.86 (2.77)	0.6	0.0, 10.4	-0.70 (2.43)	-0.3	-5.1, 6.2	0.0431*
High Dose	47	2.67 (3.13)	2.10 (3.52)	0.0	0.0, 13.9	-0.58 (3.07)	-0.4	-7.6, 9.6	0.2049
WEEK 13	57	2.80 (3.07)	1.67 (2.76)	0.6	0.0, 15.5	-1.13 (3.06)	-0.5	-12.2, 5.2	0.0070**
Low Dose	29	2.27 (2.77)	2.21 (3.48)	1.0	0.0, 15.5	-0.07 (2.42)	0.0	-4.2, 5.2	0.8809
High Dose	28	3.35 (3.32)	1.12 (1.62)	0.0	0.0, 5.9	-2.24 (3.29)	-1.3	-12.2, 3.3	0.0013**
WEEK 26	66	2.45 (2.62)	1.70 (2.52)	0.7	0.0, 12.1	-0.75 (3.07)	-0.1	-12.2, 7.2	0.0518
Low Dose	32	2.47 (2.39)	1.55 (2.41)	0.7	0.0, 12.1	-0.93 (2.54)	-0.8	-6.5, 4.6	0.0475*
High Dose	34	2.43 (2.86)	1.85 (2.64)	0.6	0.0, 11.0	-0.58 (3.53)	-0.0	-12.2, 7.2	0.3445
WEEK 39	59	2.41 (2.68)	2.30 (3.80)	0.2	0.0, 16.0	-0.11 (3.30)	-0.2	-6.4, 15.4	0.8051
Low Dose	31	2.38 (2.35)	1.98 (3.76)	0.0	0.0, 15.4	-0.40 (3.72)	-0.7	-4.4, 15.4	0.5587
High Dose	28	2.44 (3.05)	2.65 (3.88)	0.7	0.0, 16.0	0.21 (2.80)	0.0	-6.4, 5.8	0.6896

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__1.4

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 (SD)	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 52	60	2.51 (2.79)	2.50 (4.43)	0.4	0.0, 16.0	-0.01 (3.58)	-0.2	-6.5, 12.9	0.9799
Low Dose	31	2.82 (2.77)	1.98 (3.96)	0.2	0.0, 16.0	-0.84 (3.43)	-0.6	-6.5, 9.2	0.1818
High Dose	29	2.19 (2.83)	3.06 (4.89)	0.7	0.0, 16.0	0.88 (3.57)	0.0	-3.9, 12.9	0.1963
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	117		0.85 (1.53)	0.0	0.0, 8.8				
Low Dose	61		1.06 (1.77)	0.0	0.0, 8.8				
High Dose	56		0.61 (1.18)	0.0	0.0, 5.0				
WEEK 1	112	0.81 (1.48)	0.94 (2.17)	0.0	0.0, 11.7	0.13 (1.88)	0.0	-5.7, 7.0	0.4566
Low Dose	57	1.05 (1.74)	0.91 (2.18)	0.0	0.0, 11.7	-0.14 (1.82)	0.0	-5.7, 5.8	0.5637
High Dose	55	0.56 (1.12)	0.97 (2.17)	0.0	0.0, 9.8	0.42 (1.91)	0.0	-2.9, 7.0	0.1130
WEEK 6	99	0.66 (1.13)	0.47 (1.37)	0.0	0.0, 9.0	-0.19 (1.38)	0.0	-4.1, 6.9	0.1716
Low Dose	52	0.84 (1.31)	0.54 (1.64)	0.0	0.0, 9.0	-0.30 (1.64)	0.0	-4.1, 6.9	0.1924
High Dose	47	0.46 (0.86)	0.39 (1.01)	0.0	0.0, 4.4	-0.07 (1.02)	0.0	-3.4, 4.4	0.6423

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__1.4

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 (SD)	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 13	57	0.75 (1.32)	0.46 (1.45)	0.0	0.0, 8.0	-0.29 (1.31)	0.0	-4.6, 6.0	0.0964
Low Dose	29	0.78 (1.35)	0.52 (1.77)	0.0	0.0, 8.0	-0.26 (1.60)	0.0	-4.6, 6.0	0.3877
High Dose	28	0.72 (1.30)	0.39 (1.05)	0.0	0.0, 3.7	-0.33 (0.94)	0.0	-3.4, 2.6	0.0777
WEEK 26	66	0.63 (1.18)	0.49 (1.86)	0.0	0.0, 12.1	-0.14 (1.77)	0.0	-4.0, 8.8	0.5218
Low Dose	32	0.68 (1.19)	0.49 (2.15)	0.0	0.0, 12.1	-0.19 (1.69)	0.0	-3.4, 7.2	0.5202
High Dose	34	0.58 (1.18)	0.49 (1.58)	0.0	0.0, 8.8	-0.09 (1.87)	0.0	-4.0, 8.8	0.7809
WEEK 39	59	0.71 (1.29)	0.43 (1.26)	0.0	0.0, 8.1	-0.29 (1.47)	0.0	-5.0, 7.3	0.1404
Low Dose	31	0.72 (1.32)	0.24 (0.75)	0.0	0.0, 3.5	-0.48 (0.78)	0.0	-2.8, 0.0	0.0018**
High Dose	28	0.70 (1.27)	0.63 (1.65)	0.0	0.0, 8.1	-0.07 (1.97)	0.0	-5.0, 7.3	0.8528
WEEK 52	60	0.66 (1.20)	0.51 (1.86)	0.0	0.0, 13.5	-0.15 (2.07)	0.0	-5.0, 13.0	0.5705
Low Dose	31	0.67 (1.15)	0.20 (0.59)	0.0	0.0, 2.7	-0.47 (1.13)	0.0	-3.4, 1.8	0.0257*
High Dose	29	0.64 (1.27)	0.83 (2.58)	0.0	0.0, 13.5	0.19 (2.73)	0.0	-5.0, 13.0	0.7090

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__1.4

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 (SD)	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									
BASELINE	117		9.38 (2.48)	9.8	2.2, 16.0				
Low Dose	61		9.13 (2.63)	9.9	2.2, 16.0				
High Dose	56		9.65 (2.30)	9.6	4.8, 16.0				
WEEK 1	112	9.39 (2.48)	11.44 (3.65)	11.8	1.2, 16.0	2.04 (3.46)	2.0	-5.9, 8.9	<=0.001***
Low Dose	57	9.09 (2.64)	11.18 (3.62)	11.3	1.6, 16.0	2.08 (3.07)	1.9	-5.2, 8.3	<=0.001***
High Dose	55	9.71 (2.28)	11.71 (3.68)	12.0	1.2, 16.0	2.01 (3.86)	2.1	-5.9, 8.9	<=0.001***
WEEK 6	99	9.55 (2.32)	12.47 (3.22)	13.1	3.7, 16.0	2.92 (3.33)	3.5	-6.7, 9.9	<=0.001***
Low Dose	52	9.31 (2.40)	12.24 (3.24)	12.7	3.7, 16.0	2.93 (3.36)	3.6	-5.7, 9.9	<=0.001***
High Dose	47	9.81 (2.23)	12.71 (3.21)	13.5	5.1, 16.0	2.90 (3.33)	3.5	-6.7, 8.2	<=0.001***
WEEK 13	57	9.77 (2.57)	12.45 (3.86)	13.8	3.9, 16.0	2.68 (3.56)	2.9	-6.3, 9.9	<=0.001***
Low Dose	29	9.39 (2.77)	12.83 (3.82)	14.5	3.9, 16.0	3.44 (3.30)	3.3	-5.0, 9.9	<=0.001***
High Dose	28	10.16 (2.34)	12.06 (3.93)	13.6	5.3, 16.0	1.89 (3.69)	2.3	-6.3, 7.5	0.0115*

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__1.4

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 (SD)	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 26	66	9.76 (2.47)	12.96 (3.39)	14.4	1.5, 16.0	3.20 (3.33)	3.1	-5.5, 10.2	<=0.001***
Low Dose	32	9.65 (2.46)	13.00 (3.86)	14.8	1.5, 16.0	3.35 (3.79)	4.0	-5.5, 10.2	<=0.001***
High Dose	34	9.86 (2.52)	12.92 (2.95)	14.1	7.1, 16.0	3.07 (2.89)	2.7	-2.5, 9.4	<=0.001***
WEEK 39	59	9.67 (2.52)	13.26 (3.01)	14.0	2.4, 16.0	3.60 (3.28)	3.4	-9.2, 9.9	<=0.001***
Low Dose	31	9.64 (2.66)	13.55 (2.69)	14.4	4.6, 16.0	3.90 (3.23)	3.1	-5.9, 9.9	<=0.001***
High Dose	28	9.69 (2.41)	12.94 (3.35)	13.9	2.4, 16.0	3.25 (3.36)	3.4	-9.2, 9.7	<=0.001***
WEEK 52	60	9.74 (2.68)	12.87 (3.55)	14.0	2.5, 16.0	3.13 (3.18)	3.1	-5.4, 10.2	<=0.001***
Low Dose	31	9.61 (2.76)	12.99 (3.21)	13.7	5.1, 16.0	3.37 (3.41)	3.1	-5.4, 10.2	<=0.001***
High Dose	29	9.87 (2.63)	12.75 (3.94)	14.9	2.5, 16.0	2.88 (2.95)	2.9	-3.8, 8.4	<=0.001***
Age category:>= 65 years									
Average Daily Normalized 'Off' Time									
BASELINE	119		6.03 (2.30)	6.1	0.0, 12.6				
Low Dose	66		5.56 (2.32)	5.9	0.0, 10.0				
High Dose	53		6.62 (2.15)	7.0	1.5, 12.6				

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__1.4

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 (SD)	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 1	113	6.02 (2.28)	4.31 (3.54)	3.8	0.0, 16.0	-1.71 (3.97)	-2.1	-9.7, 10.4	<=0.001***
Low Dose	64	5.62 (2.31)	3.49 (3.18)	2.6	0.0, 10.3	-2.13 (3.82)	-2.5	-9.7, 5.9	<=0.001***
High Dose	49	6.55 (2.15)	5.39 (3.73)	5.6	0.0, 16.0	-1.16 (4.15)	-1.4	-8.3, 10.4	0.0551
WEEK 6	106	6.08 (2.29)	4.00 (3.41)	3.7	0.0, 16.0	-2.08 (3.88)	-2.4	-10.6, 9.9	<=0.001***
Low Dose	59	5.63 (2.29)	3.41 (3.65)	2.9	0.0, 16.0	-2.22 (3.90)	-2.4	-8.2, 9.9	<=0.001***
High Dose	47	6.65 (2.20)	4.74 (2.95)	4.5	0.0, 12.5	-1.91 (3.88)	-2.4	-10.6, 6.8	0.0016**
WEEK 13	57	5.56 (2.26)	3.08 (3.33)	1.9	0.0, 13.4	-2.47 (3.83)	-3.2	-9.2, 8.1	<=0.001***
Low Dose	35	5.06 (2.17)	3.08 (3.63)	1.7	0.0, 13.4	-1.98 (4.07)	-2.7	-7.0, 8.1	0.0069**
High Dose	22	6.35 (2.21)	3.09 (2.86)	2.5	0.0, 9.3	-3.26 (3.34)	-3.3	-9.2, 4.0	<=0.001***
WEEK 26	65	6.29 (2.14)	2.67 (3.12)	1.2	0.0, 14.3	-3.62 (3.32)	-3.7	-10.6, 7.1	<=0.001***
Low Dose	37	5.85 (1.91)	2.40 (3.21)	0.8	0.0, 14.3	-3.45 (3.30)	-3.7	-8.2, 7.1	<=0.001***
High Dose	28	6.86 (2.33)	3.03 (3.02)	2.0	0.0, 9.8	-3.83 (3.40)	-3.6	-10.6, 5.5	<=0.001***
WEEK 39	60	6.15 (2.17)	2.98 (2.97)	2.2	0.0, 13.3	-3.17 (3.35)	-3.2	-9.1, 9.6	<=0.001***
Low Dose	36	5.62 (1.86)	2.83 (3.19)	1.9	0.0, 13.3	-2.79 (3.40)	-3.1	-7.5, 9.6	<=0.001***
High Dose	24	6.95 (2.40)	3.21 (2.67)	3.0	0.0, 7.7	-3.73 (3.28)	-3.5	-9.1, 2.9	<=0.001***

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__1.4

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 (SD)	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 52	44	6.25 (2.04)	2.37 (2.42)	2.0	0.0, 8.1	-3.88 (2.95)	-3.7	-11.2, 2.8	<=0.001***
Low Dose	25	5.92 (1.78)	2.39 (2.25)	2.3	0.0, 6.7	-3.53 (2.52)	-3.6	-8.7, 1.8	<=0.001***
High Dose	19	6.68 (2.33)	2.34 (2.69)	1.4	0.0, 8.1	-4.34 (3.45)	-3.8	-11.2, 2.8	<=0.001***
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	119		6.21 (3.27)	6.5	0.0, 14.0				
Low Dose	66		6.09 (3.44)	5.9	0.0, 14.0				
High Dose	53		6.37 (3.08)	6.7	0.0, 11.6				
WEEK 1	113	6.19 (3.22)	8.01 (4.45)	8.1	0.0, 16.0	1.82 (4.46)	1.6	-8.9, 10.7	<=0.001***
Low Dose	64	5.94 (3.35)	7.41 (4.59)	7.3	0.0, 16.0	1.46 (4.54)	1.3	-8.9, 10.7	0.0122*
High Dose	49	6.52 (3.05)	8.80 (4.18)	8.9	0.0, 16.0	2.28 (4.36)	3.0	-8.1, 8.7	<=0.001***
WEEK 6	106	6.18 (3.30)	9.39 (4.36)	10.0	0.0, 16.0	3.21 (4.46)	3.2	-9.1, 13.8	<=0.001***
Low Dose	59	6.04 (3.43)	9.41 (4.62)	10.2	0.0, 16.0	3.36 (4.87)	3.9	-9.1, 13.8	<=0.001***
High Dose	47	6.34 (3.16)	9.37 (4.06)	9.9	0.0, 16.0	3.03 (3.92)	2.9	-4.9, 10.6	<=0.001***

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__1.4

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 (SD)	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 13	57	6.38 (3.07)	10.81 (4.46)	11.3	0.0, 16.0	4.43 (4.43)	4.8	-6.5, 15.2	<=0.001***
Low Dose	35	6.27 (3.01)	10.68 (4.71)	12.4	0.0, 16.0	4.41 (4.59)	4.8	-6.5, 15.2	<=0.001***
High Dose	22	6.55 (3.23)	11.03 (4.14)	11.0	0.9, 16.0	4.48 (4.29)	5.1	-4.7, 10.0	<=0.001***
WEEK 26	65	6.39 (3.30)	11.32 (4.17)	12.5	0.0, 16.0	4.93 (4.48)	5.4	-11.0, 12.7	<=0.001***
Low Dose	37	6.44 (3.35)	11.90 (3.46)	12.6	1.3, 16.0	5.45 (3.53)	5.4	-1.2, 11.5	<=0.001***
High Dose	28	6.32 (3.30)	10.57 (4.92)	11.2	0.0, 16.0	4.25 (5.48)	5.6	-11.0, 12.7	<=0.001***
WEEK 39	60	6.67 (3.20)	10.97 (4.18)	11.6	0.6, 16.0	4.30 (4.17)	4.6	-6.4, 13.5	<=0.001***
Low Dose	36	6.58 (3.21)	10.97 (4.23)	11.2	1.4, 16.0	4.39 (4.12)	5.0	-6.4, 11.4	<=0.001***
High Dose	24	6.81 (3.24)	10.97 (4.19)	11.6	0.6, 16.0	4.17 (4.34)	3.8	-3.8, 13.5	<=0.001***
WEEK 52	44	6.78 (3.11)	11.45 (3.68)	11.8	1.3, 16.0	4.67 (3.95)	4.9	-3.1, 13.8	<=0.001***
Low Dose	25	6.75 (2.86)	11.71 (3.64)	13.0	1.3, 16.0	4.95 (3.55)	5.1	-2.5, 9.3	<=0.001***
High Dose	19	6.81 (3.48)	11.11 (3.80)	11.3	1.3, 16.0	4.31 (4.49)	3.4	-3.1, 13.8	<=0.001***

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__1.4

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 (SD)	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	119		2.69 (2.40)	2.7	0.0, 8.9				
Low Dose	66		2.88 (2.32)	2.9	0.0, 8.5				
High Dose	53		2.46 (2.49)	1.9	0.0, 8.9				
WEEK 1	113	2.71 (2.38)	2.64 (3.42)	1.1	0.0, 14.9	-0.07 (3.48)	0.0	-8.5, 13.6	0.8200
Low Dose	64	2.93 (2.32)	3.49 (3.67)	2.6	0.0, 14.9	0.56 (3.98)	0.0	-8.5, 13.6	0.2661
High Dose	49	2.43 (2.45)	1.53 (2.73)	0.0	0.0, 12.8	-0.90 (2.52)	-0.2	-6.9, 8.1	0.0157*
WEEK 6	106	2.72 (2.44)	2.20 (3.44)	0.5	0.0, 15.4	-0.52 (3.25)	-0.2	-7.8, 11.6	0.1019
Low Dose	59	2.91 (2.34)	2.55 (3.48)	1.3	0.0, 15.4	-0.35 (3.52)	-0.1	-7.6, 11.6	0.4465
High Dose	47	2.49 (2.56)	1.76 (3.37)	0.0	0.0, 14.6	-0.74 (2.91)	-0.3	-7.8, 7.5	0.0896
WEEK 13	57	3.15 (2.41)	1.90 (3.79)	0.0	0.0, 16.0	-1.25 (3.94)	-1.2	-8.0, 13.2	0.0195*
Low Dose	35	3.49 (2.31)	1.95 (3.91)	0.0	0.0, 16.0	-1.53 (4.24)	-2.2	-8.0, 13.2	0.0398*
High Dose	22	2.62 (2.52)	1.81 (3.70)	0.0	0.0, 14.4	-0.81 (3.45)	-0.2	-6.9, 7.2	0.2822

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__1.4

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 (SD)	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 26	65	2.41 (2.33)	1.86 (3.31)	0.0	0.0, 15.2	-0.55 (3.42)	-0.2	-6.8, 12.0	0.1964
Low Dose	37	2.60 (2.19)	1.57 (2.39)	0.3	0.0, 10.8	-1.04 (2.97)	-0.6	-6.8, 5.4	0.0408*
High Dose	28	2.16 (2.52)	2.25 (4.25)	0.0	0.0, 15.2	0.08 (3.91)	0.0	-6.8, 12.0	0.9122
WEEK 39	60	2.45 (2.42)	1.77 (3.25)	0.0	0.0, 14.6	-0.69 (3.65)	0.0	-7.8, 9.9	0.1503
Low Dose	36	2.94 (2.42)	1.91 (3.26)	0.0	0.0, 14.6	-1.03 (3.44)	0.0	-7.8, 9.2	0.0813
High Dose	24	1.73 (2.28)	1.56 (3.31)	0.0	0.0, 12.3	-0.17 (3.95)	0.0	-7.8, 9.9	0.8335
WEEK 52	44	2.46 (2.62)	1.70 (2.86)	0.0	0.0, 12.0	-0.76 (3.07)	0.0	-7.3, 6.1	0.1070
Low Dose	25	2.59 (2.24)	1.70 (2.97)	0.0	0.0, 12.0	-0.89 (3.38)	-0.4	-6.8, 6.1	0.2002
High Dose	19	2.28 (3.11)	1.69 (2.79)	0.0	0.0, 9.3	-0.59 (2.70)	0.0	-7.3, 2.8	0.3493
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	119		1.06 (1.90)	0.0	0.0, 10.5				
Low Dose	66		1.47 (2.23)	0.3	0.0, 10.5				
High Dose	53		0.56 (1.23)	0.0	0.0, 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__1.4

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 (SD)	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 1	113	1.07 (1.91)	1.04 (2.02)	0.0	0.0, 10.5	-0.03 (1.92)	0.0	-6.0, 10.5	0.8544
Low Dose	64	1.51 (2.26)	1.62 (2.46)	0.3	0.0, 10.5	0.11 (2.31)	0.0	-6.0, 10.5	0.7076
High Dose	49	0.50 (1.11)	0.28 (0.72)	0.0	0.0, 3.4	-0.22 (1.22)	0.0	-4.9, 3.4	0.2145
WEEK 6	106	1.02 (1.95)	0.41 (1.24)	0.0	0.0, 5.8	-0.61 (1.77)	0.0	-9.2, 4.1	<=0.001***
Low Dose	59	1.42 (2.31)	0.63 (1.57)	0.0	0.0, 5.8	-0.79 (2.16)	0.0	-9.2, 4.1	0.0069**
High Dose	47	0.52 (1.22)	0.13 (0.51)	0.0	0.0, 2.8	-0.38 (1.08)	0.0	-4.9, 2.1	0.0188*
WEEK 13	57	0.91 (1.55)	0.21 (0.64)	0.0	0.0, 3.5	-0.71 (1.57)	0.0	-7.2, 1.7	0.0012**
Low Dose	35	1.18 (1.73)	0.29 (0.78)	0.0	0.0, 3.5	-0.90 (1.76)	0.0	-7.2, 1.7	0.0048**
High Dose	22	0.48 (1.13)	0.07 (0.24)	0.0	0.0, 0.9	-0.41 (1.19)	0.0	-4.9, 0.9	0.1205
WEEK 26	65	0.91 (1.78)	0.15 (0.55)	0.0	0.0, 3.7	-0.76 (1.89)	0.0	-9.2, 3.7	0.0019**
Low Dose	37	1.10 (1.96)	0.14 (0.62)	0.0	0.0, 3.7	-0.96 (2.11)	0.0	-9.2, 3.7	0.0086**
High Dose	28	0.65 (1.49)	0.16 (0.47)	0.0	0.0, 1.8	-0.49 (1.55)	0.0	-4.9, 1.7	0.1039
WEEK 39	60	0.72 (1.33)	0.28 (0.83)	0.0	0.0, 3.8	-0.45 (1.20)	0.0	-5.1, 2.7	0.0054**
Low Dose	36	0.86 (1.33)	0.29 (0.83)	0.0	0.0, 3.8	-0.57 (1.25)	0.0	-5.1, 0.8	0.0099**
High Dose	24	0.51 (1.33)	0.25 (0.86)	0.0	0.0, 3.4	-0.26 (1.11)	0.0	-3.6, 2.7	0.2594

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__1.4

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 (SD)	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 52	44	0.52 (1.14)	0.48 (1.39)	0.0	0.0, 6.3	-0.04 (1.90)	0.0	-5.1, 6.3	0.9014
Low Dose	25	0.74 (1.30)	0.20 (0.68)	0.0	0.0, 3.3	-0.54 (1.49)	0.0	-5.1, 3.3	0.0823
High Dose	19	0.23 (0.83)	0.86 (1.94)	0.0	0.0, 6.3	0.63 (2.21)	0.0	-3.6, 6.3	0.2318
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	119		8.91 (2.51)	8.9	0.3, 15.0				
Low Dose	66		8.97 (2.72)	9.0	0.3, 15.0				
High Dose	53		8.83 (2.25)	8.8	2.6, 14.5				
WEEK 1	113	8.90 (2.51)	10.65 (3.69)	10.6	0.0, 16.0	1.74 (4.07)	1.6	-10.4, 11.3	<=0.001***
Low Dose	64	8.87 (2.69)	10.89 (3.67)	10.9	3.0, 16.0	2.02 (3.93)	2.2	-5.9, 11.3	<=0.001***
High Dose	49	8.94 (2.29)	10.33 (3.73)	10.0	0.0, 16.0	1.38 (4.26)	1.4	-10.4, 8.3	0.0277*
WEEK 6	106	8.90 (2.51)	11.59 (3.46)	12.1	0.0, 16.0	2.69 (3.82)	3.0	-9.9, 10.6	<=0.001***
Low Dose	59	8.95 (2.66)	11.96 (3.77)	12.6	0.0, 16.0	3.01 (3.80)	3.1	-9.9, 10.5	<=0.001***
High Dose	47	8.84 (2.33)	11.13 (2.98)	11.5	3.5, 16.0	2.29 (3.86)	2.4	-6.8, 10.6	<=0.001***

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__1.4

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 (SD)	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 13	57	9.53 (2.11)	12.71 (3.37)	14.0	2.6, 16.0	3.18 (3.41)	3.8	-4.9, 9.2	<=0.001***
Low Dose	35	9.76 (2.02)	12.63 (3.68)	14.1	2.6, 16.0	2.87 (3.33)	3.8	-4.9, 7.2	<=0.001***
High Dose	22	9.17 (2.26)	12.84 (2.89)	13.5	6.0, 16.0	3.67 (3.55)	3.8	-4.7, 9.2	<=0.001***
WEEK 26	65	8.81 (2.65)	13.18 (3.09)	14.3	1.7, 16.0	4.38 (3.68)	4.6	-5.5, 12.5	<=0.001***
Low Dose	37	9.05 (2.82)	13.46 (3.21)	15.0	1.7, 16.0	4.42 (3.72)	4.4	-4.1, 12.5	<=0.001***
High Dose	28	8.48 (2.42)	12.81 (2.94)	13.9	6.2, 16.0	4.33 (3.69)	4.8	-5.5, 10.6	<=0.001***
WEEK 39	60	9.12 (2.42)	12.74 (3.01)	12.9	2.7, 16.0	3.61 (3.38)	3.4	-9.1, 9.6	<=0.001***
Low Dose	36	9.52 (2.23)	12.87 (3.17)	13.2	2.7, 16.0	3.36 (3.42)	3.2	-9.1, 9.4	<=0.001***
High Dose	24	8.54 (2.61)	12.53 (2.81)	12.9	6.6, 16.0	4.00 (3.36)	4.0	-2.9, 9.6	<=0.001***
WEEK 52	44	9.24 (2.05)	13.15 (2.51)	13.4	7.9, 16.0	3.91 (2.99)	3.9	-2.8, 11.2	<=0.001***
Low Dose	25	9.34 (2.01)	13.41 (2.27)	13.4	8.8, 16.0	4.06 (2.60)	4.1	-2.2, 8.7	<=0.001***
High Dose	19	9.09 (2.15)	12.80 (2.83)	13.4	7.9, 16.0	3.71 (3.50)	3.7	-2.8, 11.2	<=0.001***

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__1.4

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 (SD)	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	89		5.54 (2.32)	5.4	0.0, 10.3				
Low Dose	39		4.96 (2.40)	4.9	0.0, 9.9				
High Dose	50		5.99 (2.17)	5.9	0.6, 10.3				
WEEK 1	83	5.50 (2.29)	3.41 (3.08)	2.7	0.0, 11.8	-2.08 (3.32)	-2.2	-8.6, 5.6	<=0.001***
Low Dose	37	5.03 (2.42)	2.79 (3.05)	2.0	0.0, 10.3	-2.24 (3.38)	-2.8	-8.6, 5.6	<=0.001***
High Dose	46	5.87 (2.13)	3.91 (3.03)	3.8	0.0, 11.8	-1.96 (3.30)	-1.8	-8.3, 4.8	<=0.001***
WEEK 6	76	5.49 (2.31)	2.99 (3.29)	1.9	0.0, 14.9	-2.50 (3.57)	-2.9	-9.9, 6.7	<=0.001***
Low Dose	34	4.97 (2.31)	2.40 (3.23)	1.0	0.0, 14.9	-2.57 (3.49)	-2.6	-9.9, 6.3	<=0.001***
High Dose	42	5.92 (2.24)	3.47 (3.30)	2.5	0.0, 10.7	-2.44 (3.68)	-3.1	-8.4, 6.7	<=0.001***
WEEK 13	47	5.16 (2.43)	2.50 (3.15)	1.5	0.0, 10.3	-2.65 (3.43)	-3.2	-9.9, 6.3	<=0.001***
Low Dose	23	4.50 (2.30)	1.45 (2.09)	0.2	0.0, 7.2	-3.05 (2.94)	-3.3	-9.9, 5.0	<=0.001***
High Dose	24	5.79 (2.43)	3.51 (3.68)	2.4	0.0, 10.3	-2.28 (3.87)	-2.1	-9.2, 6.3	0.0084**

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__1.4

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 (SD)	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 26	51	5.19 (2.29)	1.83 (2.33)	0.9	0.0, 8.4	-3.37 (2.34)	-2.8	-9.2, 1.5	<=0.001***
Low Dose	25	4.81 (2.24)	1.35 (1.90)	0.3	0.0, 6.1	-3.46 (2.31)	-3.6	-9.2, 0.2	<=0.001***
High Dose	26	5.56 (2.32)	2.28 (2.64)	1.3	0.0, 8.4	-3.28 (2.42)	-2.8	-7.5, 1.5	<=0.001***
WEEK 39	49	5.20 (2.31)	2.19 (2.60)	1.3	0.0, 13.3	-3.01 (3.13)	-3.1	-9.9, 9.6	<=0.001***
Low Dose	26	4.86 (2.20)	2.21 (2.85)	1.4	0.0, 13.3	-2.66 (3.41)	-2.9	-9.9, 9.6	<=0.001***
High Dose	23	5.58 (2.42)	2.18 (2.36)	1.3	0.0, 7.0	-3.40 (2.79)	-3.6	-9.1, 1.9	<=0.001***
WEEK 52	42	5.36 (2.27)	1.80 (2.40)	0.5	0.0, 8.8	-3.56 (2.65)	-3.6	-9.9, 2.8	<=0.001***
Low Dose	21	5.06 (2.27)	1.69 (1.80)	0.9	0.0, 5.9	-3.38 (2.31)	-3.1	-9.9, 0.0	<=0.001***
High Dose	21	5.65 (2.27)	1.91 (2.92)	0.5	0.0, 8.8	-3.74 (3.00)	-4.4	-8.6, 2.8	<=0.001***
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	89		6.91 (3.64)	6.8	0.0, 15.4				
Low Dose	39		6.95 (4.09)	6.8	0.0, 15.4				
High Dose	50		6.87 (3.29)	6.7	0.0, 13.8				

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__1.4

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 (SD)	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 1	83	6.99 (3.56)	9.25 (4.26)	9.0	0.0, 16.0	2.26 (4.33)	1.7	-8.8, 12.0	<=0.001***
Low Dose	37	6.90 (3.96)	9.06 (4.70)	8.6	0.0, 16.0	2.16 (4.38)	1.7	-8.8, 10.7	0.0049**
High Dose	46	7.07 (3.25)	9.40 (3.91)	9.2	0.5, 16.0	2.33 (4.34)	2.6	-5.1, 12.0	<=0.001***
WEEK 6	76	6.91 (3.72)	10.22 (4.83)	10.4	0.0, 16.0	3.31 (4.87)	3.2	-9.1, 12.0	<=0.001***
Low Dose	34	6.92 (4.13)	9.88 (5.15)	10.0	0.0, 16.0	2.96 (5.17)	2.6	-9.1, 11.7	0.0021**
High Dose	42	6.90 (3.41)	10.50 (4.60)	10.9	0.0, 16.0	3.60 (4.65)	3.4	-6.7, 12.0	<=0.001***
WEEK 13	47	7.21 (3.88)	11.29 (4.62)	12.1	0.0, 16.0	4.07 (4.72)	3.3	-6.3, 15.2	<=0.001***
Low Dose	23	7.77 (4.14)	11.46 (4.79)	13.0	0.0, 16.0	3.70 (4.54)	2.9	-3.9, 15.2	<=0.001***
High Dose	24	6.68 (3.63)	11.12 (4.55)	11.5	0.9, 16.0	4.43 (4.96)	4.9	-6.3, 14.1	<=0.001***
WEEK 26	51	7.28 (3.81)	12.04 (4.04)	13.3	0.0, 16.0	4.76 (4.31)	4.4	-6.6, 14.1	<=0.001***
Low Dose	25	7.85 (3.88)	12.60 (3.68)	13.4	0.5, 16.0	4.75 (4.17)	4.4	-2.4, 11.5	<=0.001***
High Dose	26	6.73 (3.75)	11.50 (4.37)	13.2	0.0, 16.0	4.77 (4.53)	4.6	-6.6, 14.1	<=0.001***
WEEK 39	49	7.49 (3.79)	11.21 (4.58)	12.4	0.0, 16.0	3.72 (4.83)	4.1	-10.6, 13.5	<=0.001***
Low Dose	26	7.61 (4.00)	11.19 (4.71)	12.9	0.6, 16.0	3.58 (5.28)	4.5	-10.6, 11.4	0.0019**
High Dose	23	7.35 (3.64)	11.22 (4.52)	11.8	0.0, 16.0	3.88 (4.37)	3.3	-2.8, 13.5	<=0.001***

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__1.4

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 (SD)	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 &
Geographic region:NORTH AMERICA (Cont.)									
Average Daily Normalized 'On' Time Without Dyskinesia (Cont.)									
WEEK 52	42	7.22 (3.84)	10.98 (4.95)	12.1	0.0, 16.0	3.76 (4.84)	4.4	-12.0, 13.8	<=0.001***
Low Dose	21	7.42 (3.81)	11.93 (4.48)	13.3	0.0, 16.0	4.50 (4.07)	5.1	-2.6, 9.9	<=0.001***
High Dose	21	7.01 (3.94)	10.03 (5.32)	10.0	0.0, 16.0	3.01 (5.51)	2.8	-12.0, 13.8	0.0209*
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	89		2.82 (2.83)	2.6	0.0, 12.2				
Low Dose	39		3.05 (2.74)	2.9	0.0, 10.3				
High Dose	50		2.64 (2.91)	2.0	0.0, 12.2				
WEEK 1	83	2.84 (2.84)	2.42 (2.99)	1.5	0.0, 13.6	-0.42 (3.43)	0.0	-8.5, 13.6	0.2718
Low Dose	37	3.11 (2.76)	3.02 (3.30)	2.4	0.0, 13.6	-0.09 (3.76)	-0.4	-8.5, 13.6	0.8888
High Dose	46	2.61 (2.91)	1.93 (2.66)	0.3	0.0, 9.7	-0.68 (3.17)	0.0	-8.2, 8.8	0.1506
WEEK 6	76	2.88 (2.94)	2.29 (3.52)	0.6	0.0, 14.6	-0.59 (3.48)	-0.5	-7.8, 9.6	0.1441
Low Dose	34	3.13 (2.79)	2.88 (3.43)	1.4	0.0, 12.2	-0.24 (3.64)	-0.8	-7.6, 9.6	0.7027
High Dose	42	2.68 (3.07)	1.80 (3.56)	0.0	0.0, 14.6	-0.87 (3.37)	-0.1	-7.8, 7.5	0.1005

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__1.4

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 (SD)	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 13	47	3.01 (3.17)	1.87 (3.81)	0.0	0.0, 15.5	-1.13 (3.90)	-0.6	-12.2, 7.9	0.0520
Low Dose	23	3.00 (3.04)	2.62 (4.37)	0.0	0.0, 15.5	-0.38 (3.97)	-0.6	-8.0, 7.9	0.6477
High Dose	24	3.01 (3.35)	1.16 (3.10)	0.0	0.0, 14.4	-1.85 (3.77)	-0.7	-12.2, 7.2	0.0244*
WEEK 26	51	2.80 (2.78)	1.69 (3.10)	0.0	0.0, 15.2	-1.11 (3.76)	-0.6	-12.2, 12.0	0.0410*
Low Dose	25	2.45 (2.18)	1.35 (1.36)	1.1	0.0, 3.4	-1.10 (2.73)	-0.6	-6.8, 3.1	0.0553
High Dose	26	3.14 (3.26)	2.02 (4.16)	0.0	0.0, 15.2	-1.11 (4.60)	-0.6	-12.2, 12.0	0.2299
WEEK 39	49	2.68 (2.84)	2.18 (3.80)	0.0	0.0, 16.0	-0.49 (4.03)	0.0	-7.8, 15.4	0.3958
Low Dose	26	2.67 (2.43)	2.37 (3.77)	0.6	0.0, 15.4	-0.30 (4.32)	0.0	-7.8, 15.4	0.7267
High Dose	23	2.68 (3.31)	1.97 (3.91)	0.0	0.0, 16.0	-0.71 (3.77)	0.0	-7.8, 6.1	0.3737
WEEK 52	42	2.86 (3.15)	2.79 (4.55)	0.6	0.0, 16.0	-0.07 (3.94)	0.0	-7.3, 12.9	0.9102
Low Dose	21	2.74 (2.73)	2.22 (4.23)	0.0	0.0, 16.0	-0.53 (3.45)	-0.6	-6.8, 6.1	0.4911
High Dose	21	2.98 (3.58)	3.37 (4.89)	0.8	0.0, 16.0	0.39 (4.42)	0.0	-7.3, 12.9	0.6909

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__1.4

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 (SD)	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	89		0.74 (1.24)	0.0	0.0, 5.1				
Low Dose	39		1.03 (1.39)	0.3	0.0, 5.1				
High Dose	50		0.51 (1.07)	0.0	0.0, 4.9				
WEEK 1	83	0.67 (1.09)	0.92 (1.73)	0.0	0.0, 7.2	0.24 (1.73)	0.0	-3.7, 7.0	0.2017
Low Dose	37	0.96 (1.26)	1.12 (1.71)	0.0	0.0, 5.4	0.17 (1.61)	0.0	-3.7, 5.2	0.5292
High Dose	46	0.45 (0.89)	0.75 (1.74)	0.0	0.0, 7.2	0.31 (1.84)	0.0	-3.7, 7.0	0.2651
WEEK 6	76	0.72 (1.23)	0.50 (1.55)	0.0	0.0, 9.0	-0.22 (1.68)	0.0	-5.1, 6.9	0.2570
Low Dose	34	0.98 (1.39)	0.84 (2.19)	0.0	0.0, 9.0	-0.15 (2.22)	0.0	-5.1, 6.9	0.7033
High Dose	42	0.50 (1.04)	0.22 (0.59)	0.0	0.0, 2.6	-0.28 (1.09)	0.0	-4.9, 2.1	0.1041
WEEK 13	47	0.62 (1.12)	0.34 (1.07)	0.0	0.0, 5.5	-0.29 (1.04)	0.0	-4.9, 2.6	0.0665
Low Dose	23	0.73 (1.16)	0.46 (1.35)	0.0	0.0, 5.5	-0.27 (0.83)	0.0	-1.7, 1.7	0.1385
High Dose	24	0.52 (1.09)	0.21 (0.72)	0.0	0.0, 3.4	-0.30 (1.23)	0.0	-4.9, 2.6	0.2380

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__1.4

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 (SD)	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 26	51	0.73 (1.31)	0.44 (1.80)	0.0	0.0, 12.1	-0.29 (1.76)	0.0	-5.1, 7.2	0.2522
Low Dose	25	0.89 (1.45)	0.70 (2.51)	0.0	0.0, 12.1	-0.19 (2.16)	0.0	-5.1, 7.2	0.6644
High Dose	26	0.57 (1.17)	0.19 (0.58)	0.0	0.0, 2.4	-0.38 (1.30)	0.0	-4.9, 1.6	0.1517
WEEK 39	49	0.63 (1.19)	0.41 (1.30)	0.0	0.0, 8.1	-0.22 (1.60)	0.0	-5.1, 7.3	0.3383
Low Dose	26	0.85 (1.43)	0.22 (0.63)	0.0	0.0, 2.4	-0.63 (1.26)	0.0	-5.1, 0.8	0.0178*
High Dose	23	0.39 (0.80)	0.62 (1.78)	0.0	0.0, 8.1	0.24 (1.84)	0.0	-3.6, 7.3	0.5430
WEEK 52	42	0.56 (1.08)	0.43 (1.37)	0.0	0.0, 6.3	-0.13 (1.84)	0.0	-5.1, 6.3	0.6524
Low Dose	21	0.77 (1.26)	0.17 (0.72)	0.0	0.0, 3.3	-0.60 (1.53)	-0.2	-5.1, 3.3	0.0882
High Dose	21	0.35 (0.84)	0.69 (1.79)	0.0	0.0, 6.3	0.34 (2.04)	0.0	-3.6, 6.3	0.4532
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	89		9.72 (2.47)	9.8	3.7, 16.0				
Low Dose	39		10.01 (3.00)	10.3	3.7, 16.0				
High Dose	50		9.50 (1.97)	9.6	5.7, 14.1				

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__1.4

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 (SD)	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 1	83	9.83 (2.43)	11.67 (3.27)	11.7	3.0, 16.0	1.84 (3.34)	1.7	-5.6, 8.3	<=0.001***
Low Dose	37	10.01 (2.94)	12.09 (3.25)	12.7	3.0, 16.0	2.07 (3.27)	2.7	-5.6, 7.8	<=0.001***
High Dose	46	9.68 (1.94)	11.33 (3.29)	11.5	4.2, 16.0	1.65 (3.42)	1.4	-4.8, 8.3	0.0021**
WEEK 6	76	9.79 (2.46)	12.51 (3.36)	13.0	1.1, 16.0	2.72 (3.53)	2.9	-6.7, 10.5	<=0.001***
Low Dose	34	10.05 (2.90)	12.76 (3.48)	13.6	1.1, 16.0	2.72 (3.35)	2.7	-3.7, 10.5	<=0.001***
High Dose	42	9.58 (2.06)	12.30 (3.28)	12.7	5.1, 16.0	2.72 (3.70)	3.3	-6.7, 8.4	<=0.001***
WEEK 13	47	10.22 (2.40)	13.16 (3.38)	14.3	5.7, 16.0	2.94 (3.57)	3.3	-6.3, 9.9	<=0.001***
Low Dose	23	10.77 (2.54)	14.08 (2.60)	15.5	8.6, 16.0	3.31 (2.83)	3.8	-3.3, 9.9	<=0.001***
High Dose	24	9.70 (2.18)	12.28 (3.84)	13.5	5.7, 16.0	2.58 (4.19)	2.7	-6.3, 9.2	0.0062**
WEEK 26	51	10.08 (2.44)	13.73 (2.97)	14.9	1.5, 16.0	3.65 (2.92)	3.9	-4.5, 10.5	<=0.001***
Low Dose	25	10.30 (2.76)	13.95 (3.32)	15.7	1.5, 16.0	3.65 (3.25)	3.9	-4.5, 10.5	<=0.001***
High Dose	26	9.87 (2.12)	13.53 (2.64)	14.4	7.6, 16.0	3.66 (2.63)	3.5	-1.0, 7.8	<=0.001***
WEEK 39	49	10.17 (2.45)	13.39 (3.06)	14.3	2.4, 16.0	3.23 (3.47)	3.3	-9.2, 9.9	<=0.001***
Low Dose	26	10.28 (2.70)	13.57 (2.95)	14.3	2.7, 16.0	3.29 (3.45)	3.1	-9.1, 9.9	<=0.001***
High Dose	23	10.03 (2.18)	13.19 (3.24)	14.0	2.4, 16.0	3.16 (3.57)	3.8	-9.2, 9.1	<=0.001***

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__1.4

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 (SD)	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 52	42	10.08 (2.33)	13.77 (2.52)	14.9	7.2, 16.0	3.69 (2.51)	3.7	-2.8, 9.9	<=0.001***
Low Dose	21	10.17 (2.65)	14.14 (1.85)	14.7	10.1, 16.0	3.97 (2.25)	3.5	0.0, 9.9	<=0.001***
High Dose	21	9.99 (2.03)	13.39 (3.05)	15.2	7.2, 16.0	3.40 (2.76)	3.8	-2.8, 7.5	<=0.001***
Geographic region:EUROPE AND AUSTRALIA									
Average Daily Normalized 'Off' Time									
BASELINE	120		5.97 (2.18)	5.9	0.0, 12.6				
Low Dose	66		5.83 (1.99)	5.8	0.0, 10.2				
High Dose	54		6.15 (2.40)	6.4	0.0, 12.6				
WEEK 1	116	6.01 (2.20)	4.08 (3.63)	2.9	0.0, 16.0	-1.94 (3.92)	-2.3	-10.2, 10.4	<=0.001***
Low Dose	63	5.90 (2.01)	3.73 (3.11)	2.7	0.0, 11.2	-2.16 (3.53)	-2.5	-10.2, 5.9	<=0.001***
High Dose	53	6.16 (2.42)	4.49 (4.15)	3.1	0.0, 16.0	-1.67 (4.35)	-2.1	-8.9, 10.4	0.0074**
WEEK 6	105	6.09 (2.20)	3.41 (2.90)	3.1	0.0, 16.0	-2.67 (3.49)	-3.1	-10.6, 9.9	<=0.001***
Low Dose	58	5.97 (1.97)	3.20 (3.07)	3.1	0.0, 16.0	-2.77 (3.64)	-3.2	-10.2, 9.9	<=0.001***
High Dose	47	6.23 (2.47)	3.68 (2.70)	3.1	0.0, 10.2	-2.55 (3.34)	-2.9	-10.6, 6.8	<=0.001***

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__1.4

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 (SD)	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 13	57	5.76 (2.15)	2.94 (3.10)	1.9	0.0, 12.6	-2.82 (3.43)	-3.4	-9.3, 7.8	<=0.001***
Low Dose	31	5.95 (2.01)	2.72 (3.07)	1.9	0.0, 12.6	-3.23 (3.46)	-3.5	-9.3, 7.8	<=0.001***
High Dose	26	5.54 (2.34)	3.20 (3.18)	2.0	0.0, 10.7	-2.34 (3.40)	-3.2	-7.5, 5.2	0.0017**
WEEK 26	65	6.37 (2.21)	2.49 (2.67)	1.7	0.0, 9.8	-3.88 (3.34)	-4.5	-10.6, 5.5	<=0.001***
Low Dose	32	6.36 (1.76)	2.01 (2.45)	0.9	0.0, 7.4	-4.35 (2.97)	-4.8	-10.2, 3.3	<=0.001***
High Dose	33	6.39 (2.60)	2.96 (2.83)	2.0	0.0, 9.8	-3.42 (3.64)	-3.9	-10.6, 5.5	<=0.001***
WEEK 39	56	6.29 (2.17)	2.62 (2.70)	2.0	0.0, 11.4	-3.67 (3.06)	-3.4	-9.8, 6.4	<=0.001***
Low Dose	30	6.10 (1.85)	2.10 (2.58)	0.9	0.0, 11.4	-4.00 (3.05)	-3.7	-9.8, 6.4	<=0.001***
High Dose	26	6.52 (2.51)	3.23 (2.77)	3.1	0.0, 7.7	-3.28 (3.09)	-3.3	-9.2, 4.0	<=0.001***
WEEK 52	50	6.10 (2.37)	2.68 (3.05)	1.5	0.0, 11.5	-3.42 (3.43)	-3.6	-11.2, 5.9	<=0.001***
Low Dose	26	6.29 (1.97)	2.77 (3.17)	1.5	0.0, 10.9	-3.52 (3.56)	-4.1	-10.2, 5.9	<=0.001***
High Dose	24	5.89 (2.76)	2.58 (2.99)	1.7	0.0, 11.5	-3.30 (3.37)	-3.1	-11.2, 2.6	<=0.001***

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__1.4

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 (SD)	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									
BASELINE	120		6.41 (3.24)	6.6	0.0, 12.3				
Low Dose	66		6.35 (3.20)	6.7	0.0, 11.9				
High Dose	54		6.47 (3.31)	6.4	0.0, 12.3				
WEEK 1	116	6.33 (3.21)	8.33 (4.69)	8.5	0.0, 16.0	2.00 (3.91)	1.8	-8.2, 10.4	<=0.001***
Low Dose	63	6.17 (3.13)	8.19 (4.49)	8.3	0.0, 16.0	2.02 (3.58)	1.9	-8.2, 10.4	<=0.001***
High Dose	53	6.52 (3.32)	8.51 (4.96)	8.8	0.0, 16.0	1.99 (4.30)	1.8	-8.1, 8.9	0.0015**
WEEK 6	105	6.45 (3.18)	10.06 (4.29)	11.1	0.0, 16.0	3.61 (3.85)	4.0	-8.3, 12.7	<=0.001***
Low Dose	58	6.38 (3.10)	10.10 (4.51)	10.9	0.0, 16.0	3.72 (4.06)	4.1	-8.3, 12.7	<=0.001***
High Dose	47	6.53 (3.31)	10.00 (4.05)	11.1	0.0, 16.0	3.47 (3.61)	3.2	-2.6, 11.2	<=0.001***
WEEK 13	57	6.45 (3.05)	11.25 (4.00)	12.6	2.7, 16.0	4.80 (3.51)	5.5	-3.6, 11.0	<=0.001***
Low Dose	31	6.24 (2.89)	11.58 (4.05)	13.2	3.4, 16.0	5.34 (3.23)	6.0	-1.5, 11.0	<=0.001***
High Dose	26	6.71 (3.27)	10.85 (3.99)	10.6	2.7, 16.0	4.15 (3.77)	4.3	-3.6, 10.4	<=0.001***

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__1.4

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 (SD)	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 26	65	6.72 (3.08)	11.38 (4.09)	12.0	0.0, 16.0	4.66 (4.41)	5.5	-11.0, 11.0	<=0.001***
Low Dose	32	6.39 (3.09)	12.45 (3.21)	13.4	5.2, 16.0	6.06 (2.67)	5.9	0.4, 11.0	<=0.001***
High Dose	33	7.04 (3.08)	10.35 (4.61)	11.3	0.0, 16.0	3.30 (5.30)	4.6	-11.0, 10.6	0.0011**
WEEK 39	56	6.77 (2.81)	11.04 (4.26)	11.3	0.6, 16.0	4.27 (3.63)	4.3	-3.8, 12.4	<=0.001***
Low Dose	30	6.79 (2.42)	11.98 (4.17)	12.6	1.4, 16.0	5.19 (3.40)	5.2	-2.8, 10.9	<=0.001***
High Dose	26	6.75 (3.25)	9.95 (4.17)	9.9	0.6, 16.0	3.20 (3.65)	2.6	-3.8, 12.4	<=0.001***
WEEK 52	50	7.06 (2.88)	10.78 (4.75)	12.4	0.4, 16.0	3.72 (4.05)	3.9	-6.5, 11.3	<=0.001***
Low Dose	26	6.55 (2.76)	11.20 (4.55)	12.9	1.5, 16.0	4.66 (4.26)	4.5	-6.5, 11.3	<=0.001***
High Dose	24	7.62 (2.95)	10.32 (5.02)	12.2	0.4, 16.0	2.70 (3.64)	2.3	-3.1, 11.2	0.0014**
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	120		2.46 (2.28)	2.2	0.0, 10.0				
Low Dose	66		2.28 (1.97)	2.1	0.0, 6.8				
High Dose	54		2.69 (2.61)	2.4	0.0, 10.0				

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__1.4

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 (SD)	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 1	116	2.50 (2.30)	2.48 (3.02)	1.1	0.0, 12.8	-0.02 (2.46)	0.0	-5.3, 8.1	0.9352
Low Dose	63	2.33 (1.98)	2.56 (2.81)	1.8	0.0, 11.6	0.22 (2.59)	0.0	-5.3, 7.1	0.4948
High Dose	53	2.70 (2.64)	2.39 (3.29)	0.8	0.0, 12.8	-0.31 (2.29)	-0.2	-4.5, 8.1	0.3331
WEEK 6	105	2.53 (2.36)	2.04 (3.22)	0.5	0.0, 15.4	-0.49 (2.49)	-0.3	-5.8, 11.6	0.0477*
Low Dose	58	2.35 (2.03)	2.08 (3.18)	0.7	0.0, 15.4	-0.28 (2.64)	-0.0	-5.1, 11.6	0.4304
High Dose	47	2.75 (2.71)	2.00 (3.30)	0.0	0.0, 13.1	-0.75 (2.30)	-0.6	-5.8, 5.7	0.0304*
WEEK 13	57	2.89 (2.38)	1.43 (2.12)	0.3	0.0, 8.2	-1.47 (2.59)	-1.2	-8.6, 4.6	<=0.001***
Low Dose	31	2.77 (2.15)	1.23 (1.92)	0.3	0.0, 8.2	-1.53 (2.16)	-1.5	-5.0, 4.3	<=0.001***
High Dose	26	3.05 (2.67)	1.66 (2.36)	0.7	0.0, 8.0	-1.38 (3.08)	-0.7	-8.6, 4.6	0.0305*
WEEK 26	65	2.03 (2.01)	1.85 (2.74)	0.6	0.0, 11.0	-0.18 (2.77)	0.0	-7.4, 7.2	0.6007
Low Dose	32	2.20 (1.97)	1.49 (2.53)	0.4	0.0, 10.8	-0.71 (2.56)	-0.6	-6.5, 5.4	0.1253
High Dose	33	1.87 (2.06)	2.21 (2.93)	0.7	0.0, 11.0	0.34 (2.90)	0.0	-7.4, 7.2	0.5086
WEEK 39	56	2.09 (2.04)	1.97 (3.32)	0.0	0.0, 14.6	-0.12 (3.01)	-0.1	-5.3, 9.9	0.7747
Low Dose	30	2.30 (1.98)	1.56 (3.06)	0.0	0.0, 14.6	-0.74 (2.89)	-0.5	-5.0, 9.2	0.1709
High Dose	26	1.85 (2.13)	2.45 (3.61)	0.0	0.0, 12.3	0.61 (3.05)	0.0	-5.3, 9.9	0.3213

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__1.4

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 (SD)	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 52	50	2.14 (2.11)	1.87 (3.50)	0.1	0.0, 15.6	-0.27 (3.02)	-0.2	-6.5, 9.2	0.5286
Low Dose	26	2.42 (2.02)	1.74 (3.35)	0.1	0.0, 11.8	-0.68 (3.58)	-0.4	-6.5, 9.2	0.3413
High Dose	24	1.84 (2.21)	2.02 (3.72)	0.1	0.0, 15.6	0.17 (2.26)	-0.1	-3.9, 6.7	0.7119
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	120		1.15 (2.00)	0.0	0.0, 10.5				
Low Dose	66		1.54 (2.34)	0.2	0.0, 10.5				
High Dose	54		0.68 (1.36)	0.0	0.0, 5.3				
WEEK 1	116	1.16 (2.02)	1.11 (2.40)	0.0	0.0, 11.7	-0.05 (1.89)	0.0	-5.7, 10.5	0.7777
Low Dose	63	1.60 (2.38)	1.52 (2.81)	0.0	0.0, 11.7	-0.08 (2.16)	0.0	-5.7, 10.5	0.7662
High Dose	53	0.63 (1.32)	0.61 (1.71)	0.0	0.0, 9.8	-0.01 (1.53)	0.0	-4.9, 5.9	0.9541
WEEK 6	105	0.94 (1.80)	0.49 (1.24)	0.0	0.0, 5.8	-0.45 (1.49)	0.0	-9.2, 4.4	0.0026**
Low Dose	58	1.30 (2.15)	0.62 (1.41)	0.0	0.0, 5.8	-0.67 (1.73)	0.0	-9.2, 2.7	0.0043**
High Dose	47	0.49 (1.12)	0.32 (1.00)	0.0	0.0, 4.4	-0.17 (1.08)	0.0	-3.4, 4.4	0.2881

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__1.4

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 (SD)	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 13	57	0.89 (1.39)	0.38 (1.25)	0.0	0.0, 8.0	-0.51 (1.44)	0.0	-5.2, 6.0	0.0105*
Low Dose	31	1.05 (1.43)	0.47 (1.49)	0.0	0.0, 8.0	-0.58 (1.80)	0.0	-5.2, 6.0	0.0833
High Dose	26	0.71 (1.35)	0.29 (0.91)	0.0	0.0, 3.7	-0.42 (0.87)	0.0	-3.4, 0.9	0.0215*
WEEK 26	65	0.87 (1.72)	0.27 (1.14)	0.0	0.0, 8.8	-0.60 (2.04)	0.0	-9.2, 8.8	0.0215*
Low Dose	32	1.04 (1.94)	0.05 (0.16)	0.0	0.0, 0.7	-0.99 (1.95)	0.0	-9.2, 0.4	0.0071**
High Dose	33	0.70 (1.49)	0.48 (1.58)	0.0	0.0, 8.8	-0.21 (2.09)	0.0	-4.9, 8.8	0.5601
WEEK 39	56	0.85 (1.43)	0.36 (0.96)	0.0	0.0, 3.8	-0.48 (1.14)	0.0	-5.0, 2.7	0.0025**
Low Dose	30	0.81 (1.26)	0.37 (1.01)	0.0	0.0, 3.8	-0.44 (0.83)	0.0	-3.6, 0.5	0.0063**
High Dose	26	0.89 (1.63)	0.36 (0.91)	0.0	0.0, 3.4	-0.53 (1.43)	0.0	-5.0, 2.7	0.0730
WEEK 52	50	0.69 (1.29)	0.66 (2.04)	0.0	0.0, 13.5	-0.03 (2.30)	0.0	-5.0, 13.0	0.9283
Low Dose	26	0.74 (1.23)	0.28 (0.65)	0.0	0.0, 2.7	-0.45 (1.17)	0.0	-3.0, 1.8	0.0592
High Dose	24	0.65 (1.38)	1.08 (2.84)	0.0	0.0, 13.5	0.43 (3.06)	0.0	-5.0, 13.0	0.4985

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__1.4

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 (SD)	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									
BASELINE	120		8.87 (2.59)	9.2	0.3, 16.0				
Low Dose	66		8.63 (2.58)	9.0	0.3, 14.2				
High Dose	54		9.17 (2.60)	9.3	2.6, 16.0				
WEEK 1	116	8.83 (2.59)	10.81 (4.00)	11.5	0.0, 16.0	1.99 (4.07)	2.1	-10.4, 11.3	<=0.001***
Low Dose	63	8.50 (2.56)	10.75 (3.91)	11.2	1.6, 16.0	2.24 (3.63)	2.2	-5.9, 11.3	<=0.001***
High Dose	53	9.22 (2.60)	10.90 (4.14)	11.9	0.0, 16.0	1.68 (4.55)	1.8	-10.4, 8.9	0.0097**
WEEK 6	105	8.98 (2.49)	12.10 (3.17)	12.6	0.0, 16.0	3.12 (3.55)	3.7	-9.9, 10.6	<=0.001***
Low Dose	58	8.74 (2.41)	12.18 (3.44)	12.6	0.0, 16.0	3.44 (3.64)	4.0	-9.9, 10.2	<=0.001***
High Dose	47	9.28 (2.58)	12.00 (2.82)	12.3	5.8, 16.0	2.72 (3.44)	3.6	-6.8, 10.6	<=0.001***
WEEK 13	57	9.35 (2.28)	12.68 (3.31)	13.9	3.4, 16.0	3.33 (3.24)	3.7	-5.2, 9.3	<=0.001***
Low Dose	31	9.01 (2.04)	12.81 (3.42)	13.8	3.4, 16.0	3.81 (3.20)	4.4	-4.9, 9.3	<=0.001***
High Dose	26	9.75 (2.51)	12.51 (3.23)	13.9	5.3, 16.0	2.76 (3.27)	3.4	-5.2, 7.5	<=0.001***

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__1.4

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 (SD)	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 26	65	8.76 (2.76)	13.24 (2.79)	14.3	6.2, 16.0	4.48 (3.65)	4.6	-5.5, 12.5	<=0.001***
Low Dose	32	8.60 (2.72)	13.94 (2.47)	15.0	8.6, 16.0	5.34 (3.34)	5.4	-1.7, 12.5	<=0.001***
High Dose	33	8.91 (2.84)	12.55 (2.94)	13.8	6.2, 16.0	3.64 (3.79)	2.9	-5.5, 10.6	<=0.001***
WEEK 39	56	8.86 (2.51)	13.01 (2.86)	12.9	4.6, 16.0	4.15 (3.23)	3.4	-5.9, 9.8	<=0.001***
Low Dose	30	9.09 (2.31)	13.54 (2.68)	13.5	4.6, 16.0	4.45 (3.28)	4.1	-5.9, 9.8	<=0.001***
High Dose	26	8.60 (2.75)	12.41 (2.98)	12.5	6.6, 16.0	3.81 (3.20)	3.4	-2.9, 9.7	<=0.001***
WEEK 52	50	9.21 (2.64)	12.65 (3.51)	13.9	2.5, 16.0	3.45 (3.62)	3.5	-5.4, 11.2	<=0.001***
Low Dose	26	8.97 (2.51)	12.94 (3.16)	13.9	5.1, 16.0	3.98 (3.66)	4.1	-5.4, 10.2	<=0.001***
High Dose	24	9.47 (2.80)	12.34 (3.90)	13.6	2.5, 16.0	2.87 (3.56)	2.9	-3.8, 11.2	<=0.001***
Geographic region:JAPAN									
Average Daily Normalized 'Off' Time									
BASELINE	27		6.79 (2.05)	6.9	0.0, 10.3				
Low Dose	22		6.50 (2.09)	6.6	0.0, 10.3				
High Dose	5		8.06 (1.42)	8.3	5.7, 9.6				

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__1.4

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 (SD)	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 1	26	6.78 (2.09)	5.25 (3.32)	5.1	0.0, 13.8	-1.53 (3.77)	-1.9	-9.7, 4.7	0.0490*
Low Dose	21	6.47 (2.13)	5.15 (3.26)	4.7	0.0, 13.8	-1.33 (3.66)	-1.9	-9.7, 4.7	0.1122
High Dose	5	8.06 (1.42)	5.67 (3.95)	5.4	0.0, 10.9	-2.39 (4.56)	-3.1	-8.3, 2.8	0.3067
WEEK 6	24	6.72 (1.95)	5.88 (3.71)	4.9	0.0, 13.4	-0.84 (3.94)	-2.5	-7.5, 6.8	0.3088
Low Dose	19	6.37 (1.94)	5.32 (3.62)	4.0	0.0, 13.4	-1.05 (3.86)	-2.4	-7.5, 6.2	0.2497
High Dose	5	8.06 (1.42)	8.04 (3.59)	6.4	4.8, 12.5	-0.02 (4.60)	-2.9	-3.5, 6.8	0.9939
WEEK 13	10	5.81 (2.19)	6.67 (4.86)	7.3	0.0, 13.4	0.86 (5.02)	1.8	-6.6, 8.1	0.6010
Low Dose	10	5.81 (2.19)	6.67 (4.86)	7.3	0.0, 13.4	0.86 (5.02)	1.8	-6.6, 8.1	0.6010
High Dose	0								
WEEK 26	15	6.67 (1.31)	5.79 (4.43)	5.4	0.0, 14.3	-0.89 (4.46)	-0.7	-8.1, 7.1	0.4534
Low Dose	12	6.17 (0.82)	5.92 (4.57)	5.4	0.0, 14.3	-0.26 (4.49)	-0.4	-7.0, 7.1	0.8468
High Dose	3	8.68 (0.82)	5.27 (4.67)	6.9	0.0, 8.9	-3.42 (4.07)	-1.4	-8.1, -0.7	0.2834
WEEK 39	14	6.68 (1.36)	4.36 (3.22)	4.5	0.0, 12.3	-2.32 (3.40)	-1.7	-8.1, 5.1	0.0241*
Low Dose	11	6.13 (0.85)	4.56 (3.30)	4.7	0.0, 12.3	-1.57 (3.14)	-1.3	-7.0, 5.1	0.1294
High Dose	3	8.68 (0.82)	3.61 (3.44)	4.0	0.0, 6.8	-5.07 (3.34)	-5.6	-8.1, -1.5	0.1196

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__1.4

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 (SD)	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 52	12	6.75 (1.39)	4.34 (2.99)	4.5	0.0, 10.1	-2.41 (3.40)	-2.7	-8.1, 4.1	0.0315*
Low Dose	9	6.11 (0.79)	4.40 (3.00)	3.7	0.0, 10.1	-1.72 (3.33)	-2.4	-7.0, 4.1	0.1609
High Dose	3	8.68 (0.82)	4.17 (3.62)	6.1	0.0, 6.4	-4.51 (3.21)	-3.5	-8.1, -1.9	0.1352
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	27		5.68 (2.73)	5.7	0.0, 10.1				
Low Dose	22		5.30 (2.86)	4.8	0.0, 10.1				
High Dose	5		7.37 (0.91)	7.7	6.4, 8.4				
WEEK 1	26	5.55 (2.70)	6.23 (3.84)	6.8	0.3, 16.0	0.68 (4.00)	0.9	-8.9, 10.2	0.3968
Low Dose	21	5.12 (2.81)	5.49 (3.48)	6.2	0.3, 11.3	0.36 (3.99)	0.8	-8.9, 10.2	0.6805
High Dose	5	7.37 (0.91)	9.36 (4.06)	8.1	5.1, 16.0	1.99 (4.19)	1.3	-2.8, 8.3	0.3494
WEEK 6	24	5.79 (2.86)	8.38 (4.05)	8.4	0.0, 13.8	2.60 (5.07)	3.7	-6.4, 13.8	0.0196*
Low Dose	19	5.37 (3.07)	9.10 (3.56)	8.6	2.6, 13.8	3.73 (4.65)	3.9	-3.5, 13.8	0.0025**
High Dose	5	7.37 (0.91)	5.65 (5.05)	3.5	0.0, 11.2	-1.72 (4.59)	-3.7	-6.4, 3.5	0.4491

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__1.4

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 (SD)	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 13	10	5.40 (2.89)	5.93 (5.42)	5.2	0.0, 14.7	0.54 (5.57)	0.9	-9.0, 9.6	0.7668
Low Dose	10	5.40 (2.89)	5.93 (5.42)	5.2	0.0, 14.7	0.54 (5.57)	0.9	-9.0, 9.6	0.7668
High Dose	0								
WEEK 26	15	5.94 (2.87)	8.34 (5.26)	8.1	0.0, 16.0	2.40 (5.01)	3.2	-10.1, 9.5	0.0844
Low Dose	12	5.60 (3.12)	7.77 (5.41)	7.8	0.0, 16.0	2.18 (5.33)	3.2	-10.1, 9.5	0.1852
High Dose	3	7.32 (0.82)	10.62 (4.80)	9.1	6.8, 16.0	3.30 (4.19)	1.4	0.4, 8.1	0.3053
WEEK 39	14	5.90 (2.97)	9.83 (4.24)	10.3	0.3, 16.0	3.93 (3.21)	4.0	-1.9, 8.1	<=0.001***
Low Dose	11	5.51 (3.25)	9.36 (4.38)	10.4	0.3, 16.0	3.85 (3.32)	4.9	-1.9, 8.0	0.0032**
High Dose	3	7.32 (0.82)	11.55 (3.86)	9.5	9.2, 16.0	4.23 (3.45)	3.1	1.5, 8.1	0.1679
WEEK 52	12	6.26 (3.03)	10.48 (3.47)	10.2	4.2, 16.0	4.22 (2.22)	3.8	1.7, 8.1	<=0.001***
Low Dose	9	5.91 (3.45)	10.24 (3.44)	10.7	4.2, 16.0	4.32 (1.86)	4.5	1.9, 7.0	<=0.001***
High Dose	3	7.32 (0.82)	11.22 (4.21)	9.6	8.1, 16.0	3.90 (3.64)	1.9	1.7, 8.1	0.2043

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__1.4

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 (SD)	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	27		2.74 (2.76)	2.6	0.0, 8.0				
Low Dose	22		3.30 (2.76)	3.1	0.0, 8.0				
High Dose	5		0.26 (0.44)	0.0	0.0, 1.0				
WEEK 1	26	2.84 (2.76)	3.83 (4.01)	2.6	0.0, 14.9	0.99 (3.82)	0.0	-5.4, 13.2	0.2002
Low Dose	21	3.46 (2.73)	4.52 (4.15)	3.4	0.0, 14.9	1.06 (4.24)	0.0	-5.4, 13.2	0.2641
High Dose	5	0.26 (0.44)	0.92 (1.10)	0.6	0.0, 2.6	0.67 (1.16)	0.0	-0.4, 2.3	0.2677
WEEK 6	24	2.64 (2.71)	1.70 (2.87)	0.2	0.0, 9.6	-0.94 (3.53)	0.0	-6.7, 9.6	0.2027
Low Dose	19	3.27 (2.71)	1.54 (2.56)	0.5	0.0, 9.0	-1.73 (2.93)	-1.2	-6.7, 4.4	0.0188*
High Dose	5	0.26 (0.44)	2.31 (4.17)	0.0	0.0, 9.6	2.05 (4.34)	0.0	-1.0, 9.6	0.3496
WEEK 13	10	3.31 (2.90)	3.39 (5.59)	0.7	0.0, 16.0	0.08 (5.72)	-0.5	-6.5, 13.2	0.9655
Low Dose	10	3.31 (2.90)	3.39 (5.59)	0.7	0.0, 16.0	0.08 (5.72)	-0.5	-6.5, 13.2	0.9655
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__1.4

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 (SD)	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 26	15	2.91 (3.04)	1.76 (3.26)	0.0	0.0, 12.1	-1.15 (3.11)	0.0	-6.7, 4.6	0.1730
Low Dose	12	3.64 (2.97)	2.17 (3.55)	0.2	0.0, 12.1	-1.47 (3.43)	-2.6	-6.7, 4.6	0.1657
High Dose	3	0.00 (0.00)	0.11 (0.20)	0.0	0.0, 0.3	0.11 (0.20)	0.0	0.0, 0.3	0.4226
WEEK 39	14	2.92 (3.15)	1.72 (3.58)	0.0	0.0, 13.2	-1.20 (3.18)	-0.1	-6.7, 5.2	0.1826
Low Dose	11	3.72 (3.11)	1.96 (3.99)	0.0	0.0, 13.2	-1.75 (3.34)	-1.5	-6.7, 5.2	0.1121
High Dose	3	0.00 (0.00)	0.84 (1.46)	0.0	0.0, 2.5	0.84 (1.46)	0.0	0.0, 2.5	0.4226
WEEK 52	12	2.64 (3.29)	1.16 (1.98)	0.1	0.0, 6.7	-1.48 (2.55)	0.0	-6.7, 1.8	0.0687
Low Dose	9	3.52 (3.37)	1.34 (2.23)	0.3	0.0, 6.7	-2.18 (2.54)	-1.3	-6.7, 0.0	0.0329*
High Dose	3	0.00 (0.00)	0.61 (1.05)	0.0	0.0, 1.8	0.61 (1.05)	0.0	0.0, 1.8	0.4226
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	27		0.79 (1.74)	0.0	0.0, 7.2				
Low Dose	22		0.90 (1.91)	0.0	0.0, 7.2				
High Dose	5		0.31 (0.43)	0.0	0.0, 0.8				

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__1.4

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 (SD)	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 1	26	0.82 (1.77)	0.69 (1.59)	0.0	0.0, 7.9	-0.13 (2.37)	0.0	-6.0, 7.9	0.7790
Low Dose	21	0.95 (1.95)	0.85 (1.74)	0.0	0.0, 7.9	-0.10 (2.64)	0.0	-6.0, 7.9	0.8639
High Dose	5	0.31 (0.43)	0.05 (0.11)	0.0	0.0, 0.3	-0.26 (0.38)	0.0	-0.8, 0.0	0.1899
WEEK 6	24	0.85 (1.84)	0.04 (0.12)	0.0	0.0, 0.5	-0.82 (1.81)	0.0	-7.2, 0.4	0.0370*
Low Dose	19	0.99 (2.04)	0.04 (0.14)	0.0	0.0, 0.5	-0.95 (2.01)	0.0	-7.2, 0.4	0.0544
High Dose	5	0.31 (0.43)	0.00 (0.00)	0.0	0.0, 0.0	-0.31 (0.43)	0.0	-0.8, 0.0	0.1779
WEEK 13	10	1.48 (2.59)	0.00 (0.00)	0.0	0.0, 0.0	-1.48 (2.59)	0.0	-7.2, 0.0	0.1039
Low Dose	10	1.48 (2.59)	0.00 (0.00)	0.0	0.0, 0.0	-1.48 (2.59)	0.0	-7.2, 0.0	0.1039
High Dose	0								
WEEK 26	15	0.47 (1.12)	0.11 (0.34)	0.0	0.0, 1.3	-0.36 (1.20)	0.0	-3.4, 1.3	0.2645
Low Dose	12	0.59 (1.23)	0.14 (0.37)	0.0	0.0, 1.3	-0.45 (1.33)	0.0	-3.4, 1.3	0.2682
High Dose	3	0.00 (0.00)	0.00 (0.00)	0.0	0.0, 0.0	0.00 (0.00)	0.0	0.0, 0.0	
WEEK 39	14	0.51 (1.15)	0.09 (0.23)	0.0	0.0, 0.7	-0.42 (1.05)	0.0	-3.0, 0.0	0.1610
Low Dose	11	0.64 (1.28)	0.11 (0.26)	0.0	0.0, 0.7	-0.53 (1.17)	0.0	-3.0, 0.0	0.1630
High Dose	3	0.00 (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__1.4

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 (SD)	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 52	12	0.34 (0.97)	0.02 (0.07)	0.0	0.0, 0.2	-0.32 (0.97)	0.0	-3.4, 0.0	0.2748
Low Dose	9	0.45 (1.12)	0.03 (0.08)	0.0	0.0, 0.2	-0.43 (1.11)	0.0	-3.4, 0.0	0.2814
High Dose	3	0.00 (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	27		8.42 (1.76)	8.7	4.6, 11.1				
Low Dose	22		8.60 (1.84)	8.9	4.6, 11.1				
High Dose	5		7.63 (1.20)	7.7	6.4, 9.5				
WEEK 1	26	8.40 (1.80)	10.06 (3.19)	9.9	2.2, 16.0	1.66 (3.85)	1.1	-4.0, 9.7	0.0372*
Low Dose	21	8.58 (1.89)	10.00 (3.09)	9.8	2.2, 16.0	1.43 (3.78)	1.0	-4.0, 9.7	0.0996
High Dose	5	7.63 (1.20)	10.28 (3.95)	10.4	5.1, 16.0	2.65 (4.42)	3.7	-2.8, 8.3	0.2511
WEEK 6	24	8.43 (1.70)	10.08 (3.69)	11.1	2.6, 16.0	1.65 (3.82)	3.0	-6.0, 7.5	0.0448*
Low Dose	19	8.64 (1.77)	10.64 (3.60)	11.7	2.6, 16.0	2.00 (3.75)	3.1	-5.7, 7.5	0.0321*
High Dose	5	7.63 (1.20)	7.96 (3.59)	9.6	3.5, 11.2	0.33 (4.19)	2.9	-6.0, 3.5	0.8681

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__1.4

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 (SD)	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 &
Geographic region:JAPAN (Cont.)									
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia (Cont.)									
WEEK 13	10	8.71 (2.05)	9.33 (4.86)	8.7	2.6, 16.0	0.62 (3.76)	0.1	-5.0, 6.6	0.6148
Low Dose	10	8.71 (2.05)	9.33 (4.86)	8.7	2.6, 16.0	0.62 (3.76)	0.1	-5.0, 6.6	0.6148
High Dose	0								
WEEK 26	15	8.85 (1.64)	10.10 (4.38)	10.5	1.7, 16.0	1.25 (4.00)	0.7	-5.5, 8.1	0.2476
Low Dose	12	9.24 (1.58)	9.94 (4.50)	10.5	1.7, 16.0	0.71 (3.97)	0.5	-5.5, 7.0	0.5513
High Dose	3	7.32 (0.82)	10.73 (4.67)	9.1	7.1, 16.0	3.42 (4.07)	1.4	0.7, 8.1	0.2834
WEEK 39	14	8.82 (1.70)	11.55 (3.17)	11.5	3.7, 16.0	2.73 (2.94)	2.3	-2.1, 8.1	0.0040**
Low Dose	11	9.23 (1.66)	11.32 (3.23)	11.3	3.7, 16.0	2.10 (2.62)	1.9	-2.1, 7.0	0.0244*
High Dose	3	7.32 (0.82)	12.39 (3.44)	12.0	9.2, 16.0	5.07 (3.34)	5.6	1.5, 8.1	0.1196
WEEK 52	12	8.91 (1.47)	11.64 (3.00)	11.5	5.9, 16.0	2.74 (2.86)	2.7	-1.2, 8.1	0.0069**
Low Dose	9	9.43 (1.25)	11.58 (3.01)	12.3	5.9, 16.0	2.14 (2.66)	2.4	-1.2, 7.0	0.0420*
High Dose	3	7.32 (0.82)	11.83 (3.62)	9.9	9.6, 16.0	4.51 (3.21)	3.5	1.9, 8.1	0.1352

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__1.4

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 (SD)	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	127		6.04 (2.24)	6.0	0.0, 10.3				
Low Dose	64		6.05 (2.17)	6.0	0.0, 10.3				
High Dose	63		6.04 (2.33)	6.0	0.0, 10.3				
WEEK 1	122	6.02 (2.23)	3.67 (3.21)	2.9	0.0, 14.8	-2.35 (3.42)	-2.1	-9.7, 5.9	<=0.001***
Low Dose	62	6.10 (2.15)	3.78 (3.27)	2.8	0.0, 13.8	-2.32 (3.22)	-2.1	-9.7, 3.9	<=0.001***
High Dose	60	5.94 (2.32)	3.55 (3.18)	2.9	0.0, 14.8	-2.39 (3.64)	-2.2	-8.9, 5.9	<=0.001***
WEEK 6	112	6.05 (2.23)	3.44 (3.00)	3.1	0.0, 12.3	-2.62 (3.39)	-2.9	-9.9, 6.7	<=0.001***
Low Dose	57	5.97 (2.07)	3.29 (2.90)	3.1	0.0, 12.3	-2.68 (3.46)	-2.6	-9.9, 5.7	<=0.001***
High Dose	55	6.14 (2.41)	3.59 (3.11)	3.0	0.0, 10.7	-2.55 (3.34)	-2.9	-8.4, 6.7	<=0.001***
WEEK 13	64	5.63 (2.38)	3.04 (3.44)	1.7	0.0, 12.1	-2.58 (3.48)	-3.2	-9.9, 6.3	<=0.001***
Low Dose	32	5.85 (2.27)	2.42 (3.13)	1.3	0.0, 12.1	-3.42 (3.04)	-3.9	-9.9, 5.0	<=0.001***
High Dose	32	5.40 (2.51)	3.66 (3.66)	2.3	0.0, 10.7	-1.74 (3.74)	-2.1	-9.2, 6.3	0.0130*

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__1.4

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 (SD)	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 26	72	5.81 (2.31)	2.80 (2.98)	1.7	0.0, 11.2	-3.01 (3.16)	-3.0	-9.2, 5.5	<=0.001***
Low Dose	34	5.86 (2.04)	2.95 (3.24)	1.3	0.0, 11.2	-2.91 (3.43)	-2.9	-9.2, 5.5	<=0.001***
High Dose	38	5.77 (2.55)	2.67 (2.77)	1.9	0.0, 8.4	-3.10 (2.95)	-3.1	-9.2, 4.4	<=0.001***
WEEK 39	63	5.86 (2.31)	2.74 (2.66)	2.0	0.0, 11.4	-3.11 (3.05)	-2.8	-9.9, 6.4	<=0.001***
Low Dose	32	5.84 (2.14)	2.58 (2.70)	1.9	0.0, 11.4	-3.27 (3.26)	-2.9	-9.9, 6.4	<=0.001***
High Dose	31	5.87 (2.50)	2.92 (2.65)	3.1	0.0, 7.7	-2.95 (2.86)	-2.8	-9.2, 4.0	<=0.001***
WEEK 52	60	5.77 (2.39)	2.90 (3.15)	2.3	0.0, 11.5	-2.87 (3.22)	-2.9	-9.9, 5.9	<=0.001***
Low Dose	30	5.95 (2.11)	2.96 (3.18)	2.3	0.0, 10.9	-2.99 (3.53)	-3.3	-9.9, 5.9	<=0.001***
High Dose	30	5.59 (2.67)	2.84 (3.17)	1.6	0.0, 11.5	-2.75 (2.93)	-2.6	-9.2, 2.6	<=0.001***
Average Daily Normalized 'On' Time Without Dyskinesia									
BASELINE	127		6.79 (3.45)	6.9	0.0, 15.4				
Low Dose	64		6.61 (3.83)	7.0	0.0, 15.4				
High Dose	63		6.97 (3.04)	6.9	0.3, 13.8				

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__1.4

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 (SD)	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 1	122	6.73 (3.45)	9.04 (4.69)	9.2	0.0, 16.0	2.30 (4.04)	1.7	-8.9, 12.0	<=0.001***
Low Dose	62	6.45 (3.76)	8.41 (4.96)	8.9	0.0, 16.0	1.96 (3.92)	1.6	-8.9, 10.7	<=0.001***
High Dose	60	7.02 (3.09)	9.69 (4.33)	10.0	0.0, 16.0	2.66 (4.16)	2.6	-5.4, 12.0	<=0.001***
WEEK 6	112	6.96 (3.42)	10.60 (4.19)	11.5	0.0, 16.0	3.64 (4.26)	3.6	-6.7, 13.8	<=0.001***
Low Dose	57	6.92 (3.84)	10.59 (4.36)	11.8	0.0, 16.0	3.67 (4.32)	3.7	-6.1, 13.8	<=0.001***
High Dose	55	6.99 (2.96)	10.61 (4.05)	11.5	0.5, 16.0	3.61 (4.23)	3.5	-6.7, 12.0	<=0.001***
WEEK 13	64	7.16 (3.60)	11.34 (4.50)	12.9	0.0, 16.0	4.18 (4.66)	4.5	-9.0, 15.2	<=0.001***
Low Dose	32	7.36 (3.88)	11.84 (4.80)	13.5	0.0, 16.0	4.48 (4.85)	4.8	-9.0, 15.2	<=0.001***
High Dose	32	6.96 (3.35)	10.84 (4.20)	10.6	2.7, 16.0	3.88 (4.51)	4.0	-6.3, 14.1	<=0.001***
WEEK 26	72	7.33 (3.37)	11.29 (4.29)	12.4	0.0, 16.0	3.96 (4.45)	4.6	-10.1, 14.1	<=0.001***
Low Dose	34	7.46 (3.75)	11.63 (4.46)	13.2	0.0, 16.0	4.17 (4.53)	4.8	-10.1, 11.2	<=0.001***
High Dose	38	7.21 (3.03)	10.98 (4.17)	11.4	0.8, 16.0	3.77 (4.43)	4.3	-6.6, 14.1	<=0.001***
WEEK 39	63	7.26 (3.47)	10.88 (4.41)	11.2	0.0, 16.0	3.62 (3.72)	3.2	-5.0, 12.4	<=0.001***
Low Dose	32	7.49 (3.73)	11.98 (4.05)	12.0	0.3, 16.0	4.49 (3.77)	4.9	-5.0, 11.2	<=0.001***
High Dose	31	7.03 (3.22)	9.75 (4.54)	10.3	0.0, 16.0	2.72 (3.52)	2.6	-3.8, 12.4	<=0.001***

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__1.4

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 (SD)	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 52	60	7.36 (3.34)	10.24 (4.94)	11.3	0.0, 16.0	2.89 (4.06)	3.0	-12.0, 9.9	<=0.001***
Low Dose	30	7.09 (3.64)	11.12 (4.71)	12.5	0.0, 16.0	4.03 (3.78)	4.8	-6.5, 9.9	<=0.001***
High Dose	30	7.62 (3.05)	9.37 (5.09)	9.6	0.0, 16.0	1.74 (4.06)	1.7	-12.0, 8.8	0.0257*
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	127		2.35 (2.64)	1.7	0.0, 12.2				
Low Dose	64		2.36 (2.65)	1.7	0.0, 10.3				
High Dose	63		2.35 (2.65)	2.4	0.0, 12.2				
WEEK 1	122	2.43 (2.66)	2.46 (3.22)	1.0	0.0, 14.9	0.03 (2.80)	0.0	-8.5, 13.2	0.8929
Low Dose	62	2.44 (2.66)	2.70 (3.34)	2.1	0.0, 14.9	0.26 (2.80)	0.0	-8.5, 13.2	0.4626
High Dose	60	2.42 (2.69)	2.22 (3.10)	0.6	0.0, 11.9	-0.20 (2.80)	0.0	-8.2, 8.8	0.5775
WEEK 6	112	2.39 (2.75)	1.54 (2.81)	0.0	0.0, 13.9	-0.85 (2.58)	-0.2	-7.6, 8.3	<=0.001***
Low Dose	57	2.41 (2.78)	1.59 (2.72)	0.5	0.0, 10.4	-0.82 (2.77)	0.0	-7.6, 8.3	0.0296*
High Dose	55	2.36 (2.75)	1.49 (2.92)	0.0	0.0, 13.9	-0.87 (2.38)	-0.4	-7.6, 5.7	0.0088**

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__1.4

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 (SD)	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 13	64	2.72 (3.11)	1.41 (2.82)	0.0	0.0, 15.5	-1.31 (3.22)	-0.5	-12.2, 5.2	0.0018**
Low Dose	32	2.48 (3.06)	1.65 (3.48)	0.0	0.0, 15.5	-0.83 (3.11)	0.0	-8.0, 5.2	0.1425
High Dose	32	2.96 (3.19)	1.16 (1.99)	0.0	0.0, 8.0	-1.80 (3.31)	-0.7	-12.2, 4.6	0.0043**
WEEK 26	72	2.22 (2.61)	1.69 (3.02)	0.0	0.0, 15.2	-0.52 (3.28)	0.0	-12.2, 12.0	0.1797
Low Dose	34	2.11 (2.50)	1.21 (2.33)	0.0	0.0, 12.1	-0.89 (2.56)	0.0	-6.8, 4.6	0.0501
High Dose	38	2.32 (2.73)	2.13 (3.50)	0.0	0.0, 15.2	-0.19 (3.81)	0.0	-12.2, 12.0	0.7568
WEEK 39	63	2.28 (2.81)	2.03 (3.63)	0.0	0.0, 16.0	-0.25 (3.19)	0.0	-7.8, 9.9	0.5318
Low Dose	32	2.30 (2.75)	1.27 (2.79)	0.0	0.0, 13.2	-1.02 (2.88)	-0.1	-7.8, 5.2	0.0536
High Dose	31	2.27 (2.92)	2.81 (4.24)	0.0	0.0, 16.0	0.54 (3.35)	0.0	-6.4, 9.9	0.3755
WEEK 52	60	2.32 (2.86)	2.22 (4.23)	0.0	0.0, 16.0	-0.10 (3.34)	0.0	-6.8, 12.9	0.8226
Low Dose	30	2.43 (2.91)	1.67 (3.73)	0.0	0.0, 16.0	-0.77 (3.28)	0.0	-6.8, 9.2	0.2109
High Dose	30	2.21 (2.86)	2.78 (4.69)	0.4	0.0, 16.0	0.57 (3.33)	0.0	-3.9, 12.9	0.3550

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__1.4

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 (SD)	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									
BASELINE	127		0.82 (1.65)	0.0	0.0, 9.2				
Low Dose	64		0.98 (1.94)	0.0	0.0, 9.2				
High Dose	63		0.65 (1.28)	0.0	0.0, 5.3				
WEEK 1	122	0.82 (1.66)	0.83 (2.16)	0.0	0.0, 11.7	0.01 (1.78)	0.0	-5.7, 10.5	0.9292
Low Dose	62	1.01 (1.97)	1.11 (2.64)	0.0	0.0, 11.7	0.10 (2.11)	0.0	-5.7, 10.5	0.7154
High Dose	60	0.62 (1.25)	0.55 (1.48)	0.0	0.0, 9.8	-0.07 (1.36)	0.0	-4.9, 4.7	0.6815
WEEK 6	112	0.60 (1.31)	0.42 (1.35)	0.0	0.0, 9.0	-0.18 (1.52)	0.0	-9.2, 6.9	0.2131
Low Dose	57	0.70 (1.53)	0.53 (1.65)	0.0	0.0, 9.0	-0.17 (1.90)	0.0	-9.2, 6.9	0.5010
High Dose	55	0.50 (1.05)	0.31 (0.94)	0.0	0.0, 4.4	-0.19 (1.01)	0.0	-3.4, 4.4	0.1699
WEEK 13	64	0.50 (1.00)	0.21 (0.74)	0.0	0.0, 3.7	-0.29 (0.85)	0.0	-3.4, 2.6	0.0090**
Low Dose	32	0.31 (0.65)	0.08 (0.32)	0.0	0.0, 1.7	-0.23 (0.71)	0.0	-2.7, 1.7	0.0747
High Dose	32	0.68 (1.24)	0.34 (0.99)	0.0	0.0, 3.7	-0.34 (0.98)	0.0	-3.4, 2.6	0.0574

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__1.4

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 (SD)	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 26	72	0.64 (1.54)	0.22 (0.63)	0.0	0.0, 3.7	-0.42 (1.60)	0.0	-9.2, 3.7	0.0271*
Low Dose	34	0.57 (1.71)	0.21 (0.70)	0.0	0.0, 3.7	-0.36 (1.90)	0.0	-9.2, 3.7	0.2729
High Dose	38	0.70 (1.39)	0.22 (0.57)	0.0	0.0, 2.4	-0.48 (1.29)	0.0	-4.9, 1.7	0.0274*
WEEK 39	63	0.60 (1.28)	0.34 (1.24)	0.0	0.0, 8.1	-0.26 (1.39)	0.0	-5.0, 7.3	0.1448
Low Dose	32	0.37 (1.00)	0.17 (0.65)	0.0	0.0, 3.5	-0.21 (0.61)	0.0	-2.8, 0.8	0.0655
High Dose	31	0.83 (1.50)	0.52 (1.63)	0.0	0.0, 8.1	-0.31 (1.89)	0.0	-5.0, 7.3	0.3668
WEEK 52	60	0.55 (1.17)	0.63 (2.04)	0.0	0.0, 13.5	0.08 (2.28)	0.0	-5.0, 13.0	0.7808
Low Dose	30	0.52 (1.11)	0.25 (0.80)	0.0	0.0, 3.3	-0.27 (1.23)	0.0	-3.4, 3.3	0.2325
High Dose	30	0.58 (1.24)	1.02 (2.74)	0.0	0.0, 13.5	0.44 (2.96)	0.0	-5.0, 13.0	0.4233
Average Daily Normalized 'On' Time Without Troublesome Dyskinesia									
BASELINE	127		9.14 (2.67)	9.5	0.3, 16.0				
Low Dose	64		8.97 (2.86)	9.2	0.3, 16.0				
High Dose	63		9.31 (2.46)	9.5	2.6, 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__1.4

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 (SD)	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 1	122	9.16 (2.66)	11.50 (3.65)	11.6	1.2, 16.0	2.34 (3.53)	2.1	-5.9, 9.7	<=0.001***
Low Dose	62	8.89 (2.84)	11.11 (4.00)	11.1	1.6, 16.0	2.22 (3.24)	1.8	-3.9, 9.7	<=0.001***
High Dose	60	9.44 (2.45)	11.90 (3.23)	12.2	1.2, 16.0	2.46 (3.84)	2.3	-5.9, 8.9	<=0.001***
WEEK 6	112	9.34 (2.53)	12.14 (3.20)	12.7	3.7, 16.0	2.80 (3.44)	3.2	-6.7, 9.9	<=0.001***
Low Dose	57	9.33 (2.64)	12.19 (3.23)	12.7	3.7, 16.0	2.85 (3.41)	3.0	-5.7, 9.9	<=0.001***
High Dose	55	9.36 (2.43)	12.10 (3.19)	12.8	5.1, 16.0	2.74 (3.50)	3.5	-6.7, 8.4	<=0.001***
WEEK 13	64	9.88 (2.45)	12.74 (3.51)	14.2	3.9, 16.0	2.87 (3.50)	3.3	-6.3, 9.9	<=0.001***
Low Dose	32	9.84 (2.40)	13.49 (3.13)	14.6	3.9, 16.0	3.65 (3.06)	3.9	-5.0, 9.9	<=0.001***
High Dose	32	9.92 (2.53)	12.00 (3.76)	13.6	5.3, 16.0	2.08 (3.78)	2.6	-6.3, 9.2	0.0040**
WEEK 26	72	9.55 (2.74)	12.98 (2.99)	14.1	4.8, 16.0	3.43 (3.21)	3.1	-5.5, 10.2	<=0.001***
Low Dose	34	9.57 (2.77)	12.84 (3.26)	14.4	4.8, 16.0	3.27 (3.44)	3.1	-5.5, 9.2	<=0.001***
High Dose	38	9.53 (2.76)	13.11 (2.76)	14.0	7.6, 16.0	3.58 (3.03)	3.0	-4.4, 10.2	<=0.001***
WEEK 39	63	9.55 (2.64)	12.92 (2.97)	12.9	2.4, 16.0	3.37 (3.36)	3.1	-9.2, 9.9	<=0.001***
Low Dose	32	9.78 (2.58)	13.25 (2.73)	13.8	4.6, 16.0	3.47 (3.21)	3.1	-5.9, 9.9	<=0.001***
High Dose	31	9.30 (2.73)	12.57 (3.20)	12.9	2.4, 16.0	3.26 (3.57)	3.1	-9.2, 9.7	<=0.001***

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__1.4

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 (SD)	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 52	60	9.68 (2.58)	12.47 (3.46)	13.2	2.5, 16.0	2.79 (3.08)	2.7	-5.4, 9.9	<=0.001***
Low Dose	30	9.53 (2.57)	12.79 (3.16)	13.4	5.1, 16.0	3.27 (3.25)	3.1	-5.4, 9.9	<=0.001***
High Dose	30	9.83 (2.62)	12.14 (3.77)	12.7	2.5, 16.0	2.31 (2.87)	2.1	-3.8, 8.4	<=0.001***
PD duration (time since diagnosis) category:>=10 years									
Average Daily Normalized 'Off' Time									
BASELINE	109		5.74 (2.24)	5.7	0.0, 12.6				
Low Dose	63		5.30 (2.16)	5.3	0.0, 10.2				
High Dose	46		6.34 (2.23)	6.5	1.5, 12.6				
WEEK 1	103	5.79 (2.28)	4.33 (3.65)	3.7	0.0, 16.0	-1.46 (3.93)	-2.4	-10.2, 10.4	<=0.001***
Low Dose	59	5.35 (2.22)	3.60 (3.14)	2.9	0.0, 11.2	-1.75 (3.77)	-2.5	-10.2, 5.9	<=0.001***
High Dose	44	6.37 (2.25)	5.30 (4.08)	5.5	0.0, 16.0	-1.07 (4.14)	-1.6	-7.5, 10.4	0.0944
WEEK 6	93	5.80 (2.25)	3.68 (3.56)	3.2	0.0, 16.0	-2.12 (3.85)	-2.9	-10.6, 9.9	<=0.001***
Low Dose	54	5.48 (2.17)	3.35 (3.77)	2.9	0.0, 16.0	-2.13 (3.86)	-2.9	-10.2, 9.9	<=0.001***
High Dose	39	6.26 (2.31)	4.14 (3.23)	3.9	0.0, 12.5	-2.11 (3.89)	-2.9	-10.6, 6.8	0.0016**

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__1.4

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 (SD)	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 13	50	5.38 (2.15)	3.14 (3.53)	1.9	0.0, 13.4	-2.24 (3.99)	-3.1	-9.3, 8.1	<=0.001***
Low Dose	32	4.97 (2.11)	3.34 (3.88)	1.9	0.0, 13.4	-1.63 (4.30)	-2.6	-9.3, 8.1	0.0407*
High Dose	18	6.11 (2.07)	2.79 (2.88)	2.0	0.0, 9.3	-3.32 (3.18)	-3.3	-8.0, 4.0	<=0.001***
WEEK 26	59	6.12 (2.14)	2.38 (3.08)	1.1	0.0, 14.3	-3.74 (3.34)	-3.9	-10.6, 7.1	<=0.001***
Low Dose	35	5.68 (1.89)	1.97 (3.07)	0.0	0.0, 14.3	-3.71 (3.30)	-4.0	-10.2, 7.1	<=0.001***
High Dose	24	6.76 (2.35)	2.97 (3.05)	1.7	0.0, 9.8	-3.78 (3.46)	-2.8	-10.6, 5.5	<=0.001***
WEEK 39	56	5.93 (2.12)	2.55 (2.94)	1.7	0.0, 13.3	-3.38 (3.25)	-3.5	-9.8, 9.6	<=0.001***
Low Dose	35	5.43 (1.77)	2.51 (3.13)	1.7	0.0, 13.3	-2.91 (3.36)	-3.1	-9.8, 9.6	<=0.001***
High Dose	21	6.76 (2.44)	2.60 (2.66)	2.2	0.0, 7.3	-4.16 (2.97)	-4.4	-8.1, 2.9	<=0.001***
WEEK 52	44	6.02 (2.11)	1.99 (2.40)	0.8	0.0, 8.1	-4.02 (2.89)	-4.1	-11.2, 2.8	<=0.001***
Low Dose	26	5.63 (1.94)	2.24 (2.31)	1.5	0.0, 6.7	-3.39 (2.61)	-3.6	-10.2, 1.8	<=0.001***
High Dose	18	6.58 (2.26)	1.64 (2.54)	0.4	0.0, 8.1	-4.94 (3.10)	-4.7	-11.2, 2.8	<=0.001***

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__1.4

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 (SD)	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									
BASELINE	109		6.19 (3.22)	6.2	0.0, 12.6				
Low Dose	63		6.10 (3.06)	5.9	0.0, 12.6				
High Dose	46		6.32 (3.46)	6.4	0.0, 12.3				
WEEK 1	103	6.19 (3.14)	7.71 (4.22)	7.8	0.0, 16.0	1.52 (4.12)	1.3	-8.8, 10.2	<=0.001***
Low Dose	59	5.96 (2.94)	7.54 (4.03)	7.3	0.0, 16.0	1.58 (3.97)	1.4	-8.8, 10.2	0.0033**
High Dose	44	6.51 (3.39)	7.93 (4.50)	8.0	0.0, 16.0	1.43 (4.37)	1.3	-8.1, 8.0	0.0358*
WEEK 6	93	6.04 (3.24)	9.10 (4.70)	9.8	0.0, 16.0	3.06 (4.54)	3.4	-9.1, 12.7	<=0.001***
Low Dose	54	5.80 (2.91)	9.09 (4.65)	9.8	0.0, 16.0	3.29 (4.71)	4.1	-9.1, 12.7	<=0.001***
High Dose	39	6.38 (3.65)	9.12 (4.84)	9.9	0.0, 16.0	2.74 (4.35)	2.4	-6.4, 11.2	<=0.001***
WEEK 13	50	6.05 (3.10)	10.11 (4.70)	10.7	0.0, 16.0	4.05 (3.99)	4.1	-6.5, 11.0	<=0.001***
Low Dose	32	5.95 (2.87)	9.47 (4.82)	9.6	0.0, 16.0	3.52 (3.93)	3.4	-6.5, 11.0	<=0.001***
High Dose	18	6.23 (3.56)	11.23 (4.38)	11.7	0.9, 16.0	5.00 (4.04)	5.5	-4.7, 10.0	<=0.001***

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__1.4

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 (SD)	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 26	59	6.27 (3.30)	11.29 (4.41)	12.8	0.0, 16.0	5.03 (4.46)	5.6	-11.0, 12.7	<=0.001***
Low Dose	35	6.12 (3.07)	11.75 (3.96)	12.8	0.5, 16.0	5.63 (3.30)	5.7	-1.6, 11.5	<=0.001***
High Dose	24	6.48 (3.67)	10.63 (5.01)	12.3	0.0, 16.0	4.15 (5.73)	4.9	-11.0, 12.7	0.0017**
WEEK 39	56	6.63 (3.05)	11.06 (4.37)	12.0	0.6, 16.0	4.43 (4.48)	5.0	-10.6, 13.5	<=0.001***
Low Dose	35	6.36 (2.75)	10.57 (4.74)	11.8	0.6, 16.0	4.21 (4.66)	5.1	-10.6, 11.4	<=0.001***
High Dose	21	7.07 (3.53)	11.87 (3.63)	12.6	5.1, 16.0	4.80 (4.24)	4.3	-2.9, 13.5	<=0.001***
WEEK 52	44	6.59 (3.22)	11.62 (4.20)	13.4	1.3, 16.0	5.03 (4.14)	5.0	-2.9, 13.8	<=0.001***
Low Dose	26	6.41 (2.85)	11.55 (3.93)	12.8	1.3, 16.0	5.14 (3.91)	5.0	-2.9, 11.3	<=0.001***
High Dose	18	6.86 (3.77)	11.72 (4.69)	14.1	1.3, 16.0	4.87 (4.56)	4.8	-2.9, 13.8	<=0.001***
Average Daily Normalized 'On' Time With Non-Troublesome Dyskinesia									
BASELINE	109		2.95 (2.42)	2.7	0.0, 9.3				
Low Dose	63		3.03 (2.07)	2.9	0.0, 7.5				
High Dose	46		2.84 (2.84)	1.9	0.0, 9.3				

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__1.4

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 (SD)	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 1	103	2.94 (2.42)	2.79 (3.09)	1.7	0.0, 13.6	-0.15 (3.31)	0.0	-6.9, 13.6	0.6497
Low Dose	59	3.11 (2.07)	3.40 (3.20)	2.4	0.0, 13.6	0.29 (3.77)	0.0	-6.4, 13.6	0.5614
High Dose	44	2.71 (2.83)	1.98 (2.77)	1.0	0.0, 12.8	-0.73 (2.51)	0.0	-6.9, 5.8	0.0593
WEEK 6	93	3.01 (2.42)	2.75 (3.69)	1.2	0.0, 15.4	-0.26 (3.45)	-0.3	-7.8, 11.6	0.4726
Low Dose	54	3.10 (1.93)	2.90 (3.49)	1.7	0.0, 15.4	-0.19 (3.32)	-0.5	-6.7, 11.6	0.6711
High Dose	39	2.90 (2.99)	2.55 (3.99)	0.6	0.0, 14.6	-0.35 (3.66)	-0.3	-7.8, 9.6	0.5565
WEEK 13	50	3.31 (2.19)	2.27 (3.81)	0.7	0.0, 16.0	-1.04 (3.87)	-1.1	-6.9, 13.2	0.0636
Low Dose	32	3.40 (1.93)	2.48 (3.91)	1.0	0.0, 16.0	-0.91 (4.06)	-1.3	-6.5, 13.2	0.2137
High Dose	18	3.15 (2.66)	1.88 (3.72)	0.0	0.0, 14.4	-1.27 (3.63)	-0.7	-6.9, 7.2	0.1557
WEEK 26	59	2.70 (2.28)	1.89 (2.83)	0.8	0.0, 14.9	-0.81 (3.21)	-1.0	-6.8, 7.8	0.0577
Low Dose	35	2.97 (1.96)	1.89 (2.42)	1.0	0.0, 10.8	-1.08 (2.98)	-1.0	-6.7, 5.4	0.0397*
High Dose	24	2.30 (2.68)	1.88 (3.39)	0.7	0.0, 14.9	-0.42 (3.55)	-0.2	-6.8, 7.8	0.5680
WEEK 39	56	2.59 (2.20)	2.03 (3.44)	0.0	0.0, 15.4	-0.56 (3.79)	-0.1	-7.8, 15.4	0.2718
Low Dose	35	3.03 (1.96)	2.55 (3.93)	0.8	0.0, 15.4	-0.47 (4.11)	-0.7	-6.7, 15.4	0.5000
High Dose	21	1.87 (2.43)	1.16 (2.23)	0.0	0.0, 8.9	-0.71 (3.29)	0.0	-7.8, 5.8	0.3337

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__1.4

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 (SD)	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 52	44	2.72 (2.50)	2.08 (3.30)	0.6	0.0, 12.0	-0.65 (3.44)	-0.3	-7.3, 7.5	0.2194
Low Dose	26	3.05 (1.99)	2.07 (3.33)	0.7	0.0, 12.0	-0.98 (3.55)	-2.2	-6.7, 6.1	0.1730
High Dose	18	2.26 (3.09)	2.09 (3.33)	0.2	0.0, 10.6	-0.17 (3.30)	0.0	-7.3, 7.5	0.8336
Average Daily Normalized 'On' Time With Troublesome Dyskinesia									
BASELINE	109		1.12 (1.81)	0.0	0.0, 10.5				
Low Dose	63		1.57 (2.08)	0.8	0.0, 10.5				
High Dose	46		0.50 (1.10)	0.0	0.0, 4.9				
WEEK 1	103	1.08 (1.77)	1.17 (1.99)	0.0	0.0, 7.9	0.09 (2.03)	0.0	-6.0, 7.9	0.6507
Low Dose	59	1.58 (2.08)	1.46 (2.00)	0.6	0.0, 7.9	-0.12 (2.08)	0.0	-6.0, 7.9	0.6572
High Dose	44	0.41 (0.89)	0.78 (1.93)	0.0	0.0, 7.3	0.37 (1.96)	0.0	-3.7, 7.0	0.2108
WEEK 6	93	1.14 (1.88)	0.46 (1.25)	0.0	0.0, 5.8	-0.68 (1.66)	0.0	-7.2, 4.1	<=0.001***
Low Dose	54	1.63 (2.18)	0.66 (1.55)	0.0	0.0, 5.8	-0.97 (1.92)	-0.2	-7.2, 4.1	<=0.001***
High Dose	39	0.47 (1.06)	0.19 (0.57)	0.0	0.0, 2.6	-0.28 (1.13)	0.0	-4.9, 2.1	0.1308

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__1.4

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 (SD)	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 13	50	1.26 (1.77)	0.48 (1.47)	0.0	0.0, 8.0	-0.78 (1.95)	0.0	-7.2, 6.0	0.0071**
Low Dose	32	1.69 (1.90)	0.70 (1.79)	0.0	0.0, 8.0	-0.99 (2.26)	-0.6	-7.2, 6.0	0.0195*
High Dose	18	0.50 (1.23)	0.10 (0.29)	0.0	0.0, 1.1	-0.40 (1.19)	0.0	-4.9, 0.7	0.1689
WEEK 26	59	0.92 (1.47)	0.44 (1.95)	0.0	0.0, 12.1	-0.48 (2.13)	0.0	-5.1, 8.8	0.0907
Low Dose	35	1.23 (1.55)	0.39 (2.05)	0.0	0.0, 12.1	-0.84 (1.99)	-0.2	-5.1, 7.2	0.0173*
High Dose	24	0.46 (1.23)	0.52 (1.83)	0.0	0.0, 8.8	0.05 (2.26)	0.0	-4.9, 8.8	0.9071
WEEK 39	56	0.85 (1.32)	0.36 (0.84)	0.0	0.0, 3.8	-0.49 (1.28)	0.0	-5.1, 2.7	0.0058**
Low Dose	35	1.19 (1.45)	0.36 (0.89)	0.0	0.0, 3.8	-0.82 (1.28)	-0.2	-5.1, 0.5	<=0.001***
High Dose	21	0.30 (0.83)	0.37 (0.78)	0.0	0.0, 2.7	0.07 (1.09)	0.0	-3.6, 2.7	0.7769
WEEK 52	44	0.66 (1.18)	0.31 (0.94)	0.0	0.0, 5.3	-0.36 (1.51)	0.0	-5.1, 5.3	0.1254
Low Dose	26	0.91 (1.31)	0.14 (0.35)	0.0	0.0, 1.5	-0.77 (1.32)	0.0	-5.1, 0.7	0.0066**
High Dose	18	0.31 (0.90)	0.55 (1.40)	0.0	0.0, 5.3	0.24 (1.61)	0.0	-3.6, 5.3	0.5396

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__1.4

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 (SD)	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									
BASELINE	109		9.14 (2.31)	9.4	3.4, 14.5				
Low Dose	63		9.13 (2.47)	9.7	3.5, 14.2				
High Dose	46		9.16 (2.09)	9.1	3.4, 14.5				
WEEK 1	103	9.13 (2.31)	10.50 (3.66)	10.6	0.0, 16.0	1.37 (4.00)	1.8	-10.4, 11.3	<=0.001***
Low Dose	59	9.07 (2.46)	10.94 (3.24)	11.5	3.9, 16.0	1.87 (3.84)	2.5	-5.9, 11.3	<=0.001***
High Dose	44	9.22 (2.11)	9.91 (4.13)	9.9	0.0, 16.0	0.69 (4.15)	1.3	-10.4, 7.5	0.2733
WEEK 6	93	9.05 (2.33)	11.86 (3.57)	12.4	0.0, 16.0	2.80 (3.77)	3.3	-9.9, 10.6	<=0.001***
Low Dose	54	8.89 (2.43)	11.99 (3.83)	12.6	0.0, 16.0	3.10 (3.78)	3.6	-9.9, 10.5	<=0.001***
High Dose	39	9.28 (2.19)	11.67 (3.20)	12.0	3.5, 16.0	2.39 (3.77)	2.9	-6.8, 10.6	<=0.001***
WEEK 13	50	9.36 (2.21)	12.37 (3.75)	13.4	2.6, 16.0	3.01 (3.48)	3.4	-4.9, 9.3	<=0.001***
Low Dose	32	9.35 (2.36)	11.96 (4.12)	13.3	2.6, 16.0	2.61 (3.51)	3.0	-4.9, 9.3	<=0.001***
High Dose	18	9.39 (1.96)	13.11 (2.95)	13.7	6.0, 16.0	3.73 (3.41)	3.8	-4.7, 8.2	<=0.001***

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__1.4

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 (SD)	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 26	59	8.96 (2.39)	13.18 (3.54)	14.5	1.5, 16.0	4.22 (3.89)	4.7	-5.5, 12.5	<=0.001***
Low Dose	35	9.09 (2.56)	13.64 (3.74)	15.7	1.5, 16.0	4.55 (4.00)	4.8	-4.5, 12.5	<=0.001***
High Dose	24	8.78 (2.16)	12.51 (3.20)	13.7	6.2, 16.0	3.73 (3.76)	3.3	-5.5, 10.6	<=0.001***
WEEK 39	56	9.22 (2.28)	13.09 (3.07)	13.7	2.7, 16.0	3.87 (3.28)	3.8	-9.1, 9.8	<=0.001***
Low Dose	35	9.38 (2.29)	13.12 (3.18)	13.7	2.7, 16.0	3.74 (3.47)	3.2	-9.1, 9.8	<=0.001***
High Dose	21	8.94 (2.30)	13.03 (2.96)	13.8	6.6, 16.0	4.09 (3.00)	4.4	-2.9, 8.1	<=0.001***
WEEK 52	44	9.32 (2.24)	13.70 (2.51)	14.6	7.9, 16.0	4.38 (2.95)	4.3	-2.8, 11.2	<=0.001***
Low Dose	26	9.46 (2.33)	13.62 (2.34)	14.0	8.8, 16.0	4.16 (2.84)	3.9	-2.2, 10.2	<=0.001***
High Dose	18	9.11 (2.15)	13.81 (2.80)	15.3	7.9, 16.0	4.70 (3.16)	4.7	-2.8, 11.2	<=0.001***

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23　パーキンソン病日誌に基づく，早朝覚醒時状態の分布（FAS）：M15-741試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 1.5

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	238	129 (77.7)	29 (17.5)	5 (3.0)	3 (1.8)	166 (100)
Low Dose	129	68 (76.4)	15 (16.9)	3 (3.4)	3 (3.4)	89 (100)
High Dose	109	61 (79.2)	14 (18.2)	2 (2.6)	0	77 (100)
WEEK 1	231	49 (31.0)	79 (50.0)	20 (12.7)	10 (6.3)	158 (100)
Low Dose	125	25 (29.1)	38 (44.2)	16 (18.6)	7 (8.1)	86 (100)
High Dose	106	24 (33.3)	41 (56.9)	4 (5.6)	3 (4.2)	72 (100)
WEEK 6	213	54 (30.9)	104 (59.4)	14 (8.0)	3 (1.7)	175 (100)
Low Dose	116	23 (23.5)	61 (62.2)	11 (11.2)	3 (3.1)	98 (100)
High Dose	97	31 (40.3)	43 (55.8)	3 (3.9)	0	77 (100)
WEEK 13	122	27 (28.7)	59 (62.8)	7 (7.4)	1 (1.1)	94 (100)
Low Dose	68	15 (28.3)	32 (60.4)	6 (11.3)	0	53 (100)
High Dose	54	12 (29.3)	27 (65.9)	1 (2.4)	1 (2.4)	41 (100)
WEEK 26	139	20 (19.2)	71 (68.3)	12 (11.5)	1 (1.0)	104 (100)
Low Dose	75	10 (18.5)	38 (70.4)	6 (11.1)	0	54 (100)
High Dose	64	10 (20.0)	33 (66.0)	6 (12.0)	1 (2.0)	50 (100)
WEEK 39	126	22 (24.7)	61 (68.5)	6 (6.7)	0	89 (100)
Low Dose	71	12 (25.0)	33 (68.8)	3 (6.3)	0	48 (100)
High Dose	55	10 (24.4)	28 (68.3)	3 (7.3)	0	41 (100)
WEEK 52	113	23 (28.4)	51 (63.0)	5 (6.2)	2 (2.5)	81 (100)
Low Dose	63	16 (34.0)	27 (57.4)	2 (4.3)	2 (4.3)	47 (100)
High Dose	50	7 (20.6)	24 (70.6)	3 (8.8)	0	34 (100)

Program Source Code: [redacted]

表24　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）：M15-741試験

[redacted]20[redacted] 10:49 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 1.5.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	27	14 (93.3)	0	0	1 (6.7)	15 (100)
Low Dose	22	11 (91.7)	0	0	1 (8.3)	12 (100)
High Dose	5	3 (100)	0	0	0	3 (100)
WEEK 1	26	5 (29.4)	7 (41.2)	4 (23.5)	1 (5.9)	17 (100)
Low Dose	21	4 (28.6)	5 (35.7)	4 (28.6)	1 (7.1)	14 (100)
High Dose	5	1 (33.3)	2 (66.7)	0	0	3 (100)
WEEK 6	24	10 (52.6)	7 (36.8)	2 (10.5)	0	19 (100)
Low Dose	19	7 (43.8)	7 (43.8)	2 (12.5)	0	16 (100)
High Dose	5	3 (100)	0	0	0	3 (100)
WEEK 13	10	5 (55.6)	4 (44.4)	0	0	9 (100)
Low Dose	10	5 (55.6)	4 (44.4)	0	0	9 (100)
High Dose	0	0	0	0	0	0
WEEK 26	15	3 (33.3)	4 (44.4)	2 (22.2)	0	9 (100)
Low Dose	12	3 (33.3)	4 (44.4)	2 (22.2)	0	9 (100)
High Dose	3	0	0	0	0	0
WEEK 39	14	3 (37.5)	5 (62.5)	0	0	8 (100)
Low Dose	11	3 (37.5)	5 (62.5)	0	0	8 (100)
High Dose	3	0	0	0	0	0
WEEK 52	12	6 (66.7)	3 (33.3)	0	0	9 (100)
Low Dose	9	4 (57.1)	3 (42.9)	0	0	7 (100)
High Dose	3	2 (100)	0	0	0	2 (100)

Program Source Code: [redacted]

表25　MDS-UPDRSスコア（FAS）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 (SD)	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	244		50.4 (18.89)	50.0	13, 117				
Low dose	132		49.9 (19.55)	46.5	13, 117				
High dose	112		51.0 (18.15)	51.0	14, 109				
DAY 2	222	51.0 (18.94)	45.9 (20.28)	44.0	4, 100	-5.0 (12.19)	-4.0	-42, 38	<=0.001***
Low dose	121	49.9 (19.43)	43.9 (18.94)	42.0	5, 100	-6.0 (11.67)	-4.0	-42, 28	<=0.001***
High dose	101	52.2 (18.35)	48.3 (21.62)	46.0	4, 100	-3.9 (12.76)	-4.0	-36, 38	0.0028**
WEEK 1	224	50.4 (19.14)	46.4 (22.58)	43.0	3, 114	-4.0 (16.62)	-4.0	-45, 68	<=0.001***
Low dose	119	49.6 (19.70)	45.2 (21.66)	42.0	3, 109	-4.3 (15.85)	-3.0	-45, 68	0.0034**
High dose	105	51.4 (18.53)	47.8 (23.61)	43.0	10, 114	-3.6 (17.53)	-6.0	-41, 51	0.0378*
WEEK 2	211	50.2 (18.40)	47.5 (23.46)	44.0	2, 114	-2.6 (18.19)	-5.0	-39, 60	0.0367*
Low dose	118	50.0 (19.16)	48.6 (23.95)	44.0	2, 111	-1.4 (18.47)	-5.5	-35, 60	0.4011
High dose	93	50.4 (17.47)	46.2 (22.88)	44.0	6, 114	-4.2 (17.81)	-5.0	-39, 49	0.0268*
WEEK 3	203	49.9 (18.72)	46.8 (22.87)	45.0	1, 135	-3.2 (18.50)	-4.0	-50, 94	0.0156*
Low dose	108	49.2 (18.82)	47.2 (23.93)	43.0	1, 135	-2.0 (18.01)	-3.0	-39, 94	0.2531
High dose	95	50.7 (18.66)	46.2 (21.73)	45.0	7, 104	-4.5 (19.06)	-5.0	-50, 58	0.0234*
WEEK 4	201	49.8 (18.65)	45.3 (22.94)	41.0	5, 107	-4.5 (18.42)	-6.0	-53, 63	<=0.001***
Low dose	109	48.9 (18.69)	47.2 (24.53)	40.0	5, 107	-1.7 (19.35)	-4.0	-43, 63	0.3699
High dose	92	50.9 (18.65)	42.9 (20.80)	41.0	6, 106	-7.9 (16.73)	-8.0	-53, 34	<=0.001***

&: 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

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 (SD)	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 6	193	50.2 (18.90)	46.5 (22.63)	43.0	3, 118	-3.7 (19.60)	-6.0	-59, 75	0.0099**
Low dose	105	49.5 (18.87)	48.4 (25.11)	43.0	5, 118	-1.0 (21.92)	-5.0	-39, 75	0.6282
High dose	88	51.1 (19.00)	44.2 (19.14)	43.0	3, 93	-6.8 (15.98)	-6.0	-59, 44	<=0.001***
WEEK 13	162	50.0 (18.48)	44.7 (22.63)	39.0	10, 141	-5.3 (19.94)	-6.0	-58, 66	<=0.001***
Low dose	92	48.8 (17.30)	45.6 (23.90)	41.0	11, 141	-3.2 (21.10)	-5.0	-51, 66	0.1470
High dose	70	51.6 (19.94)	43.5 (20.96)	39.0	10, 103	-8.1 (18.09)	-8.0	-58, 34	<=0.001***
WEEK 26	139	50.4 (18.11)	47.3 (21.75)	45.0	7, 122	-3.1 (17.34)	-2.0	-55, 39	0.0364*
Low dose	76	49.2 (17.36)	47.0 (23.65)	44.0	7, 122	-2.2 (16.90)	-2.0	-40, 39	0.2550
High dose	63	51.8 (19.00)	47.7 (19.39)	47.0	11, 95	-4.2 (17.93)	-2.0	-55, 24	0.0695
WEEK 39	125	49.9 (18.23)	49.0 (24.28)	47.0	11, 132	-0.9 (20.16)	-1.0	-58, 60	0.6010
Low dose	73	49.1 (17.49)	48.0 (25.69)	46.0	15, 132	-1.1 (19.34)	-3.0	-42, 60	0.6212
High dose	52	51.1 (19.33)	50.4 (22.33)	47.5	11, 98	-0.7 (21.45)	2.0	-58, 55	0.8159
WEEK 52	120	50.2 (18.32)	48.3 (23.19)	47.0	6, 117	-1.9 (19.58)	-2.5	-50, 47	0.2816
Low dose	68	48.0 (17.18)	47.5 (23.23)	46.0	8, 117	-0.6 (19.33)	-1.5	-50, 47	0.8074
High dose	52	53.1 (19.51)	49.3 (23.31)	47.0	6, 105	-3.7 (19.96)	-3.5	-49, 47	0.1858

&: 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

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 (SD)	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	244		11.1 (6.39)	10.0	0, 37				
Low dose	132		11.0 (6.66)	10.0	0, 31				
High dose	112		11.3 (6.09)	10.0	1, 37				
DAY 2	222	11.2 (6.41)	9.0 (5.86)	8.0	0, 32	-2.3 (4.00)	-1.0	-16, 6	<=0.001***
Low dose	121	11.1 (6.69)	8.5 (5.91)	7.0	0, 32	-2.6 (4.27)	-2.0	-16, 6	<=0.001***
High dose	101	11.4 (6.08)	9.6 (5.76)	9.0	0, 27	-1.9 (3.62)	-1.0	-14, 6	<=0.001***
WEEK 1	225	11.3 (6.48)	8.3 (5.73)	7.0	0, 32	-3.0 (5.62)	-3.0	-29, 18	<=0.001***
Low dose	120	11.2 (6.73)	8.5 (6.05)	7.0	0, 30	-2.6 (5.74)	-2.0	-18, 18	<=0.001***
High dose	105	11.5 (6.20)	8.0 (5.34)	7.0	0, 32	-3.4 (5.48)	-3.0	-29, 11	<=0.001***
WEEK 2	212	11.1 (6.08)	8.8 (5.71)	8.0	0, 27	-2.3 (5.20)	-2.0	-18, 11	<=0.001***
Low dose	118	10.9 (6.52)	8.6 (5.85)	8.0	0, 27	-2.3 (5.42)	-2.0	-18, 11	<=0.001***
High dose	94	11.2 (5.50)	9.0 (5.54)	8.0	0, 26	-2.2 (4.95)	-2.0	-15, 8	<=0.001***
WEEK 3	203	11.1 (6.31)	8.5 (5.58)	7.0	0, 31	-2.6 (5.77)	-2.0	-22, 10	<=0.001***
Low dose	108	11.2 (6.49)	8.9 (6.18)	7.5	0, 31	-2.3 (5.63)	-2.0	-16, 10	<=0.001***
High dose	95	11.1 (6.14)	8.1 (4.82)	7.0	0, 23	-2.9 (5.94)	-2.0	-22, 9	<=0.001***
WEEK 4	203	11.1 (6.31)	8.8 (5.81)	8.0	0, 36	-2.3 (5.88)	-2.0	-21, 27	<=0.001***
Low dose	110	11.0 (6.53)	9.3 (6.71)	8.0	0, 36	-1.7 (6.24)	-2.0	-16, 27	0.0058**
High dose	93	11.2 (6.07)	8.1 (4.47)	8.0	0, 22	-3.1 (5.37)	-2.0	-21, 9	<=0.001***

&: 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

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 (SD)	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 &
MDS-UPDRS Part I Score									
WEEK 6	193	11.1 (6.20)	9.8 (6.42)	9.0	0, 39	-1.4 (6.21)	-2.0	-17, 30	0.0026**
Low dose	105	11.3 (6.52)	10.3 (7.20)	9.0	1, 39	-1.0 (7.07)	-2.0	-17, 30	0.1580
High dose	88	10.9 (5.83)	9.1 (5.30)	9.0	0, 23	-1.8 (5.00)	-2.0	-16, 15	<=0.001***
WEEK 13	170	11.4 (6.24)	9.7 (5.77)	8.0	0, 30	-1.7 (5.69)	-2.0	-18, 16	<=0.001***
Low dose	94	11.3 (6.46)	9.5 (5.68)	8.0	0, 30	-1.8 (5.77)	-2.0	-18, 14	0.0034**
High dose	76	11.5 (5.99)	9.8 (5.92)	8.0	1, 28	-1.7 (5.62)	-2.0	-15, 16	0.0103*
WEEK 26	148	11.6 (6.26)	10.7 (6.24)	10.0	1, 29	-0.9 (5.42)	-1.0	-21, 15	0.0354*
Low dose	80	11.2 (6.17)	10.1 (6.08)	9.0	1, 25	-1.1 (4.99)	-1.0	-12, 15	0.0550
High dose	68	12.2 (6.36)	11.4 (6.39)	10.5	1, 29	-0.8 (5.92)	0.0	-21, 9	0.2813
WEEK 39	130	11.2 (6.23)	11.0 (6.33)	10.0	0, 26	-0.2 (5.84)	-1.0	-14, 14	0.6533
Low dose	73	11.0 (6.25)	10.6 (6.49)	9.0	0, 26	-0.4 (5.83)	-1.0	-14, 14	0.5623
High dose	57	11.6 (6.24)	11.6 (6.13)	11.0	2, 25	-0.0 (5.91)	-1.0	-12, 13	0.9822
WEEK 52	120	11.3 (6.39)	10.5 (5.87)	10.0	0, 27	-0.8 (5.87)	-1.0	-17, 14	0.1379
Low dose	68	10.8 (6.35)	10.3 (5.52)	10.0	0, 27	-0.5 (5.34)	-1.0	-13, 11	0.4837
High dose	52	12.0 (6.44)	10.8 (6.35)	10.0	2, 25	-1.3 (6.52)	-1.0	-17, 14	0.1728

&: 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

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 (SD)	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									
BASELINE	244		15.8 (7.38)	15.0	1, 37				
Low dose	132		15.2 (7.48)	14.5	1, 36				
High dose	112		16.4 (7.23)	16.0	2, 37				
DAY 2	222	15.9 (7.52)	13.9 (7.62)	13.0	0, 35	-2.1 (4.47)	-1.0	-19, 12	<=0.001***
Low dose	121	15.1 (7.62)	12.4 (7.12)	11.0	0, 31	-2.7 (4.54)	-1.0	-15, 6	<=0.001***
High dose	101	16.9 (7.33)	15.6 (7.86)	15.0	0, 35	-1.3 (4.26)	-1.0	-19, 12	0.0038**
WEEK 1	225	15.8 (7.39)	12.0 (7.32)	11.0	0, 34	-3.8 (5.39)	-4.0	-18, 14	<=0.001***
Low dose	120	15.0 (7.42)	11.4 (7.16)	10.0	0, 30	-3.7 (4.94)	-3.0	-17, 8	<=0.001***
High dose	105	16.7 (7.29)	12.8 (7.46)	12.0	1, 34	-3.9 (5.88)	-4.0	-18, 14	<=0.001***
WEEK 2	212	15.8 (7.21)	12.5 (7.69)	11.0	0, 37	-3.3 (6.26)	-4.0	-19, 18	<=0.001***
Low dose	118	15.4 (7.35)	12.1 (7.67)	11.0	0, 33	-3.3 (6.03)	-3.5	-19, 16	<=0.001***
High dose	94	16.4 (7.02)	13.1 (7.73)	12.0	0, 37	-3.4 (6.56)	-4.0	-18, 18	<=0.001***
WEEK 3	203	15.9 (7.30)	12.2 (7.47)	12.0	0, 37	-3.7 (6.21)	-3.0	-23, 12	<=0.001***
Low dose	108	15.2 (7.18)	11.7 (7.74)	11.0	0, 37	-3.5 (5.81)	-3.0	-19, 12	<=0.001***
High dose	95	16.6 (7.39)	12.8 (7.15)	12.0	0, 34	-3.8 (6.66)	-2.0	-23, 12	<=0.001***
WEEK 4	203	15.8 (7.26)	12.2 (6.92)	11.0	0, 31	-3.7 (5.98)	-4.0	-29, 12	<=0.001***
Low dose	110	15.2 (7.18)	12.5 (7.40)	11.5	0, 31	-2.7 (5.47)	-3.0	-14, 12	<=0.001***
High dose	93	16.6 (7.31)	11.8 (6.33)	11.0	1, 28	-4.9 (6.36)	-4.0	-29, 7	<=0.001***

&: 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

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 (SD)	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 6	193	15.8 (7.15)	12.5 (7.42)	12.0	0, 32	-3.3 (6.41)	-3.0	-22, 17	<=0.001***
Low dose	105	15.1 (7.01)	12.6 (8.00)	12.0	0, 32	-2.5 (6.56)	-3.0	-16, 17	<=0.001***
High dose	88	16.5 (7.29)	12.3 (6.72)	12.0	0, 31	-4.2 (6.12)	-3.0	-22, 10	<=0.001***
WEEK 13	170	15.8 (7.06)	12.1 (7.06)	11.0	0, 35	-3.7 (6.50)	-3.0	-24, 15	<=0.001***
Low dose	94	15.1 (6.89)	11.9 (7.40)	11.0	0, 35	-3.2 (6.41)	-3.5	-19, 15	<=0.001***
High dose	76	16.6 (7.23)	12.3 (6.67)	11.0	2, 31	-4.3 (6.60)	-3.0	-24, 7	<=0.001***
WEEK 26	148	15.9 (7.07)	12.7 (7.55)	12.0	0, 38	-3.2 (6.65)	-3.0	-21, 21	<=0.001***
Low dose	80	15.0 (6.89)	12.4 (7.85)	10.5	0, 38	-2.6 (6.24)	-3.0	-15, 21	<=0.001***
High dose	68	17.0 (7.19)	13.0 (7.22)	13.0	0, 33	-3.9 (7.08)	-3.0	-21, 10	<=0.001***
WEEK 39	130	15.3 (6.76)	12.2 (7.60)	11.0	0, 38	-3.1 (6.70)	-2.0	-21, 19	<=0.001***
Low dose	73	14.6 (6.73)	12.1 (8.36)	11.0	1, 38	-2.5 (6.46)	-3.0	-16, 19	0.0014**
High dose	57	16.1 (6.76)	12.2 (6.58)	12.0	0, 27	-3.9 (6.98)	-2.0	-21, 8	<=0.001***
WEEK 52	120	15.3 (7.03)	12.3 (7.47)	12.0	0, 35	-3.0 (7.17)	-3.0	-19, 18	<=0.001***
Low dose	68	14.1 (6.48)	12.3 (7.93)	11.0	0, 35	-1.8 (6.87)	-2.0	-14, 18	0.0378*
High dose	52	16.8 (7.47)	12.2 (6.88)	12.0	1, 29	-4.6 (7.31)	-4.5	-19, 13	<=0.001***

&: 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

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 (SD)	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	244		23.5 (11.47)	23.0	2, 63				
Low dose	132		23.7 (11.85)	22.0	2, 63				
High dose	112		23.2 (11.05)	23.0	3, 55				
DAY 2	222	23.8 (11.44)	23.1 (12.96)	21.0	1, 66	-0.7 (8.78)	-1.0	-24, 30	0.2315
Low dose	121	23.7 (11.69)	23.0 (12.25)	21.0	1, 66	-0.6 (8.43)	-1.0	-24, 30	0.4080
High dose	101	23.9 (11.18)	23.1 (13.83)	21.0	1, 59	-0.8 (9.23)	-1.0	-20, 28	0.3904
WEEK 1	224	23.3 (11.62)	26.1 (14.93)	25.0	0, 76	2.8 (11.31)	1.0	-36, 67	<=0.001***
Low dose	119	23.4 (11.90)	25.4 (14.19)	24.0	0, 76	1.9 (11.53)	1.0	-36, 67	0.0719
High dose	105	23.2 (11.35)	27.0 (15.76)	26.0	1, 70	3.7 (11.04)	2.0	-17, 37	<=0.001***
WEEK 2	211	23.3 (11.41)	26.2 (14.91)	23.0	0, 77	2.9 (12.18)	2.0	-29, 68	<=0.001***
Low dose	118	23.7 (11.66)	27.9 (15.17)	24.0	0, 77	4.2 (12.98)	2.5	-29, 68	<=0.001***
High dose	93	22.8 (11.12)	24.1 (14.38)	23.0	1, 68	1.3 (10.94)	0.0	-24, 35	0.2401
WEEK 3	203	22.9 (11.06)	26.0 (14.64)	24.0	0, 84	3.1 (12.02)	2.0	-24, 75	<=0.001***
Low dose	108	22.9 (11.03)	26.7 (14.66)	24.0	0, 84	3.8 (11.94)	2.0	-20, 75	0.0013**
High dose	95	23.0 (11.15)	25.3 (14.67)	24.0	3, 66	2.3 (12.13)	1.0	-24, 40	0.0707
WEEK 4	200	23.0 (10.97)	24.4 (15.00)	22.0	0, 80	1.5 (12.05)	0.0	-36, 53	0.0891
Low dose	108	22.7 (10.84)	25.5 (15.35)	22.5	0, 80	2.8 (12.80)	1.0	-23, 53	0.0251*
High dose	92	23.2 (11.18)	23.1 (14.55)	21.0	1, 75	-0.1 (10.97)	0.0	-36, 48	0.9170

&: 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

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 (SD)	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									
WEEK 6	193	23.3 (11.13)	24.3 (14.12)	23.0	0, 74	0.9 (12.07)	0.0	-36, 60	0.2764
Low dose	105	23.0 (11.12)	25.5 (15.53)	23.0	0, 74	2.4 (13.69)	0.0	-36, 60	0.0719
High dose	88	23.6 (11.20)	22.8 (12.16)	22.5	0, 55	-0.8 (9.57)	0.0	-31, 28	0.4242
WEEK 13	159	22.9 (10.79)	23.0 (14.51)	22.0	0, 82	0.1 (13.01)	0.0	-47, 37	0.9274
Low dose	90	22.5 (9.92)	24.0 (14.61)	23.5	0, 82	1.5 (13.73)	2.0	-38, 37	0.2998
High dose	69	23.4 (11.88)	21.7 (14.39)	20.0	0, 60	-1.8 (11.86)	-1.0	-47, 33	0.2241
WEEK 26	139	22.9 (10.93)	23.7 (14.63)	22.0	0, 83	0.8 (12.19)	0.0	-34, 39	0.4403
Low dose	76	23.4 (10.99)	24.7 (16.04)	22.0	0, 83	1.4 (12.64)	-0.5	-34, 39	0.3483
High dose	63	22.4 (10.91)	22.5 (12.74)	23.0	0, 59	0.1 (11.70)	0.0	-30, 27	0.9380
WEEK 39	125	23.4 (11.23)	25.6 (15.57)	23.0	1, 76	2.1 (13.00)	1.0	-28, 47	0.0693
Low dose	73	23.6 (11.20)	25.4 (16.49)	22.0	4, 76	1.8 (12.84)	0.0	-28, 47	0.2399
High dose	52	23.3 (11.38)	25.9 (14.34)	25.0	1, 63	2.6 (13.34)	2.0	-28, 40	0.1622
WEEK 52	120	23.6 (10.92)	25.5 (15.27)	23.0	1, 66	1.8 (12.86)	1.5	-35, 42	0.1193
Low dose	68	23.1 (11.25)	24.8 (15.64)	22.0	1, 66	1.6 (12.47)	1.5	-35, 35	0.2801
High dose	52	24.3 (10.55)	26.3 (14.87)	26.0	2, 62	2.1 (13.46)	1.5	-26, 42	0.2667

&: 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

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 (SD)	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 &
MDS-UPDRS Part IV Score									
BASELINE	244		9.5 (3.17)	9.0	0, 20				
Low dose	132		9.6 (3.21)	9.0	0, 20				
High dose	112		9.5 (3.13)	9.0	1, 18				
DAY 2	218	9.6 (3.18)	8.2 (4.01)	8.0	0, 20	-1.5 (3.52)	-1.0	-12, 9	<=0.001***
Low dose	118	9.7 (3.27)	8.0 (4.07)	8.0	0, 20	-1.7 (3.56)	-1.0	-12, 9	<=0.001***
High dose	100	9.5 (3.09)	8.4 (3.94)	8.0	0, 19	-1.1 (3.46)	0.0	-11, 8	0.0018**
WEEK 1	221	9.6 (3.21)	7.9 (4.13)	8.0	0, 19	-1.7 (3.97)	-2.0	-17, 10	<=0.001***
Low dose	117	9.6 (3.26)	7.9 (4.12)	8.0	0, 18	-1.7 (3.86)	-2.0	-17, 9	<=0.001***
High dose	104	9.6 (3.16)	7.9 (4.17)	8.0	0, 19	-1.7 (4.11)	-2.0	-14, 10	<=0.001***
WEEK 2	208	9.7 (3.15)	7.3 (3.92)	7.0	0, 17	-2.4 (3.57)	-2.0	-13, 6	<=0.001***
Low dose	116	9.7 (3.19)	7.3 (4.01)	7.0	0, 17	-2.5 (3.57)	-2.0	-11, 6	<=0.001***
High dose	92	9.6 (3.13)	7.3 (3.83)	7.0	0, 16	-2.3 (3.58)	-2.0	-13, 6	<=0.001***
WEEK 3	198	9.5 (3.26)	7.3 (4.03)	7.0	0, 19	-2.2 (3.90)	-2.0	-15, 8	<=0.001***
Low dose	103	9.6 (3.31)	7.4 (4.35)	7.0	0, 19	-2.2 (4.09)	-3.0	-11, 8	<=0.001***
High dose	95	9.5 (3.21)	7.2 (3.67)	7.0	0, 16	-2.3 (3.72)	-2.0	-15, 5	<=0.001***
WEEK 4	200	9.5 (3.23)	6.7 (4.17)	7.0	0, 21	-2.8 (3.73)	-3.0	-15, 7	<=0.001***
Low dose	107	9.6 (3.31)	6.6 (4.50)	7.0	0, 21	-3.0 (3.69)	-3.0	-14, 5	<=0.001***
High dose	93	9.5 (3.15)	6.8 (3.78)	7.0	0, 16	-2.7 (3.78)	-3.0	-15, 7	<=0.001***

&: 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

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 (SD)	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									
WEEK 6	190	9.5 (3.25)	6.8 (4.05)	7.0	0, 17	-2.7 (3.61)	-3.0	-15, 5	<=0.001***
Low dose	102	9.5 (3.35)	7.0 (4.13)	7.0	0, 17	-2.5 (3.37)	-3.0	-9, 5	<=0.001***
High dose	88	9.4 (3.15)	6.6 (3.97)	6.0	0, 17	-2.9 (3.88)	-3.0	-15, 5	<=0.001***
WEEK 13	166	9.5 (3.20)	6.0 (3.85)	6.0	0, 15	-3.5 (3.74)	-3.0	-15, 10	<=0.001***
Low dose	90	9.3 (3.29)	5.6 (3.87)	5.5	0, 15	-3.7 (3.46)	-4.0	-12, 10	<=0.001***
High dose	76	9.7 (3.09)	6.5 (3.78)	6.0	0, 14	-3.2 (4.06)	-3.0	-15, 6	<=0.001***
WEEK 26	146	9.5 (3.29)	6.0 (3.90)	6.0	0, 16	-3.5 (3.76)	-3.0	-15, 6	<=0.001***
Low dose	78	9.3 (3.43)	5.8 (3.87)	6.0	0, 16	-3.5 (3.41)	-3.0	-14, 5	<=0.001***
High dose	68	9.7 (3.13)	6.1 (3.94)	6.0	0, 14	-3.5 (4.15)	-3.0	-15, 6	<=0.001***
WEEK 39	128	9.4 (3.37)	6.0 (4.03)	6.0	0, 17	-3.4 (4.09)	-3.0	-15, 6	<=0.001***
Low dose	72	9.4 (3.54)	6.0 (4.08)	6.0	0, 17	-3.5 (4.07)	-3.5	-14, 6	<=0.001***
High dose	56	9.4 (3.18)	6.0 (4.00)	6.0	0, 17	-3.4 (4.15)	-3.0	-15, 5	<=0.001***
WEEK 52	120	9.3 (3.31)	5.4 (3.94)	5.0	0, 21	-3.8 (4.29)	-3.5	-17, 13	<=0.001***
Low dose	68	9.4 (3.53)	5.5 (3.53)	6.0	0, 16	-3.9 (3.75)	-4.0	-17, 6	<=0.001***
High dose	52	9.1 (3.02)	5.4 (4.45)	5.0	0, 21	-3.7 (4.94)	-3.0	-15, 13	<=0.001***

&: 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26　MDS-UPDRSスコア（FAS，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 (SD)	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 &
MDS-UPDRS Total Score of Parts I-III									
BASELINE	27		41.0 (17.88)	37.0	13, 83				
Low dose	22		37.9 (16.32)	37.0	13, 68				
High dose	5		54.6 (19.92)	47.0	35, 83				
DAY 2	26	41.0 (18.23)	37.5 (21.58)	30.5	6, 91	-3.5 (11.09)	-3.5	-37, 24	0.1163
Low dose	21	37.8 (16.70)	32.1 (16.25)	28.0	6, 63	-5.6 (10.19)	-5.0	-37, 13	0.0200*
High dose	5	54.6 (19.92)	59.8 (28.58)	51.0	30, 91	5.2 (11.48)	4.0	-5, 24	0.3683
WEEK 1	25	42.2 (17.67)	47.0 (24.91)	42.0	18, 114	4.8 (20.22)	-2.0	-18, 68	0.2474
Low dose	20	39.1 (16.12)	42.1 (21.08)	40.0	18, 109	3.0 (17.47)	-1.0	-17, 68	0.4457
High dose	5	54.6 (19.92)	66.4 (31.98)	65.0	31, 114	11.8 (30.43)	-2.0	-18, 47	0.4349
WEEK 2	24	43.4 (17.13)	50.0 (26.57)	43.5	19, 114	6.6 (21.88)	-1.5	-25, 60	0.1532
Low dose	19	40.4 (15.58)	47.2 (24.72)	40.0	19, 101	6.8 (19.79)	-1.0	-19, 60	0.1538
High dose	5	54.6 (19.92)	60.6 (33.67)	58.0	30, 114	6.0 (31.47)	-11.0	-25, 47	0.6925
WEEK 3	21	41.3 (17.01)	50.2 (28.13)	44.0	14, 135	8.9 (24.14)	5.0	-28, 94	0.1065
Low dose	18	38.7 (15.12)	50.7 (30.40)	44.5	14, 135	12.0 (24.17)	9.0	-18, 94	0.0504
High dose	3	57.0 (22.72)	47.3 (6.66)	44.0	43, 55	-9.7 (16.07)	-3.0	-28, 2	0.4069
WEEK 4	20	41.5 (17.42)	50.6 (25.42)	46.5	16, 106	9.1 (20.05)	5.5	-27, 56	0.0571
Low dose	17	38.8 (15.58)	52.1 (26.98)	50.0	16, 106	13.3 (18.30)	12.0	-14, 56	0.0084**
High dose	3	57.0 (22.72)	42.0 (13.53)	41.0	29, 56	-15.0 (10.82)	-12.0	-27, -6	0.1383

&: 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 (SD)	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 6	18	40.1 (17.19)	48.2 (27.44)	43.0	12, 113	8.1 (25.37)	2.5	-45, 72	0.1929
Low dose	15	36.7 (14.56)	50.7 (29.50)	47.0	12, 113	13.9 (22.37)	11.0	-15, 72	0.0302*
High dose	3	57.0 (22.72)	36.0 (6.24)	38.0	29, 41	-21.0 (21.00)	-12.0	-45, -6	0.2254
WEEK 13	17	41.2 (17.03)	51.9 (24.01)	56.0	13, 96	10.6 (23.19)	17.0	-32, 66	0.0766
Low dose	14	37.9 (14.42)	53.8 (25.22)	59.0	13, 96	15.9 (20.59)	18.0	-19, 66	0.0126*
High dose	3	57.0 (22.72)	43.0 (18.36)	51.0	22, 56	-14.0 (20.95)	-19.0	-32, 9	0.3667
WEEK 26	15	42.6 (17.59)	46.8 (22.02)	42.0	14, 84	4.2 (17.96)	-1.0	-28, 39	0.3803
Low dose	12	39.0 (15.14)	48.5 (23.68)	43.5	14, 84	9.5 (15.39)	9.5	-10, 39	0.0558
High dose	3	57.0 (22.72)	40.0 (15.00)	40.0	25, 55	-17.0 (10.54)	-16.0	-28, -7	0.1077
WEEK 39	12	39.3 (16.95)	42.7 (23.13)	41.5	17, 95	3.3 (21.23)	-1.0	-20, 54	0.5974
Low dose	9	33.4 (10.48)	41.7 (24.43)	40.0	17, 95	8.2 (21.86)	-1.0	-14, 54	0.2919
High dose	3	57.0 (22.72)	45.7 (23.18)	49.0	21, 67	-11.3 (11.72)	-16.0	-20, 2	0.2359
WEEK 52	12	39.3 (16.95)	42.0 (19.02)	46.0	15, 71	2.7 (16.97)	-2.5	-26, 30	0.5970
Low dose	9	33.4 (10.48)	41.4 (17.31)	47.0	17, 66	8.0 (15.22)	0.0	-7, 30	0.1534
High dose	3	57.0 (22.72)	43.7 (28.02)	45.0	15, 71	-13.3 (12.06)	-12.0	-26, -2	0.1955

&: 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 (SD)	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 &
MDS-UPDRS Part I Score									
BASELINE	27		7.9 (4.53)	7.0	2, 19				
Low dose	22		7.3 (4.62)	6.0	2, 19				
High dose	5		10.4 (3.36)	9.0	7, 14				
DAY 2	26	8.0 (4.55)	7.0 (3.89)	6.5	0, 14	-1.0 (2.16)	-1.0	-7, 2	0.0217*
Low dose	21	7.4 (4.68)	6.5 (4.09)	6.0	0, 14	-1.0 (2.18)	-1.0	-7, 2	0.0589
High dose	5	10.4 (3.36)	9.0 (2.12)	9.0	7, 12	-1.4 (2.30)	-1.0	-5, 1	0.2455
WEEK 1	25	8.2 (4.47)	8.4 (5.70)	7.0	1, 22	0.1 (3.76)	-1.0	-4, 11	0.8744
Low dose	20	7.7 (4.62)	7.6 (5.51)	7.0	1, 22	-0.2 (3.23)	-0.5	-4, 9	0.8378
High dose	5	10.4 (3.36)	11.6 (5.86)	10.0	6, 20	1.2 (5.76)	-1.0	-4, 11	0.6657
WEEK 2	24	7.9 (4.53)	7.5 (4.32)	7.0	1, 19	-0.4 (2.99)	0.0	-7, 4	0.5018
Low dose	19	7.2 (4.64)	7.2 (4.67)	6.0	1, 19	0.0 (2.54)	0.0	-4, 4	>0.999
High dose	5	10.4 (3.36)	8.4 (2.79)	7.0	6, 13	-2.0 (4.30)	-2.0	-7, 4	0.3572
WEEK 3	21	7.3 (4.31)	9.0 (6.16)	7.0	1, 23	1.7 (3.62)	2.0	-4, 8	0.0479*
Low dose	18	6.9 (4.36)	8.8 (6.53)	6.5	1, 23	1.9 (3.80)	2.0	-4, 8	0.0442*
High dose	3	9.7 (3.79)	9.7 (4.04)	9.0	6, 14	0.0 (2.00)	0.0	-2, 2	>0.999
WEEK 4	20	7.5 (4.31)	8.9 (6.93)	7.0	1, 29	1.4 (5.03)	0.0	-8, 17	0.2447
Low dose	17	7.1 (4.39)	9.4 (7.43)	8.0	1, 29	2.2 (4.76)	1.0	-3, 17	0.0709
High dose	3	9.7 (3.79)	6.0 (0.00)	6.0	6, 6	-3.7 (3.79)	-2.0	-8, -1	0.2354

&: 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 (SD)	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									
WEEK 6	18	7.7 (4.47)	9.0 (6.68)	7.5	1, 25	1.3 (5.28)	0.0	-8, 10	0.3188
Low dose	15	7.3 (4.61)	9.9 (6.92)	9.0	1, 25	2.5 (4.58)	1.0	-4, 10	0.0503
High dose	3	9.7 (3.79)	4.7 (3.21)	6.0	1, 7	-5.0 (4.36)	-7.0	-8, 0	0.1853
WEEK 13	17	7.9 (4.51)	9.2 (5.95)	7.0	0, 20	1.2 (5.43)	1.0	-10, 14	0.3619
Low dose	14	7.6 (4.69)	10.0 (6.21)	8.0	0, 20	2.4 (4.78)	2.0	-7, 14	0.0799
High dose	3	9.7 (3.79)	5.3 (2.31)	4.0	4, 8	-4.3 (5.51)	-4.0	-10, 1	0.3061
WEEK 26	15	8.3 (4.62)	7.9 (5.33)	8.0	1, 23	-0.4 (3.25)	0.0	-6, 4	0.6406
Low dose	12	7.9 (4.89)	8.3 (5.58)	8.5	1, 23	0.4 (3.00)	1.0	-6, 4	0.6397
High dose	3	9.7 (3.79)	6.0 (4.58)	5.0	2, 11	-3.7 (2.08)	-3.0	-6, -2	0.0927
WEEK 39	12	7.1 (3.73)	6.0 (3.77)	6.5	0, 12	-1.1 (3.58)	-1.0	-6, 4	0.3169
Low dose	9	6.2 (3.49)	5.7 (4.33)	5.0	0, 12	-0.6 (3.75)	1.0	-6, 4	0.6681
High dose	3	9.7 (3.79)	7.0 (1.00)	7.0	6, 8	-2.7 (3.06)	-2.0	-6, 0	0.2697
WEEK 52	12	7.1 (3.73)	6.9 (3.73)	6.0	0, 14	-0.2 (4.61)	0.5	-11, 7	0.9026
Low dose	9	6.2 (3.49)	7.3 (4.09)	6.0	0, 14	1.1 (3.55)	1.0	-4, 7	0.3754
High dose	3	9.7 (3.79)	5.7 (2.52)	6.0	3, 8	-4.0 (6.08)	-1.0	-11, 0	0.3727

&: 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 (SD)	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 &
MDS-UPDRS Part II Score									
BASELINE	27		14.4 (7.84)	13.0	1, 33				
Low dose	22		12.9 (7.38)	11.5	1, 27				
High dose	5		21.0 (6.82)	18.0	17, 33				
DAY 2	26	14.7 (7.88)	11.9 (7.77)	11.5	0, 33	-2.8 (3.82)	-1.5	-15, 3	0.0011**
Low dose	21	13.1 (7.48)	9.8 (6.28)	10.0	0, 21	-3.4 (3.90)	-2.0	-15, 3	<=0.001***
High dose	5	21.0 (6.82)	20.8 (7.56)	17.0	14, 33	-0.2 (2.17)	0.0	-3, 3	0.8466
WEEK 1	25	14.6 (7.73)	11.5 (6.75)	10.0	3, 29	-3.1 (5.80)	-3.0	-17, 9	0.0129*
Low dose	20	13.1 (7.24)	10.1 (5.88)	8.5	3, 26	-3.0 (5.03)	-2.5	-17, 4	0.0152*
High dose	5	21.0 (6.82)	17.4 (7.40)	18.0	10, 29	-3.6 (9.04)	-6.0	-15, 9	0.4237
WEEK 2	24	15.7 (7.28)	12.7 (7.62)	11.0	3, 37	-3.0 (7.48)	-3.0	-18, 17	0.0615
Low dose	19	14.3 (6.89)	10.9 (5.60)	9.0	3, 21	-3.3 (5.80)	-3.0	-18, 8	0.0227*
High dose	5	21.0 (6.82)	19.2 (11.19)	17.0	9, 37	-1.8 (12.95)	-6.0	-16, 17	0.7715
WEEK 3	21	15.4 (7.79)	13.0 (7.97)	11.0	3, 37	-2.5 (6.19)	-2.0	-17, 12	0.0819
Low dose	18	14.2 (7.15)	12.8 (8.58)	11.0	3, 37	-1.4 (5.51)	-1.5	-10, 12	0.2817
High dose	3	22.7 (8.96)	14.0 (2.65)	15.0	11, 16	-8.7 (7.64)	-7.0	-17, -2	0.1883
WEEK 4	20	15.6 (7.95)	14.2 (7.42)	14.0	3, 27	-1.4 (5.90)	-1.5	-17, 8	0.3017
Low dose	17	14.4 (7.35)	14.4 (7.99)	14.0	3, 27	0.1 (4.55)	-1.0	-9, 8	0.9581
High dose	3	22.7 (8.96)	13.0 (3.00)	13.0	10, 16	-9.7 (6.66)	-8.0	-17, -4	0.1284

&: 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 (SD)	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 6	18	14.8 (7.98)	13.1 (8.29)	11.0	3, 32	-1.7 (6.62)	-0.5	-21, 6	0.2853
Low dose	15	13.3 (7.08)	13.4 (9.09)	10.0	3, 32	0.1 (4.45)	1.0	-9, 6	0.9093
High dose	3	22.7 (8.96)	11.7 (1.53)	12.0	10, 13	-11.0 (8.89)	-8.0	-21, -4	0.1653
WEEK 13	17	15.2 (8.04)	14.1 (7.72)	14.0	1, 29	-1.1 (8.81)	-1.0	-21, 15	0.6081
Low dose	14	13.6 (7.19)	14.4 (8.38)	15.0	1, 29	0.8 (7.59)	0.5	-10, 15	0.7047
High dose	3	22.7 (8.96)	12.7 (4.04)	12.0	9, 17	-10.0 (10.15)	-8.0	-21, -1	0.2300
WEEK 26	15	16.2 (8.07)	12.9 (8.29)	14.0	0, 30	-3.3 (7.38)	-2.0	-18, 13	0.1023
Low dose	12	14.6 (7.35)	13.5 (8.91)	15.5	0, 30	-1.1 (5.93)	-1.0	-8, 13	0.5398
High dose	3	22.7 (8.96)	10.3 (5.69)	12.0	4, 15	-12.3 (6.03)	-13.0	-18, -6	0.0712
WEEK 39	12	15.0 (8.37)	11.5 (8.90)	10.0	1, 28	-3.5 (7.01)	-3.5	-15, 10	0.1118
Low dose	9	12.4 (6.84)	11.8 (9.60)	9.0	1, 28	-0.7 (4.97)	-1.0	-7, 10	0.6982
High dose	3	22.7 (8.96)	10.7 (8.08)	12.0	2, 18	-12.0 (5.20)	-15.0	-15, -6	0.0572
WEEK 52	12	15.0 (8.37)	11.3 (7.00)	9.5	0, 22	-3.8 (6.89)	-3.5	-17, 8	0.0861
Low dose	9	12.4 (6.84)	11.6 (7.76)	10.0	0, 22	-0.9 (4.91)	-1.0	-8, 8	0.6019
High dose	3	22.7 (8.96)	10.3 (5.13)	9.0	6, 16	-12.3 (4.16)	-11.0	-17, -9	0.0359*

&: 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 (SD)	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 &
MDS-UPDRS Part III Score									
BASELINE	27		18.7 (10.66)	18.0	2, 42				
Low dose	22		17.7 (9.78)	17.0	2, 36				
High dose	5		23.2 (14.38)	22.0	9, 42				
DAY 2	26	18.3 (10.67)	18.6 (14.95)	14.0	2, 59	0.3 (8.79)	-0.5	-19, 26	0.8772
Low dose	21	17.2 (9.68)	15.9 (11.30)	14.0	2, 44	-1.3 (7.55)	-1.0	-19, 14	0.4444
High dose	5	23.2 (14.38)	30.0 (23.60)	27.0	6, 59	6.8 (11.50)	5.0	-3, 26	0.2566
WEEK 1	25	19.3 (10.85)	27.1 (18.35)	27.0	0, 76	7.8 (16.56)	1.0	-8, 67	0.0268*
Low dose	20	18.3 (10.01)	24.5 (17.07)	23.0	0, 76	6.2 (16.28)	0.5	-8, 67	0.1041
High dose	5	23.2 (14.38)	37.4 (21.66)	39.0	11, 70	14.2 (17.96)	5.0	-2, 37	0.1519
WEEK 2	24	19.8 (10.49)	29.9 (19.79)	23.5	5, 77	10.1 (17.20)	4.5	-7, 68	0.0087**
Low dose	19	18.9 (9.52)	29.1 (19.78)	23.0	5, 77	10.1 (17.42)	5.0	-5, 68	0.0206*
High dose	5	23.2 (14.38)	33.0 (21.80)	32.0	12, 68	9.8 (18.34)	2.0	-7, 35	0.2977
WEEK 3	21	18.6 (9.77)	28.3 (18.14)	24.0	6, 84	9.7 (17.24)	4.0	-9, 75	0.0178*
Low dose	18	17.6 (8.60)	29.1 (19.29)	24.5	6, 84	11.5 (17.89)	7.0	-4, 75	0.0143*
High dose	3	24.7 (16.17)	23.7 (9.50)	24.0	14, 33	-1.0 (7.00)	2.0	-9, 4	0.8277
WEEK 4	20	18.4 (9.99)	27.5 (15.42)	26.0	6, 62	9.1 (14.33)	3.0	-8, 53	0.0102*
Low dose	17	17.3 (8.79)	28.3 (16.10)	27.0	6, 62	11.1 (14.63)	13.0	-3, 53	0.0067**
High dose	3	24.7 (16.17)	23.0 (12.12)	25.0	10, 34	-1.7 (5.69)	0.0	-8, 3	0.6621

&: 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 (SD)	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 &
MDS-UPDRS Part III Score									
WEEK 6	18	17.6 (9.61)	26.1 (16.34)	24.0	5, 69	8.6 (16.93)	3.0	-17, 60	0.0466*
Low dose	15	16.1 (7.85)	27.4 (17.42)	24.0	5, 69	11.3 (16.88)	10.0	-7, 60	0.0215*
High dose	3	24.7 (16.17)	19.7 (8.39)	24.0	10, 25	-5.0 (10.44)	0.0	-17, 2	0.4941
WEEK 13	17	18.1 (9.65)	28.6 (15.08)	29.0	1, 57	10.5 (12.99)	9.0	-9, 37	0.0042**
Low dose	14	16.6 (7.89)	29.3 (15.69)	27.9	1, 57	12.7 (12.99)	14.0	-9, 37	0.0029**
High dose	3	24.7 (16.17)	25.0 (14.00)	31.0	9, 35	0.3 (8.08)	-1.0	-7, 9	0.9496
WEEK 26	15	18.1 (10.27)	26.1 (15.72)	28.0	4, 51	7.9 (13.75)	1.0	-6, 39	0.0423*
Low dose	12	16.5 (8.50)	26.7 (16.64)	28.0	4, 51	10.2 (14.57)	6.0	-6, 39	0.0341*
High dose	3	24.7 (16.17)	23.7 (14.01)	23.0	10, 38	-1.0 (2.65)	0.0	-4, 1	0.5799
WEEK 39	12	17.3 (10.56)	25.2 (17.46)	24.5	4, 56	7.9 (15.40)	2.0	-7, 47	0.1026
Low dose	9	14.8 (7.77)	24.2 (18.72)	24.0	4, 56	9.4 (17.65)	2.0	-7, 47	0.1471
High dose	3	24.7 (16.17)	28.0 (16.09)	30.0	11, 43	3.3 (4.04)	1.0	1, 8	0.2893
WEEK 52	12	17.3 (10.56)	23.8 (16.38)	28.0	1, 51	6.6 (11.05)	4.5	-9, 23	0.0634
Low dose	9	14.8 (7.77)	22.6 (15.99)	26.0	1, 51	7.8 (12.32)	4.0	-9, 23	0.0948
High dose	3	24.7 (16.17)	27.7 (20.60)	30.0	6, 47	3.0 (6.24)	5.0	-4, 8	0.4929

&: 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 (SD)	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 &
MDS-UPDRS Part IV Score									
BASELINE	27		8.7 (2.84)	9.0	0, 14				
Low dose	22		8.6 (3.02)	8.5	0, 14				
High dose	5		9.0 (2.12)	9.0	7, 12				
DAY 2	26	8.8 (2.85)	6.5 (3.78)	6.0	0, 14	-2.3 (3.76)	-1.0	-12, 6	0.0044**
Low dose	21	8.7 (3.04)	6.5 (3.97)	6.0	0, 14	-2.2 (3.95)	-1.0	-12, 6	0.0172*
High dose	5	9.0 (2.12)	6.4 (3.21)	8.0	1, 9	-2.6 (3.21)	-1.0	-6, 1	0.1443
WEEK 1	25	8.7 (2.95)	7.9 (3.40)	8.0	1, 15	-0.8 (3.76)	-1.0	-8, 9	0.2985
Low dose	20	8.6 (3.17)	8.0 (2.96)	8.0	2, 15	-0.7 (3.65)	-1.0	-6, 9	0.4351
High dose	5	9.0 (2.12)	7.6 (5.22)	6.0	1, 15	-1.4 (4.62)	-1.0	-8, 5	0.5348
WEEK 2	24	8.7 (2.93)	7.4 (2.95)	7.5	2, 12	-1.3 (2.87)	-1.5	-7, 5	0.0375*
Low dose	19	8.6 (3.15)	7.7 (2.67)	8.0	3, 12	-0.9 (2.66)	-1.0	-7, 5	0.1374
High dose	5	9.0 (2.12)	6.4 (4.04)	7.0	2, 12	-2.6 (3.58)	-4.0	-7, 2	0.1795
WEEK 3	21	8.0 (2.84)	8.3 (2.87)	8.0	3, 15	0.2 (3.36)	0.0	-5, 8	0.7488
Low dose	18	8.1 (3.05)	8.5 (3.00)	8.5	3, 15	0.4 (3.52)	0.0	-5, 8	0.6449
High dose	3	7.7 (1.15)	7.0 (1.73)	6.0	6, 9	-0.7 (2.52)	-1.0	-3, 2	0.6914
WEEK 4	20	8.0 (2.90)	6.8 (2.78)	7.0	2, 12	-1.2 (2.76)	-1.0	-5, 5	0.0672
Low dose	17	8.1 (3.13)	7.2 (2.66)	8.0	2, 12	-0.8 (2.65)	-1.0	-5, 5	0.2186
High dose	3	7.7 (1.15)	4.3 (2.52)	4.0	2, 7	-3.3 (2.89)	-5.0	-5, 0	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 (SD)	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									
WEEK 6	18	7.8 (3.01)	6.4 (2.73)	6.0	2, 12	-1.4 (3.20)	-1.5	-8, 5	0.0727
Low dose	15	7.9 (3.29)	6.5 (2.88)	6.0	2, 12	-1.3 (3.33)	-1.0	-8, 5	0.1434
High dose	3	7.7 (1.15)	5.7 (2.08)	5.0	4, 8	-2.0 (3.00)	-2.0	-5, 1	0.3675
WEEK 13	17	7.5 (2.67)	6.1 (2.82)	6.0	2, 11	-1.4 (3.97)	-2.0	-6, 10	0.1619
Low dose	14	7.4 (2.93)	6.4 (3.00)	6.5	2, 11	-1.1 (4.25)	-2.0	-6, 10	0.3629
High dose	3	7.7 (1.15)	4.7 (1.15)	4.0	4, 6	-3.0 (2.00)	-3.0	-5, -1	0.1217
WEEK 26	15	7.6 (2.82)	5.8 (3.03)	5.0	2, 12	-1.8 (3.59)	-1.0	-10, 5	0.0725
Low dose	12	7.6 (3.15)	6.1 (3.23)	6.0	2, 12	-1.5 (3.83)	-1.0	-10, 5	0.2016
High dose	3	7.7 (1.15)	4.7 (2.08)	4.0	3, 7	-3.0 (2.65)	-4.0	-5, 0	0.1885
WEEK 39	12	7.3 (3.11)	5.7 (2.90)	5.5	0, 9	-1.7 (3.23)	-2.0	-6, 5	0.1013
Low dose	9	7.2 (3.60)	5.9 (2.85)	6.0	0, 9	-1.3 (3.12)	-2.0	-6, 5	0.2361
High dose	3	7.7 (1.15)	5.0 (3.61)	4.0	2, 9	-2.7 (4.04)	-5.0	-5, 2	0.3715
WEEK 52	12	7.3 (3.11)	5.8 (2.48)	6.0	2, 10	-1.5 (3.75)	-2.5	-5, 6	0.1937
Low dose	9	7.2 (3.60)	6.2 (2.33)	6.0	3, 10	-1.0 (3.91)	-2.0	-5, 6	0.4644
High dose	3	7.7 (1.15)	4.7 (3.06)	4.0	2, 8	-3.0 (3.46)	-5.0	-5, 1	0.2724

&: 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27　MDS-UPDRSスコア（Hoehn-Yahr 重症度分類，FAS）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - 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 (SD)	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	244		2.2 (0.68)	2.0	0, 5				
Low dose	132		2.2 (0.61)	2.0	1, 5				
High dose	112		2.2 (0.74)	2.0	0, 5				
DAY 2	222	2.2 (0.69)	2.2 (0.67)	2.0	0, 5	-0.0 (0.52)	0.0	-2, 2	0.4398
Low dose	121	2.2 (0.63)	2.2 (0.65)	2.0	0, 5	-0.0 (0.47)	0.0	-2, 2	0.5659
High dose	101	2.3 (0.76)	2.2 (0.69)	2.0	1, 4	-0.0 (0.57)	0.0	-2, 2	0.6040
WEEK 1	224	2.2 (0.67)	2.2 (0.73)	2.0	1, 5	0.0 (0.61)	0.0	-2, 3	0.3839
Low dose	119	2.2 (0.58)	2.2 (0.64)	2.0	1, 5	0.0 (0.58)	0.0	-2, 3	0.7533
High dose	105	2.2 (0.77)	2.3 (0.82)	2.0	1, 5	0.1 (0.65)	0.0	-2, 2	0.3682
WEEK 2	211	2.2 (0.64)	2.2 (0.74)	2.0	0, 5	0.1 (0.64)	0.0	-2, 3	0.2016
Low dose	118	2.2 (0.57)	2.3 (0.79)	2.0	0, 5	0.1 (0.70)	0.0	-2, 3	0.1155
High dose	93	2.2 (0.72)	2.2 (0.69)	2.0	0, 5	0.0 (0.57)	0.0	-2, 2	>0.999
WEEK 3	203	2.2 (0.66)	2.2 (0.69)	2.0	0, 5	-0.0 (0.64)	0.0	-3, 3	0.3783
Low dose	108	2.2 (0.54)	2.1 (0.72)	2.0	0, 5	-0.0 (0.68)	0.0	-3, 3	0.6703
High dose	95	2.2 (0.77)	2.2 (0.66)	2.0	1, 5	-0.1 (0.59)	0.0	-2, 1	0.3869
WEEK 4	201	2.2 (0.63)	2.2 (0.70)	2.0	0, 5	0.0 (0.69)	0.0	-2, 3	0.9186
Low dose	109	2.2 (0.51)	2.2 (0.78)	2.0	0, 5	0.0 (0.73)	0.0	-2, 3	0.6930
High dose	92	2.2 (0.75)	2.2 (0.58)	2.0	1, 4	-0.0 (0.65)	0.0	-2, 2	0.7475

&: 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__2.2

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 (SD)	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 &
MDS-UPDRS Hoehn and Yahr Stage									
WEEK 6	192	2.2 (0.66)	2.1 (0.76)	2.0	0, 5	-0.1 (0.68)	0.0	-2, 3	0.0747
Low dose	105	2.2 (0.58)	2.2 (0.81)	2.0	0, 5	0.0 (0.69)	0.0	-2, 3	>0.999
High dose	87	2.2 (0.75)	2.0 (0.70)	2.0	0, 4	-0.2 (0.66)	0.0	-2, 1	0.0072**
WEEK 13	162	2.2 (0.65)	2.1 (0.82)	2.0	0, 5	-0.1 (0.78)	0.0	-4, 2	0.1923
Low dose	92	2.2 (0.53)	2.1 (0.81)	2.0	0, 5	-0.1 (0.72)	0.0	-2, 2	0.4688
High dose	70	2.2 (0.78)	2.1 (0.84)	2.0	0, 5	-0.1 (0.86)	0.0	-4, 1	0.2703
WEEK 26	141	2.2 (0.71)	2.1 (0.87)	2.0	0, 5	-0.1 (0.84)	0.0	-4, 2	0.1361
Low dose	76	2.2 (0.65)	2.2 (0.96)	2.0	0, 5	-0.1 (0.79)	0.0	-2, 2	0.4695
High dose	65	2.2 (0.78)	2.0 (0.75)	2.0	0, 4	-0.2 (0.91)	0.0	-4, 2	0.1755
WEEK 39	125	2.2 (0.70)	2.2 (0.75)	2.0	0, 5	-0.0 (0.72)	0.0	-2, 2	0.8037
Low dose	73	2.2 (0.62)	2.2 (0.77)	2.0	0, 5	0.1 (0.61)	0.0	-2, 2	0.3394
High dose	52	2.2 (0.81)	2.1 (0.72)	2.0	0, 4	-0.1 (0.84)	0.0	-2, 1	0.2537
WEEK 52	120	2.2 (0.65)	2.1 (0.67)	2.0	0, 5	-0.0 (0.67)	0.0	-2, 1	0.5883
Low dose	68	2.1 (0.60)	2.1 (0.65)	2.0	0, 5	0.0 (0.59)	0.0	-2, 1	0.8366
High dose	52	2.2 (0.72)	2.1 (0.70)	2.0	0, 4	-0.1 (0.77)	0.0	-2, 1	0.3743

&: 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28　PDSS-2スコア（FAS）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 3

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDSS-2 Total Score									
BASELINE	243		20.4 (9.64)	19.0	0.0, 56.0				
Low dose	132		19.6 (9.41)	18.0	2.0, 56.0				
High dose	111		21.3 (9.87)	20.0	0.0, 47.0				
WEEK 6	196	20.2 (9.42)	14.2 (8.54)	12.5	0.0, 45.0	-6.1 (10.31)	-6.0	-50.0, 27.0	<=0.001***
Low dose	106	19.8 (9.40)	14.8 (8.84)	13.0	1.0, 45.0	-5.0 (11.35)	-4.0	-50.0, 27.0	<=0.001***
High dose	90	20.7 (9.47)	13.5 (8.15)	12.0	0.0, 43.0	-7.3 (8.85)	-7.0	-27.0, 14.0	<=0.001***
WEEK 13	170	20.7 (9.61)	13.2 (8.37)	11.0	0.0, 45.0	-7.5 (9.94)	-6.0	-48.0, 21.0	<=0.001***
Low dose	94	19.8 (9.49)	12.9 (8.67)	9.5	0.0, 45.0	-6.9 (10.70)	-6.0	-48.0, 17.0	<=0.001***
High dose	76	21.8 (9.70)	13.6 (8.02)	13.0	2.0, 43.0	-8.2 (8.94)	-8.0	-27.0, 21.0	<=0.001***
WEEK 26	148	20.5 (9.61)	13.9 (9.24)	12.0	0.0, 51.0	-6.6 (11.14)	-7.0	-48.0, 40.0	<=0.001***
Low dose	80	19.2 (9.44)	14.0 (9.80)	11.0	0.0, 51.0	-5.2 (13.07)	-6.0	-48.0, 40.0	<=0.001***
High dose	68	22.1 (9.66)	13.8 (8.59)	12.5	0.0, 35.0	-8.3 (8.11)	-8.0	-34.0, 10.0	<=0.001***
WEEK 39	132	20.2 (9.51)	13.4 (8.36)	12.0	1.0, 53.0	-6.8 (10.34)	-6.0	-53.0, 18.0	<=0.001***
Low dose	74	19.5 (9.52)	12.9 (7.63)	12.0	2.0, 43.0	-6.6 (11.10)	-5.5	-53.0, 18.0	<=0.001***
High dose	58	21.2 (9.48)	14.1 (9.23)	12.0	1.0, 53.0	-7.1 (9.37)	-7.0	-30.0, 16.0	<=0.001***
WEEK 52	118	20.5 (9.92)	13.4 (8.45)	11.5	0.0, 47.0	-7.1 (10.55)	-7.5	-53.0, 21.0	<=0.001***
Low dose	67	19.6 (9.79)	13.4 (7.98)	12.0	2.0, 44.0	-6.2 (11.88)	-6.0	-53.0, 21.0	<=0.001***
High dose	51	21.8 (10.05)	13.4 (9.11)	11.0	0.0, 47.0	-8.4 (8.45)	-8.0	-33.0, 7.0	<=0.001***

&: 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__3

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	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 &
PDSS-2 Motor Symptoms at Night Score									
BASELINE	243		5.2 (4.10)	5.0	0.0, 20.0				
Low dose	132		5.1 (4.06)	4.5	0.0, 20.0				
High dose	111		5.3 (4.16)	5.0	0.0, 16.0				
WEEK 6	196	5.2 (3.99)	3.5 (3.59)	2.0	0.0, 15.0	-1.7 (4.61)	-2.0	-19.0, 12.0	<=0.001***
Low dose	106	5.2 (4.08)	3.7 (3.63)	3.0	0.0, 14.0	-1.5 (4.95)	-1.0	-19.0, 12.0	0.0025**
High dose	90	5.1 (3.90)	3.1 (3.53)	2.0	0.0, 15.0	-2.0 (4.18)	-2.0	-11.0, 10.0	<=0.001***
WEEK 13	170	5.5 (4.20)	3.1 (3.47)	2.0	0.0, 16.0	-2.3 (4.41)	-2.0	-19.0, 11.0	<=0.001***
Low dose	94	5.3 (4.22)	3.0 (3.61)	2.0	0.0, 16.0	-2.3 (4.59)	-2.0	-19.0, 9.0	<=0.001***
High dose	76	5.7 (4.18)	3.3 (3.31)	2.0	0.0, 15.0	-2.4 (4.22)	-2.5	-13.0, 11.0	<=0.001***
WEEK 26	148	5.3 (4.15)	3.5 (3.94)	2.0	0.0, 20.0	-1.8 (5.07)	-2.0	-20.0, 20.0	<=0.001***
Low dose	80	4.9 (4.09)	3.7 (4.18)	2.0	0.0, 20.0	-1.2 (5.90)	-2.0	-20.0, 20.0	0.0725
High dose	68	5.8 (4.20)	3.3 (3.65)	2.0	0.0, 16.0	-2.5 (3.81)	-2.0	-12.0, 11.0	<=0.001***
WEEK 39	132	5.2 (4.20)	3.4 (3.67)	2.0	0.0, 20.0	-1.9 (4.54)	-1.0	-18.0, 12.0	<=0.001***
Low dose	74	5.1 (4.12)	3.2 (3.49)	2.0	0.0, 16.0	-1.9 (4.73)	-1.5	-18.0, 12.0	<=0.001***
High dose	58	5.4 (4.33)	3.6 (3.89)	3.0	0.0, 20.0	-1.8 (4.32)	-1.0	-12.0, 12.0	0.0021**
WEEK 52	118	5.4 (4.30)	3.3 (3.59)	2.0	0.0, 16.0	-2.1 (4.73)	-2.0	-19.0, 14.0	<=0.001***
Low dose	67	5.1 (4.17)	3.3 (3.58)	2.0	0.0, 14.0	-1.8 (5.42)	-2.0	-19.0, 14.0	0.0098**
High dose	51	5.7 (4.48)	3.3 (3.64)	2.0	0.0, 16.0	-2.5 (3.66)	-2.0	-13.0, 6.0	<=0.001***

&: 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__3

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	Visit Mean (SD)	Visit Median	Visit Min, Max	Change from Baseline Mean (SD)	Change from Baseline Median	Change from Baseline Min, Max	P-Value &
PDSS-2 PD Symptoms at Night Score									
BASELINE	243		5.0 (3.99)	4.0	0.0, 20.0				
Low dose	132		4.7 (3.88)	4.0	0.0, 20.0				
High dose	111		5.4 (4.11)	5.0	0.0, 16.0				
WEEK 6	196	4.9 (3.81)	2.9 (3.41)	2.0	0.0, 18.0	-2.0 (3.81)	-2.0	-19.0, 12.0	<=0.001***
Low dose	106	4.8 (3.79)	2.9 (3.59)	2.0	0.0, 18.0	-1.8 (4.04)	-1.5	-19.0, 12.0	<=0.001***
High dose	90	5.2 (3.85)	2.9 (3.21)	2.0	0.0, 15.0	-2.3 (3.51)	-2.0	-12.0, 5.0	<=0.001***
WEEK 13	170	5.0 (3.86)	2.7 (3.17)	2.0	0.0, 18.0	-2.2 (3.98)	-2.0	-16.0, 11.0	<=0.001***
Low dose	94	4.7 (3.69)	2.7 (3.22)	2.0	0.0, 18.0	-2.0 (3.98)	-2.0	-16.0, 10.0	<=0.001***
High dose	76	5.3 (4.07)	2.8 (3.14)	2.0	0.0, 16.0	-2.5 (3.98)	-2.0	-11.0, 11.0	<=0.001***
WEEK 26	148	4.9 (3.91)	3.0 (3.63)	2.0	0.0, 19.0	-2.0 (4.27)	-2.0	-16.0, 17.0	<=0.001***
Low dose	80	4.5 (3.69)	3.2 (3.95)	2.0	0.0, 19.0	-1.4 (4.63)	-1.0	-16.0, 17.0	0.0108*
High dose	68	5.4 (4.14)	2.7 (3.21)	1.5	0.0, 12.0	-2.7 (3.72)	-3.0	-14.0, 5.0	<=0.001***
WEEK 39	132	4.7 (3.86)	2.4 (3.11)	1.0	0.0, 20.0	-2.3 (3.95)	-2.0	-19.0, 8.0	<=0.001***
Low dose	74	4.5 (3.80)	2.4 (2.81)	1.0	0.0, 13.0	-2.1 (4.31)	-2.0	-19.0, 7.0	<=0.001***
High dose	58	5.0 (3.96)	2.5 (3.48)	1.5	0.0, 20.0	-2.5 (3.47)	-2.0	-12.0, 8.0	<=0.001***
WEEK 52	118	4.8 (4.05)	2.5 (3.06)	2.0	0.0, 15.0	-2.4 (4.25)	-2.0	-19.0, 14.0	<=0.001***
Low dose	67	4.5 (3.91)	2.6 (3.06)	2.0	0.0, 15.0	-2.0 (4.50)	-2.0	-19.0, 14.0	<=0.001***
High dose	51	5.3 (4.24)	2.4 (3.10)	1.0	0.0, 14.0	-2.9 (3.86)	-3.0	-12.0, 5.0	<=0.001***

&: 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__3

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	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 &
PDSS-2 Disturbed Sleep Score									
BASELINE	243		10.2 (3.71)	10.0	0.0, 19.0				
Low dose	132		9.8 (3.66)	10.0	1.0, 19.0				
High dose	111		10.6 (3.73)	11.0	0.0, 19.0				
WEEK 6	196	10.1 (3.72)	7.8 (3.63)	8.0	0.0, 19.0	-2.3 (4.56)	-2.0	-12.0, 17.0	<=0.001***
Low dose	106	9.8 (3.76)	8.1 (3.75)	8.0	1.0, 19.0	-1.7 (4.78)	-2.0	-12.0, 17.0	<=0.001***
High dose	90	10.4 (3.66)	7.4 (3.47)	8.0	0.0, 16.0	-3.0 (4.20)	-2.0	-11.0, 8.0	<=0.001***
WEEK 13	170	10.3 (3.78)	7.4 (4.01)	7.0	0.0, 20.0	-2.9 (4.51)	-3.0	-13.0, 11.0	<=0.001***
Low dose	94	9.9 (3.82)	7.2 (3.96)	7.0	0.0, 17.0	-2.6 (4.60)	-2.0	-13.0, 11.0	<=0.001***
High dose	76	10.9 (3.68)	7.6 (4.09)	8.0	0.0, 20.0	-3.3 (4.42)	-3.0	-13.0, 6.0	<=0.001***
WEEK 26	148	10.3 (3.79)	7.4 (3.70)	7.0	0.0, 17.0	-2.9 (4.42)	-2.0	-14.0, 10.0	<=0.001***
Low dose	80	9.8 (3.76)	7.1 (3.49)	7.0	0.0, 14.0	-2.6 (4.56)	-2.0	-12.0, 10.0	<=0.001***
High dose	68	10.9 (3.76)	7.8 (3.95)	7.0	0.0, 17.0	-3.1 (4.27)	-2.5	-14.0, 7.0	<=0.001***
WEEK 39	132	10.3 (3.71)	7.6 (3.68)	7.0	0.0, 16.0	-2.7 (4.57)	-2.0	-16.0, 7.0	<=0.001***
Low dose	74	9.9 (3.66)	7.3 (3.69)	7.0	0.0, 16.0	-2.6 (4.67)	-2.0	-16.0, 7.0	<=0.001***
High dose	58	10.8 (3.76)	7.9 (3.67)	8.0	0.0, 15.0	-2.8 (4.47)	-2.0	-13.0, 5.0	<=0.001***
WEEK 52	118	10.3 (3.74)	7.6 (3.85)	7.0	0.0, 17.0	-2.7 (4.61)	-3.0	-15.0, 10.0	<=0.001***
Low dose	67	10.0 (3.65)	7.5 (3.70)	7.0	0.0, 15.0	-2.5 (4.63)	-2.0	-15.0, 10.0	<=0.001***
High dose	51	10.7 (3.86)	7.8 (4.07)	8.0	0.0, 17.0	-3.0 (4.62)	-3.0	-11.0, 7.0	<=0.001***

&: 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29　PDSS-2スコア（FAS，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 3.J

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS - Japan Subjects)

Parameter / Time Point / Dose Category	N	Baseline Mean (SD)	Visit: Mean (SD)	Visit: Median	Visit: Min, Max	Change from Baseline: Mean (SD)	Change from Baseline: Median	Change from Baseline: Min, Max	P-Value &
PDSS-2 Total Score									
BASELINE	27		16.1 (6.58)	14.0	5.0, 29.0				
Low dose	22		15.4 (6.45)	13.5	5.0, 26.0				
High dose	5		19.2 (6.94)	21.0	12.0, 29.0				
WEEK 6	19	16.3 (7.13)	17.9 (10.61)	15.0	4.0, 45.0	1.6 (10.82)	-1.0	-15.0, 27.0	0.5327
Low dose	16	15.4 (6.88)	18.2 (11.33)	15.5	4.0, 45.0	2.8 (10.94)	0.0	-11.0, 27.0	0.3306
High dose	3	21.0 (8.00)	16.3 (6.81)	14.0	11.0, 24.0	-4.7 (9.29)	-2.0	-15.0, 3.0	0.4761
WEEK 13	17	16.4 (6.59)	18.0 (8.66)	17.0	0.0, 36.0	1.6 (11.02)	1.0	-18.0, 17.0	0.5608
Low dose	14	15.4 (6.14)	18.7 (9.41)	19.5	0.0, 36.0	3.3 (11.08)	3.5	-18.0, 17.0	0.2871
High dose	3	21.0 (8.00)	14.7 (2.08)	14.0	13.0, 17.0	-6.3 (7.77)	-4.0	-15.0, 0.0	0.2934
WEEK 26	15	17.1 (6.60)	21.0 (8.68)	19.0	8.0, 42.0	3.9 (9.32)	3.0	-12.0, 19.0	0.1304
Low dose	12	16.2 (6.22)	22.1 (8.59)	19.5	8.0, 42.0	5.9 (8.90)	6.5	-8.0, 19.0	0.0418*
High dose	3	21.0 (8.00)	16.7 (9.29)	14.0	9.0, 27.0	-4.3 (6.81)	-2.0	-12.0, 1.0	0.3851
WEEK 39	12	17.3 (7.00)	15.6 (4.70)	16.5	7.0, 22.0	-1.8 (8.85)	-2.5	-16.0, 12.0	0.5077
Low dose	9	16.1 (6.68)	16.0 (4.85)	18.0	7.0, 22.0	-0.1 (9.57)	4.0	-16.0, 12.0	0.9731
High dose	3	21.0 (8.00)	14.3 (4.93)	12.0	11.0, 20.0	-6.7 (4.04)	-9.0	-9.0, -2.0	0.1038
WEEK 52	12	17.3 (7.00)	17.7 (4.79)	16.5	9.0, 25.0	0.3 (8.73)	-0.5	-14.0, 14.0	0.8972
Low dose	9	16.1 (6.68)	17.3 (5.24)	16.0	9.0, 25.0	1.2 (9.68)	3.0	-14.0, 14.0	0.7147
High dose	3	21.0 (8.00)	18.7 (3.79)	17.0	16.0, 23.0	-2.3 (5.51)	-5.0	-6.0, 4.0	0.5394

&: 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__3.J

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	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 &
PDSS-2 Motor Symptoms at Night Score									
BASELINE	27		3.1 (3.07)	2.0	0.0, 9.0				
Low dose	22		2.7 (2.77)	2.0	0.0, 9.0				
High dose	5		5.0 (3.94)	4.0	0.0, 9.0				
WEEK 6	19	3.1 (2.79)	4.7 (4.08)	5.0	0.0, 13.0	1.6 (4.21)	0.0	-6.0, 10.0	0.1081
Low dose	16	2.7 (2.60)	4.8 (4.31)	5.0	0.0, 13.0	2.1 (4.03)	0.5	-3.0, 10.0	0.0522
High dose	3	5.3 (3.21)	4.3 (3.21)	3.0	2.0, 8.0	-1.0 (5.00)	-1.0	-6.0, 4.0	0.7621
WEEK 13	17	3.2 (2.81)	4.2 (3.85)	4.0	0.0, 13.0	1.1 (4.67)	1.0	-9.0, 9.0	0.3638
Low dose	14	2.7 (2.61)	4.6 (4.07)	4.5	0.0, 13.0	1.9 (4.28)	1.5	-6.0, 9.0	0.1281
High dose	3	5.3 (3.21)	2.7 (2.52)	3.0	0.0, 5.0	-2.7 (5.51)	0.0	-9.0, 1.0	0.4899
WEEK 26	15	3.6 (2.72)	5.7 (4.15)	5.0	0.0, 16.0	2.1 (4.53)	2.0	-4.0, 11.0	0.0988
Low dose	12	3.2 (2.55)	6.4 (4.21)	7.0	0.0, 16.0	3.3 (4.18)	3.5	-3.0, 11.0	0.0209*
High dose	3	5.3 (3.21)	2.7 (2.52)	3.0	0.0, 5.0	-2.7 (2.31)	-4.0	-4.0, 0.0	0.1835
WEEK 39	12	3.8 (2.83)	3.3 (2.22)	3.5	0.0, 7.0	-0.5 (3.12)	-1.0	-5.0, 4.0	0.5898
Low dose	9	3.2 (2.68)	3.6 (2.30)	4.0	0.0, 7.0	0.3 (3.04)	0.0	-4.0, 4.0	0.7508
High dose	3	5.3 (3.21)	2.3 (2.08)	3.0	0.0, 4.0	-3.0 (2.00)	-3.0	-5.0, -1.0	0.1217
WEEK 52	12	3.8 (2.83)	4.3 (2.39)	4.0	1.0, 10.0	0.6 (4.17)	0.5	-6.0, 10.0	0.6372
Low dose	9	3.2 (2.68)	4.7 (2.50)	4.0	2.0, 10.0	1.4 (4.42)	2.0	-6.0, 10.0	0.3555
High dose	3	5.3 (3.21)	3.3 (2.08)	4.0	1.0, 5.0	-2.0 (2.00)	-2.0	-4.0, 0.0	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]

TABLE 14.2__3.J

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	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 &
PDSS-2 PD Symptoms at Night Score									
BASELINE	27		4.0 (2.90)	3.0	0.0, 10.0				
Low dose	22		3.9 (2.96)	3.0	0.0, 10.0				
High dose	5		4.8 (2.77)	6.0	1.0, 8.0				
WEEK 6	19	4.4 (2.99)	4.0 (4.77)	2.0	0.0, 18.0	-0.4 (4.02)	-1.0	-6.0, 12.0	0.6533
Low dose	16	4.3 (2.98)	4.1 (5.09)	2.0	0.0, 18.0	-0.3 (4.34)	-1.0	-6.0, 12.0	0.8210
High dose	3	5.0 (3.61)	3.7 (3.21)	5.0	0.0, 6.0	-1.3 (1.53)	-1.0	-3.0, 0.0	0.2697
WEEK 13	17	4.3 (2.71)	4.0 (3.26)	4.0	0.0, 10.0	-0.3 (4.25)	0.0	-7.0, 7.0	0.7792
Low dose	14	4.1 (2.63)	4.3 (3.36)	4.0	0.0, 10.0	0.1 (4.31)	1.0	-7.0, 7.0	0.9032
High dose	3	5.0 (3.61)	2.7 (2.89)	1.0	1.0, 6.0	-2.3 (4.04)	0.0	-7.0, 0.0	0.4226
WEEK 26	15	4.7 (2.55)	5.7 (3.43)	5.0	1.0, 12.0	1.0 (3.21)	1.0	-3.0, 6.0	0.2472
Low dose	12	4.7 (2.42)	6.0 (3.25)	5.5	1.0, 12.0	1.3 (3.37)	1.5	-3.0, 6.0	0.1974
High dose	3	5.0 (3.61)	4.7 (4.73)	3.0	1.0, 10.0	-0.3 (2.52)	0.0	-3.0, 2.0	0.8399
WEEK 39	12	4.3 (2.71)	3.7 (2.46)	4.0	0.0, 8.0	-0.7 (3.37)	-1.5	-6.0, 6.0	0.5069
Low dose	9	4.1 (2.57)	3.8 (2.44)	4.0	0.0, 8.0	-0.3 (3.87)	0.0	-6.0, 6.0	0.8028
High dose	3	5.0 (3.61)	3.3 (3.06)	4.0	0.0, 6.0	-1.7 (0.58)	-2.0	-2.0, -1.0	0.0377*
WEEK 52	12	4.3 (2.71)	3.8 (1.82)	4.0	0.0, 7.0	-0.6 (2.94)	-2.0	-3.0, 5.0	0.5058
Low dose	9	4.1 (2.57)	3.4 (1.94)	4.0	0.0, 7.0	-0.7 (3.12)	-2.0	-3.0, 5.0	0.5397
High dose	3	5.0 (3.61)	4.7 (1.15)	4.0	4.0, 6.0	-0.3 (2.89)	-2.0	-2.0, 3.0	0.8600

&: 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__3.J

Change from Baseline to Each Planned Visit in Sleep Symptoms as Assessed
by The Parkinson's Disease Sleep Scale - 2
(FAS - Japan Subjects)

Parameter Time Point Dose Category	N	Baseline Mean (SD)	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 &
PDSS-2 Disturbed Sleep Score									
BASELINE	27		9.0 (3.11)	9.0	2.0, 14.0				
Low dose	22		8.9 (3.30)	9.0	2.0, 14.0				
High dose	5		9.4 (2.30)	9.0	6.0, 12.0				
WEEK 6	19	8.8 (3.29)	9.2 (3.64)	9.0	3.0, 19.0	0.4 (5.00)	0.0	-6.0, 17.0	0.7519
Low dose	16	8.4 (3.44)	9.3 (3.89)	9.0	3.0, 19.0	0.9 (5.19)	0.0	-4.0, 17.0	0.5102
High dose	3	10.7 (1.53)	8.3 (2.08)	9.0	6.0, 10.0	-2.3 (3.21)	-1.0	-6.0, 0.0	0.3356
WEEK 13	17	8.9 (3.23)	9.8 (4.32)	10.0	0.0, 15.0	0.8 (4.84)	1.0	-7.0, 11.0	0.4928
Low dose	14	8.6 (3.41)	9.9 (4.59)	11.0	0.0, 15.0	1.3 (5.09)	1.0	-7.0, 11.0	0.3619
High dose	3	10.7 (1.53)	9.3 (3.51)	9.0	6.0, 13.0	-1.3 (3.21)	0.0	-5.0, 1.0	0.5471
WEEK 26	15	8.8 (3.08)	9.6 (2.47)	10.0	5.0, 14.0	0.8 (3.05)	1.0	-5.0, 8.0	0.3272
Low dose	12	8.3 (3.23)	9.7 (2.46)	10.0	5.0, 14.0	1.3 (2.90)	1.0	-2.0, 8.0	0.1398
High dose	3	10.7 (1.53)	9.3 (3.06)	10.0	6.0, 12.0	-1.3 (3.21)	0.0	-5.0, 1.0	0.5471
WEEK 39	12	9.3 (2.53)	8.7 (2.71)	9.0	4.0, 13.0	-0.6 (4.25)	-1.0	-7.0, 7.0	0.6439
Low dose	9	8.8 (2.68)	8.7 (2.74)	9.0	4.0, 13.0	-0.1 (4.46)	-1.0	-7.0, 7.0	0.9422
High dose	3	10.7 (1.53)	8.7 (3.21)	10.0	5.0, 11.0	-2.0 (4.00)	-2.0	-6.0, 2.0	0.4778
WEEK 52	12	9.3 (2.53)	9.6 (2.61)	10.5	6.0, 13.0	0.3 (3.47)	0.0	-5.0, 6.0	0.7458
Low dose	9	8.8 (2.68)	9.2 (2.73)	10.0	6.0, 13.0	0.4 (3.78)	0.0	-5.0, 6.0	0.7333
High dose	3	10.7 (1.53)	10.7 (2.31)	12.0	8.0, 12.0	0.0 (3.00)	0.0	-3.0, 3.0	>0.999

&: 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30　PDQ-39スコア（FAS）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 4

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 (SD)	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-39 Summary Index Total Score									
BASELINE	243		34.5 (15.01)	32.7	4.5, 79.5				
Low dose	132		34.2 (16.27)	31.4	4.5, 79.5				
High dose	111		34.8 (13.41)	34.0	6.4, 61.5				
WEEK 6	196	33.7 (14.25)	26.0 (15.09)	25.0	1.9, 76.3	-7.6 (12.81)	-8.3	-44.6, 42.9	<=0.001***
Low dose	106	33.0 (14.64)	26.1 (16.06)	26.0	1.9, 76.3	-6.9 (14.53)	-8.7	-44.6, 42.9	<=0.001***
High dose	90	34.5 (13.82)	25.9 (13.94)	24.7	1.9, 57.7	-8.5 (10.45)	-8.3	-29.5, 19.2	<=0.001***
WEEK 13	170	34.1 (14.37)	25.8 (15.00)	25.6	0.0, 69.9	-8.3 (13.57)	-8.7	-58.2, 42.9	<=0.001***
Low dose	94	33.1 (15.06)	24.8 (16.23)	21.2	0.0, 69.9	-8.3 (15.26)	-8.0	-58.2, 42.9	<=0.001***
High dose	76	35.3 (13.45)	27.1 (13.33)	27.2	1.9, 55.1	-8.3 (11.24)	-9.0	-26.9, 21.8	<=0.001***
WEEK 26	148	34.6 (14.49)	27.3 (14.98)	25.0	3.2, 61.5	-7.3 (12.62)	-7.7	-53.2, 27.6	<=0.001***
Low dose	80	33.9 (15.20)	26.8 (15.30)	24.7	3.2, 61.5	-7.1 (13.21)	-7.7	-41.0, 27.6	<=0.001***
High dose	68	35.4 (13.67)	27.9 (14.68)	27.6	3.2, 57.7	-7.5 (11.99)	-8.4	-53.2, 22.4	<=0.001***
WEEK 39	132	33.9 (14.61)	26.3 (15.76)	24.4	0.0, 65.4	-7.5 (13.75)	-7.7	-53.2, 34.0	<=0.001***
Low dose	74	33.2 (15.33)	26.1 (15.93)	24.0	1.3, 65.4	-7.1 (14.15)	-7.4	-48.7, 34.0	<=0.001***
High dose	58	34.7 (13.71)	26.7 (15.68)	24.7	0.0, 64.1	-8.0 (13.32)	-7.7	-53.2, 30.1	<=0.001***
WEEK 52	119	33.5 (14.75)	26.7 (16.51)	23.7	3.2, 76.9	-6.8 (13.56)	-6.9	-49.2, 25.0	<=0.001***
Low dose	68	33.0 (15.49)	26.7 (16.89)	23.1	3.2, 64.1	-6.3 (14.53)	-5.1	-49.2, 25.0	<=0.001***
High dose	51	34.0 (13.85)	26.7 (16.17)	25.0	3.2, 76.9	-7.3 (12.27)	-8.3	-41.7, 20.5	<=0.001***

&: 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__4

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 (SD)	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-39 Mobility Domain Score									
BASELINE	243		45.9 (24.94)	45.0	2.5, 95.0				
Low dose	132		45.0 (25.73)	42.5	2.5, 95.0				
High dose	111		47.0 (24.03)	47.5	2.5, 92.5				
WEEK 6	196	45.3 (24.48)	33.5 (24.98)	27.5	0.0, 100.0	-11.8 (20.74)	-12.5	-77.5, 65.0	<=0.001***
Low dose	106	43.4 (24.29)	33.4 (25.51)	27.5	0.0, 100.0	-10.0 (23.28)	-11.3	-77.5, 65.0	<=0.001***
High dose	90	47.5 (24.66)	33.6 (24.47)	28.8	0.0, 87.5	-13.9 (17.16)	-12.5	-60.0, 30.0	<=0.001***
WEEK 13	170	45.4 (24.51)	32.6 (25.57)	27.5	0.0, 97.5	-12.8 (22.01)	-12.5	-82.5, 67.5	<=0.001***
Low dose	94	44.0 (25.11)	30.8 (25.71)	26.3	0.0, 97.5	-13.2 (24.01)	-12.5	-82.5, 67.5	<=0.001***
High dose	76	47.2 (23.79)	34.8 (25.39)	31.3	0.0, 90.0	-12.4 (19.41)	-10.0	-70.0, 25.0	<=0.001***
WEEK 26	148	45.6 (24.80)	34.2 (24.70)	30.0	0.0, 92.5	-11.3 (20.27)	-10.0	-67.5, 57.5	<=0.001***
Low dose	80	45.2 (25.52)	34.7 (24.33)	28.8	0.0, 87.5	-10.5 (21.05)	-10.0	-67.5, 57.5	<=0.001***
High dose	68	46.0 (24.10)	33.7 (25.29)	30.0	0.0, 92.5	-12.3 (19.41)	-10.0	-57.5, 57.5	<=0.001***
WEEK 39	132	44.3 (24.59)	32.3 (25.24)	25.0	0.0, 97.5	-12.0 (20.94)	-12.5	-67.5, 62.5	<=0.001***
Low dose	74	44.0 (25.75)	32.9 (25.50)	27.5	0.0, 97.5	-11.1 (21.40)	-11.3	-57.5, 62.5	<=0.001***
High dose	58	44.8 (23.25)	31.5 (25.11)	25.0	0.0, 85.0	-13.3 (20.45)	-12.5	-67.5, 30.0	<=0.001***
WEEK 52	119	43.2 (24.20)	33.0 (25.25)	27.5	0.0, 100.0	-10.2 (20.63)	-5.0	-67.5, 57.5	<=0.001***
Low dose	68	43.5 (25.21)	33.1 (25.20)	27.5	0.0, 92.5	-10.3 (22.53)	-5.0	-67.5, 57.5	<=0.001***
High dose	51	42.9 (23.02)	32.9 (25.56)	27.5	0.0, 100.0	-10.0 (18.00)	-10.0	-45.0, 32.5	<=0.001***

&: 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__4

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 (SD)	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-39 Activities of Daily Living Domain Score									
BASELINE	243		40.7 (22.11)	37.5	0.0, 100.0				
Low dose	132		39.8 (23.33)	37.5	0.0, 100.0				
High dose	111		41.7 (20.62)	37.5	0.0, 91.7				
WEEK 6	196	39.7 (21.26)	30.2 (21.74)	29.2	0.0, 100.0	-9.5 (21.16)	-12.5	-70.8, 75.0	<=0.001***
Low dose	106	38.2 (21.38)	30.4 (22.04)	29.2	0.0, 100.0	-7.8 (22.53)	-6.3	-70.8, 75.0	<=0.001***
High dose	90	41.4 (21.12)	30.0 (21.49)	25.0	0.0, 100.0	-11.5 (19.36)	-12.5	-54.2, 58.3	<=0.001***
WEEK 13	170	40.6 (21.12)	30.3 (22.48)	25.0	0.0, 100.0	-10.4 (21.78)	-12.5	-75.0, 58.3	<=0.001***
Low dose	94	38.2 (21.93)	29.3 (22.93)	25.0	0.0, 91.7	-9.0 (24.17)	-4.2	-75.0, 58.3	<=0.001***
High dose	76	43.6 (19.81)	31.5 (22.01)	27.1	4.2, 100.0	-12.1 (18.41)	-12.5	-50.0, 29.2	<=0.001***
WEEK 26	148	41.2 (21.30)	29.9 (21.26)	25.0	0.0, 100.0	-11.3 (19.33)	-8.3	-54.2, 37.5	<=0.001***
Low dose	80	40.1 (21.99)	30.6 (21.49)	25.0	0.0, 87.5	-9.5 (19.96)	-8.3	-54.2, 37.5	<=0.001***
High dose	68	42.5 (20.55)	29.2 (21.12)	25.0	0.0, 100.0	-13.4 (18.49)	-12.5	-54.2, 25.0	<=0.001***
WEEK 39	132	40.7 (21.44)	29.5 (21.17)	25.0	0.0, 87.5	-11.2 (21.87)	-8.3	-79.2, 41.7	<=0.001***
Low dose	74	39.7 (21.79)	29.8 (21.59)	25.0	0.0, 87.5	-9.9 (23.64)	-6.3	-79.2, 41.7	<=0.001***
High dose	58	42.0 (21.10)	29.1 (20.80)	25.0	0.0, 79.2	-12.9 (19.47)	-8.3	-58.3, 41.7	<=0.001***
WEEK 52	119	40.2 (21.33)	30.1 (21.32)	25.0	0.0, 87.5	-10.1 (20.35)	-8.3	-70.8, 37.5	<=0.001***
Low dose	68	39.3 (21.96)	30.7 (22.42)	29.2	0.0, 87.5	-8.6 (22.74)	-8.3	-70.8, 37.5	0.0027**
High dose	51	41.4 (20.62)	29.3 (19.95)	25.0	0.0, 87.5	-12.1 (16.65)	-12.5	-54.2, 25.0	<=0.001***

&: 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__4

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 (SD)	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-39 Emotional Well-being Domain Score									
BASELINE	243		30.3 (20.66)	25.0	0.0, 95.8				
Low dose	132		31.4 (21.68)	27.1	0.0, 95.8				
High dose	111		29.0 (19.39)	25.0	0.0, 87.5				
WEEK 6	196	29.4 (19.88)	26.4 (18.97)	25.0	0.0, 87.5	-3.0 (17.97)	-4.2	-58.3, 66.7	0.0206*
Low dose	106	30.0 (20.17)	26.5 (19.01)	25.0	0.0, 87.5	-3.6 (20.13)	-8.3	-58.3, 66.7	0.0702
High dose	90	28.7 (19.64)	26.4 (19.03)	20.8	0.0, 70.8	-2.3 (15.12)	-2.1	-37.5, 37.5	0.1500
WEEK 13	170	30.0 (20.09)	25.8 (17.88)	25.0	0.0, 83.3	-4.1 (17.38)	-4.2	-62.5, 50.0	0.0024**
Low dose	94	30.4 (20.63)	24.8 (18.97)	22.9	0.0, 83.3	-5.6 (17.57)	-4.2	-62.5, 41.7	0.0027**
High dose	76	29.4 (19.53)	27.1 (16.48)	25.0	0.0, 66.7	-2.3 (17.10)	-2.1	-54.2, 50.0	0.2441
WEEK 26	148	30.9 (20.32)	28.3 (20.64)	25.0	0.0, 91.7	-2.6 (17.14)	0.0	-66.7, 50.0	0.0651
Low dose	80	30.9 (20.74)	27.0 (20.77)	25.0	0.0, 91.7	-3.9 (19.10)	-4.2	-50.0, 50.0	0.0712
High dose	68	31.0 (19.97)	29.9 (20.53)	25.0	0.0, 75.0	-1.1 (14.48)	0.0	-66.7, 29.2	0.5321
WEEK 39	132	30.5 (20.40)	27.4 (20.00)	25.0	0.0, 87.5	-3.0 (19.07)	0.0	-66.7, 62.5	0.0702
Low dose	74	30.5 (20.36)	27.3 (20.47)	22.9	0.0, 87.5	-3.2 (20.51)	0.0	-62.5, 62.5	0.1825
High dose	58	30.5 (20.62)	27.7 (19.55)	25.0	0.0, 70.8	-2.8 (17.23)	0.0	-66.7, 37.5	0.2207
WEEK 52	119	30.5 (20.00)	27.1 (19.66)	25.0	0.0, 79.2	-3.4 (19.32)	0.0	-54.2, 50.0	0.0575
Low dose	68	31.1 (20.37)	27.0 (19.22)	27.1	0.0, 75.0	-4.1 (18.19)	0.0	-54.2, 45.8	0.0671
High dose	51	29.8 (19.67)	27.4 (20.43)	25.0	0.0, 79.2	-2.5 (20.87)	0.0	-50.0, 50.0	0.4056

&: 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__4

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 (SD)	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-39 Stigma Domain Score									
BASELINE	243		24.7 (23.82)	18.8	0.0, 100.0				
Low dose	132		26.1 (24.61)	18.8	0.0, 100.0				
High dose	111		23.1 (22.84)	12.5	0.0, 75.0				
WEEK 6	196	23.5 (22.48)	17.1 (19.75)	12.5	0.0, 75.0	-6.4 (19.74)	-6.3	-68.8, 56.3	<=0.001***
Low dose	106	24.5 (22.66)	18.3 (21.43)	12.5	0.0, 75.0	-6.1 (21.02)	-6.3	-56.3, 56.3	0.0033**
High dose	90	22.3 (22.33)	15.6 (17.56)	12.5	0.0, 75.0	-6.7 (18.22)	0.0	-68.8, 56.3	<=0.001***
WEEK 13	170	23.9 (23.04)	15.7 (19.31)	9.4	0.0, 100.0	-8.2 (20.46)	-6.3	-87.5, 75.0	<=0.001***
Low dose	94	23.9 (22.51)	16.5 (20.06)	9.4	0.0, 100.0	-7.4 (21.24)	-6.3	-87.5, 56.3	0.0011**
High dose	76	23.9 (23.84)	14.7 (18.42)	9.4	0.0, 93.8	-9.2 (19.54)	-6.3	-62.5, 75.0	<=0.001***
WEEK 26	148	24.0 (22.36)	16.9 (20.36)	12.5	0.0, 87.5	-7.1 (20.41)	-6.3	-75.0, 68.8	<=0.001***
Low dose	80	23.0 (21.11)	16.1 (17.67)	12.5	0.0, 75.0	-6.9 (20.87)	-6.3	-56.3, 68.8	0.0042**
High dose	68	25.3 (23.84)	17.9 (23.23)	6.3	0.0, 87.5	-7.4 (20.00)	0.0	-75.0, 37.5	0.0035**
WEEK 39	132	22.7 (21.15)	15.3 (19.27)	6.3	0.0, 81.3	-7.3 (21.09)	-6.3	-75.0, 62.5	<=0.001***
Low dose	74	21.6 (20.20)	16.0 (17.56)	12.5	0.0, 62.5	-5.6 (19.53)	-6.3	-75.0, 50.0	0.0165*
High dose	58	24.0 (22.42)	14.4 (21.37)	6.3	0.0, 81.3	-9.6 (22.89)	-6.3	-75.0, 62.5	0.0023**
WEEK 52	119	23.3 (21.76)	15.9 (20.04)	6.3	0.0, 75.0	-7.4 (22.47)	-6.3	-75.0, 50.0	<=0.001***
Low dose	68	21.7 (20.36)	17.1 (18.78)	12.5	0.0, 62.5	-4.6 (24.38)	0.0	-75.0, 50.0	0.1248
High dose	51	25.4 (23.53)	14.3 (21.70)	0.0	0.0, 75.0	-11.0 (19.27)	-6.3	-75.0, 31.3	<=0.001***

&: 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__4

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 (SD)	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-39 Social Support Domain Score									
BASELINE	218		12.4 (16.94)	8.3	0.0, 83.3				
Low dose	118		12.6 (18.19)	8.3	0.0, 83.3				
High dose	100		12.2 (15.42)	8.3	0.0, 58.3				
WEEK 6	174	11.4 (15.27)	10.6 (15.14)	0.0	0.0, 83.3	-0.8 (14.19)	0.0	-41.7, 66.7	0.4500
Low dose	93	11.6 (16.21)	10.8 (15.43)	0.0	0.0, 66.7	-0.8 (13.35)	0.0	-33.3, 33.3	0.5616
High dose	81	11.2 (14.20)	10.4 (14.88)	0.0	0.0, 83.3	-0.8 (15.17)	0.0	-41.7, 66.7	0.6267
WEEK 13	153	12.3 (15.74)	10.8 (15.47)	0.0	0.0, 75.0	-1.5 (16.90)	0.0	-58.3, 58.3	0.2660
Low dose	82	12.3 (16.31)	13.4 (18.18)	8.3	0.0, 75.0	1.1 (17.99)	0.0	-58.3, 58.3	0.5752
High dose	71	12.3 (15.16)	7.7 (10.94)	0.0	0.0, 41.7	-4.6 (15.09)	0.0	-50.0, 33.3	0.0128*
WEEK 26	132	13.2 (15.89)	14.2 (17.10)	8.3	0.0, 75.0	1.0 (14.96)	0.0	-41.7, 41.7	0.4392
Low dose	69	13.4 (17.04)	14.4 (17.96)	8.3	0.0, 66.7	1.0 (15.16)	0.0	-33.3, 41.7	0.5983
High dose	63	13.0 (14.65)	14.0 (16.25)	8.3	0.0, 75.0	1.1 (14.85)	0.0	-41.7, 41.7	0.5738
WEEK 39	117	13.0 (15.84)	14.0 (18.27)	8.3	0.0, 66.7	1.0 (15.33)	0.0	-33.3, 41.7	0.4830
Low dose	64	12.6 (16.47)	13.8 (18.68)	8.3	0.0, 66.7	1.2 (13.92)	0.0	-33.3, 41.7	0.5030
High dose	53	13.4 (15.19)	14.2 (17.95)	8.3	0.0, 66.7	0.8 (17.00)	0.0	-33.3, 41.7	0.7378
WEEK 52	103	12.9 (15.95)	14.3 (20.19)	8.3	0.0, 91.7	1.5 (18.21)	0.0	-41.7, 66.7	0.4188
Low dose	56	13.1 (17.10)	15.3 (20.21)	8.3	0.0, 75.0	2.2 (16.63)	0.0	-41.7, 50.0	0.3195
High dose	47	12.6 (14.63)	13.1 (20.32)	0.0	0.0, 91.7	0.5 (20.07)	0.0	-41.7, 66.7	0.8566

&: 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__4

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 (SD)	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-39 Cognition Domain Score									
BASELINE	243		26.8 (17.24)	25.0	0.0, 81.3				
Low dose	132		26.8 (17.75)	25.0	0.0, 81.3				
High dose	111		26.9 (16.68)	25.0	0.0, 68.8				
WEEK 6	196	26.3 (16.90)	21.8 (19.15)	18.8	0.0, 87.5	-4.5 (18.88)	-6.3	-50.0, 56.3	0.0011**
Low dose	106	25.9 (17.80)	22.1 (21.01)	12.5	0.0, 87.5	-3.9 (20.07)	-6.3	-50.0, 56.3	0.0485*
High dose	90	26.7 (15.87)	21.5 (16.82)	18.8	0.0, 81.3	-5.1 (17.47)	-6.3	-37.5, 56.3	0.0064**
WEEK 13	170	27.2 (17.72)	24.6 (18.58)	18.8	0.0, 75.0	-2.6 (17.02)	-3.1	-56.3, 50.0	0.0503
Low dose	94	27.1 (18.06)	24.1 (20.03)	18.8	0.0, 75.0	-2.9 (17.77)	-6.3	-56.3, 50.0	0.1137
High dose	76	27.4 (17.41)	25.2 (16.72)	25.0	0.0, 75.0	-2.1 (16.16)	0.0	-37.5, 37.5	0.2522
WEEK 26	148	27.4 (17.45)	26.5 (17.63)	25.0	0.0, 75.0	-0.9 (16.74)	0.0	-50.0, 43.8	0.5007
Low dose	80	26.8 (17.26)	25.9 (18.79)	18.8	0.0, 75.0	-0.9 (16.63)	0.0	-43.8, 43.8	0.6453
High dose	68	28.2 (17.76)	27.2 (16.26)	25.0	0.0, 75.0	-1.0 (16.99)	0.0	-50.0, 37.5	0.6253
WEEK 39	132	27.4 (17.48)	26.0 (18.19)	25.0	0.0, 75.0	-1.4 (17.83)	0.0	-50.0, 68.8	0.3780
Low dose	74	26.9 (17.55)	24.0 (17.65)	25.0	0.0, 75.0	-2.9 (18.94)	0.0	-50.0, 68.8	0.1962
High dose	58	28.0 (17.53)	28.6 (18.70)	25.0	0.0, 68.8	0.5 (16.28)	0.0	-50.0, 37.5	0.8019
WEEK 52	119	27.0 (17.88)	25.0 (18.45)	25.0	0.0, 81.3	-2.0 (18.12)	0.0	-56.3, 56.3	0.2201
Low dose	68	26.2 (17.55)	24.4 (18.04)	18.8	0.0, 62.5	-1.8 (18.42)	0.0	-56.3, 56.3	0.4135
High dose	51	28.2 (18.43)	25.9 (19.12)	25.0	0.0, 81.3	-2.3 (17.90)	0.0	-50.0, 37.5	0.3573

&: 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__4

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 (SD)	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-39 Communication Domain Score									
BASELINE	243		27.9 (21.82)	25.0	0.0, 100.0				
Low dose	132		26.3 (22.48)	25.0	0.0, 100.0				
High dose	111		29.9 (20.95)	25.0	0.0, 83.3				
WEEK 6	196	26.8 (21.13)	21.7 (20.52)	16.7	0.0, 83.3	-5.1 (19.58)	0.0	-83.3, 58.3	<=0.001***
Low dose	106	25.2 (20.94)	20.2 (21.82)	16.7	0.0, 83.3	-5.0 (20.30)	0.0	-83.3, 58.3	0.0122*
High dose	90	28.7 (21.31)	23.5 (18.85)	16.7	0.0, 66.7	-5.2 (18.80)	0.0	-58.3, 50.0	0.0105*
WEEK 13	170	27.4 (21.13)	21.9 (19.23)	16.7	0.0, 91.7	-5.5 (18.60)	0.0	-58.3, 41.7	<=0.001***
Low dose	94	24.6 (20.21)	17.5 (17.46)	12.5	0.0, 66.7	-7.1 (17.19)	-4.2	-58.3, 33.3	<=0.001***
High dose	76	30.8 (21.86)	27.3 (20.03)	25.0	0.0, 91.7	-3.5 (20.15)	0.0	-58.3, 41.7	0.1332
WEEK 26	148	28.7 (21.83)	22.5 (21.40)	16.7	0.0, 83.3	-6.2 (21.19)	0.0	-75.0, 50.0	<=0.001***
Low dose	80	26.5 (21.16)	19.1 (19.41)	16.7	0.0, 66.7	-7.4 (19.08)	-4.2	-75.0, 33.3	<=0.001***
High dose	68	31.3 (22.46)	26.5 (23.03)	20.8	0.0, 83.3	-4.8 (23.50)	0.0	-75.0, 50.0	0.0981
WEEK 39	132	28.7 (22.28)	24.5 (21.74)	16.7	0.0, 91.7	-4.2 (20.01)	0.0	-75.0, 50.0	0.0165*
Low dose	74	25.6 (21.34)	22.3 (21.64)	16.7	0.0, 91.7	-3.3 (18.80)	0.0	-66.7, 50.0	0.1395
High dose	58	32.8 (22.99)	27.3 (21.73)	25.0	0.0, 75.0	-5.5 (21.55)	0.0	-75.0, 33.3	0.0586
WEEK 52	119	28.4 (22.08)	26.2 (21.84)	25.0	0.0, 83.3	-2.2 (21.63)	0.0	-66.7, 41.7	0.2758
Low dose	68	25.4 (21.57)	23.8 (21.56)	16.7	0.0, 75.0	-1.6 (20.22)	0.0	-66.7, 41.7	0.5181
High dose	51	32.4 (22.34)	29.4 (22.01)	25.0	0.0, 83.3	-2.9 (23.56)	0.0	-66.7, 41.7	0.3769

&: 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__4

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 (SD)	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-39 Bodily Discomfort Domain Score									
BASELINE	243		42.9 (22.42)	41.7	0.0, 100.0				
Low dose	132		41.9 (23.65)	41.7	0.0, 100.0				
High dose	111		44.1 (20.91)	41.7	0.0, 91.7				
WEEK 6	196	42.1 (22.21)	28.6 (21.63)	25.0	0.0, 100.0	-13.5 (23.84)	-16.7	-66.7, 66.7	<=0.001***
Low dose	106	41.5 (23.34)	29.2 (20.93)	25.0	0.0, 75.0	-12.3 (24.32)	-8.3	-66.7, 66.7	<=0.001***
High dose	90	42.8 (20.91)	28.0 (22.53)	25.0	0.0, 100.0	-14.8 (23.33)	-16.7	-66.7, 50.0	<=0.001***
WEEK 13	170	41.6 (21.78)	28.2 (21.21)	25.0	0.0, 91.7	-13.3 (24.25)	-16.7	-66.7, 50.0	<=0.001***
Low dose	94	40.6 (22.84)	27.6 (20.08)	29.2	0.0, 75.0	-13.0 (25.82)	-8.3	-66.7, 50.0	<=0.001***
High dose	76	42.8 (20.47)	29.1 (22.63)	25.0	0.0, 91.7	-13.7 (22.31)	-16.7	-66.7, 41.7	<=0.001***
WEEK 26	148	41.6 (22.08)	29.8 (22.21)	25.0	0.0, 91.7	-11.7 (20.91)	-8.3	-58.3, 41.7	<=0.001***
Low dose	80	40.8 (23.41)	29.2 (23.57)	25.0	0.0, 91.7	-11.7 (21.40)	-8.3	-50.0, 33.3	<=0.001***
High dose	68	42.4 (20.55)	30.6 (20.64)	25.0	0.0, 83.3	-11.8 (20.48)	-16.7	-58.3, 41.7	<=0.001***
WEEK 39	132	40.2 (21.50)	27.7 (20.52)	25.0	0.0, 100.0	-12.5 (21.16)	-16.7	-66.7, 58.3	<=0.001***
Low dose	74	40.8 (23.27)	26.7 (21.01)	25.0	0.0, 91.7	-14.1 (23.16)	-16.7	-66.7, 58.3	<=0.001***
High dose	58	39.4 (19.17)	28.9 (20.00)	33.3	0.0, 100.0	-10.5 (18.31)	-8.3	-41.7, 33.3	<=0.001***
WEEK 52	119	39.8 (22.09)	28.1 (22.99)	25.0	0.0, 91.7	-11.7 (21.49)	-16.7	-66.7, 50.0	<=0.001***
Low dose	68	40.3 (23.68)	27.7 (22.37)	25.0	0.0, 91.7	-12.6 (23.01)	-16.7	-66.7, 50.0	<=0.001***
High dose	51	39.1 (19.96)	28.6 (23.99)	25.0	0.0, 91.7	-10.5 (19.43)	-8.3	-41.7, 33.3	<=0.001***

&: 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31　EQ-5D-5Lスコア（FAS）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 5

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 (SD)	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	229		2.8 (1.08)	3.0	1.0, 5.0				
Low dose	125		2.8 (1.11)	3.0	1.0, 5.0				
High dose	104		2.9 (1.03)	3.0	1.0, 5.0				
WEEK 6	175	2.8 (1.07)	2.0 (0.99)	2.0	1.0, 5.0	-0.7 (1.18)	-1.0	-4.0, 3.0	<=0.001***
Low dose	93	2.7 (1.09)	2.1 (1.05)	2.0	1.0, 5.0	-0.6 (1.21)	-1.0	-3.0, 3.0	<=0.001***
High dose	82	2.8 (1.06)	2.0 (0.92)	2.0	1.0, 5.0	-0.8 (1.15)	-1.0	-4.0, 2.0	<=0.001***
WEEK 13	146	2.7 (1.05)	2.1 (0.99)	2.0	1.0, 5.0	-0.6 (1.20)	-1.0	-4.0, 2.0	<=0.001***
Low dose	80	2.7 (1.09)	2.2 (1.04)	2.0	1.0, 5.0	-0.6 (1.16)	-1.0	-3.0, 2.0	<=0.001***
High dose	66	2.8 (1.01)	2.0 (0.93)	2.0	1.0, 4.0	-0.7 (1.25)	-1.0	-4.0, 2.0	<=0.001***
WEEK 26	128	2.8 (1.09)	2.0 (0.93)	2.0	1.0, 5.0	-0.8 (1.18)	-1.0	-3.0, 2.0	<=0.001***
Low dose	70	2.8 (1.14)	2.1 (0.99)	2.0	1.0, 5.0	-0.7 (1.17)	-1.0	-3.0, 1.0	<=0.001***
High dose	58	2.7 (1.04)	1.9 (0.86)	2.0	1.0, 4.0	-0.8 (1.19)	-1.0	-3.0, 2.0	<=0.001***
WEEK 39	116	2.8 (1.09)	2.1 (0.96)	2.0	1.0, 5.0	-0.6 (1.17)	-1.0	-3.0, 2.0	<=0.001***
Low dose	69	2.7 (1.16)	2.2 (1.04)	2.0	1.0, 5.0	-0.5 (1.23)	0.0	-3.0, 2.0	<=0.001***
High dose	47	2.8 (0.99)	2.0 (0.82)	2.0	1.0, 4.0	-0.8 (1.05)	-1.0	-3.0, 1.0	<=0.001***
WEEK 52	111	2.7 (1.12)	2.0 (0.99)	2.0	1.0, 5.0	-0.7 (1.28)	-1.0	-4.0, 2.0	<=0.001***
Low dose	64	2.7 (1.17)	2.0 (1.02)	2.0	1.0, 5.0	-0.7 (1.31)	-1.0	-4.0, 2.0	<=0.001***
High dose	47	2.7 (1.04)	2.0 (0.95)	2.0	1.0, 5.0	-0.7 (1.25)	-1.0	-4.0, 2.0	<=0.001***

&: 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__5

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 (SD)	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									
BASELINE	229		2.3 (1.03)	2.0	1.0, 5.0				
Low dose	125		2.3 (1.07)	2.0	1.0, 5.0				
High dose	104		2.3 (0.99)	2.0	1.0, 5.0				
WEEK 6	175	2.2 (0.98)	1.8 (0.86)	2.0	1.0, 5.0	-0.3 (1.09)	0.0	-4.0, 3.0	<=0.001***
Low dose	93	2.2 (1.02)	1.9 (0.94)	2.0	1.0, 5.0	-0.3 (1.12)	0.0	-3.0, 3.0	0.0234*
High dose	82	2.2 (0.93)	1.8 (0.77)	2.0	1.0, 4.0	-0.4 (1.06)	0.0	-4.0, 2.0	<=0.001***
WEEK 13	146	2.2 (1.01)	1.9 (0.91)	2.0	1.0, 5.0	-0.3 (1.06)	0.0	-4.0, 3.0	<=0.001***
Low dose	80	2.3 (1.06)	1.9 (0.94)	2.0	1.0, 5.0	-0.4 (1.03)	0.0	-3.0, 2.0	0.0024**
High dose	66	2.2 (0.95)	1.9 (0.89)	2.0	1.0, 4.0	-0.3 (1.10)	0.0	-4.0, 3.0	0.0165*
WEEK 26	128	2.3 (1.03)	1.8 (0.80)	2.0	1.0, 5.0	-0.5 (1.09)	0.0	-4.0, 2.0	<=0.001***
Low dose	70	2.3 (1.09)	1.8 (0.86)	2.0	1.0, 5.0	-0.5 (1.20)	0.0	-4.0, 2.0	0.0012**
High dose	58	2.3 (0.95)	1.7 (0.72)	2.0	1.0, 3.0	-0.5 (0.94)	0.0	-3.0, 1.0	<=0.001***
WEEK 39	116	2.3 (1.05)	1.8 (0.85)	2.0	1.0, 5.0	-0.5 (1.10)	0.0	-4.0, 2.0	<=0.001***
Low dose	69	2.3 (1.11)	1.9 (0.86)	2.0	1.0, 5.0	-0.4 (1.11)	0.0	-3.0, 2.0	0.0064**
High dose	47	2.3 (0.95)	1.7 (0.81)	1.0	1.0, 4.0	-0.6 (1.07)	0.0	-4.0, 1.0	<=0.001***
WEEK 52	111	2.2 (1.05)	1.7 (0.80)	2.0	1.0, 4.0	-0.5 (1.20)	0.0	-4.0, 3.0	<=0.001***
Low dose	64	2.2 (1.09)	1.8 (0.74)	2.0	1.0, 4.0	-0.4 (1.23)	0.0	-3.0, 3.0	0.0061**
High dose	47	2.2 (1.01)	1.6 (0.87)	1.0	1.0, 4.0	-0.5 (1.16)	0.0	-4.0, 2.0	0.0029**

&: 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__5

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 (SD)	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 Usual Activities									
BASELINE	229		2.8 (1.05)	3.0	1.0, 5.0				
Low dose	125		2.7 (1.11)	3.0	1.0, 5.0				
High dose	104		2.9 (0.96)	3.0	1.0, 5.0				
WEEK 6	175	2.7 (1.03)	2.2 (0.91)	2.0	1.0, 5.0	-0.6 (1.06)	0.0	-4.0, 2.0	<=0.001***
Low dose	93	2.6 (1.10)	2.2 (1.02)	2.0	1.0, 5.0	-0.4 (1.09)	0.0	-3.0, 2.0	<=0.001***
High dose	82	2.8 (0.94)	2.1 (0.78)	2.0	1.0, 4.0	-0.7 (1.01)	-1.0	-4.0, 1.0	<=0.001***
WEEK 13	146	2.7 (1.05)	2.1 (1.03)	2.0	1.0, 5.0	-0.6 (1.23)	-1.0	-4.0, 4.0	<=0.001***
Low dose	80	2.6 (1.13)	2.2 (1.10)	2.0	1.0, 5.0	-0.5 (1.25)	0.0	-3.0, 4.0	0.0014**
High dose	66	2.9 (0.94)	2.1 (0.94)	2.0	1.0, 4.0	-0.8 (1.19)	-1.0	-4.0, 3.0	<=0.001***
WEEK 26	128	2.8 (1.04)	2.1 (0.85)	2.0	1.0, 5.0	-0.7 (1.04)	-1.0	-3.0, 2.0	<=0.001***
Low dose	70	2.7 (1.14)	2.2 (0.90)	2.0	1.0, 5.0	-0.5 (1.11)	0.0	-3.0, 2.0	<=0.001***
High dose	58	2.9 (0.89)	2.0 (0.78)	2.0	1.0, 4.0	-0.9 (0.92)	-1.0	-3.0, 1.0	<=0.001***
WEEK 39	116	2.8 (1.07)	2.0 (0.90)	2.0	1.0, 5.0	-0.8 (1.13)	-1.0	-3.0, 2.0	<=0.001***
Low dose	69	2.7 (1.13)	2.1 (0.89)	2.0	1.0, 5.0	-0.6 (1.10)	-1.0	-3.0, 2.0	<=0.001***
High dose	47	3.0 (0.96)	1.8 (0.92)	2.0	1.0, 4.0	-1.2 (1.11)	-1.0	-3.0, 1.0	<=0.001***
WEEK 52	111	2.8 (1.08)	2.1 (0.98)	2.0	1.0, 5.0	-0.6 (1.23)	-1.0	-4.0, 2.0	<=0.001***
Low dose	64	2.7 (1.13)	2.2 (1.02)	2.0	1.0, 5.0	-0.5 (1.23)	0.0	-3.0, 2.0	0.0026**
High dose	47	2.9 (1.00)	2.0 (0.93)	2.0	1.0, 5.0	-0.9 (1.21)	-1.0	-4.0, 2.0	<=0.001***

&: 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__5

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 (SD)	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	229		2.4 (1.04)	2.0	1.0, 5.0				
Low dose	125		2.3 (1.07)	2.0	1.0, 5.0				
High dose	104		2.5 (0.99)	3.0	1.0, 5.0				
WEEK 6	175	2.4 (1.05)	1.9 (0.85)	2.0	1.0, 5.0	-0.5 (1.14)	0.0	-4.0, 3.0	<=0.001***
Low dose	93	2.4 (1.06)	2.0 (0.88)	2.0	1.0, 5.0	-0.4 (1.20)	0.0	-4.0, 3.0	0.0032**
High dose	82	2.5 (1.04)	1.9 (0.81)	2.0	1.0, 4.0	-0.6 (1.08)	0.0	-3.0, 2.0	<=0.001***
WEEK 13	146	2.4 (1.07)	1.9 (0.88)	2.0	1.0, 4.0	-0.5 (1.20)	0.0	-4.0, 2.0	<=0.001***
Low dose	80	2.3 (1.07)	1.9 (0.89)	2.0	1.0, 4.0	-0.4 (1.16)	0.0	-4.0, 2.0	0.0050**
High dose	66	2.5 (1.06)	2.0 (0.88)	2.0	1.0, 4.0	-0.6 (1.24)	-0.5	-4.0, 2.0	<=0.001***
WEEK 26	128	2.4 (1.09)	1.9 (0.93)	2.0	1.0, 5.0	-0.4 (1.24)	0.0	-4.0, 3.0	<=0.001***
Low dose	70	2.3 (1.11)	1.9 (1.00)	2.0	1.0, 5.0	-0.4 (1.20)	0.0	-4.0, 3.0	0.0087**
High dose	58	2.4 (1.08)	1.9 (0.85)	2.0	1.0, 4.0	-0.5 (1.30)	-1.0	-4.0, 2.0	0.0065**
WEEK 39	116	2.3 (1.11)	1.9 (0.82)	2.0	1.0, 4.0	-0.4 (1.19)	0.0	-4.0, 2.0	<=0.001***
Low dose	69	2.2 (1.10)	1.9 (0.89)	2.0	1.0, 4.0	-0.3 (1.17)	0.0	-4.0, 2.0	0.0556
High dose	47	2.4 (1.12)	1.8 (0.70)	2.0	1.0, 4.0	-0.6 (1.19)	0.0	-4.0, 2.0	0.0013**
WEEK 52	111	2.2 (1.10)	1.9 (0.88)	2.0	1.0, 5.0	-0.4 (1.21)	0.0	-4.0, 3.0	0.0028**
Low dose	64	2.2 (1.13)	1.9 (0.89)	2.0	1.0, 5.0	-0.3 (1.12)	0.0	-4.0, 1.0	0.0383*
High dose	47	2.2 (1.07)	1.8 (0.88)	2.0	1.0, 4.0	-0.4 (1.33)	0.0	-4.0, 3.0	0.0335*

&: 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__5

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 (SD)	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 Anxiety/Depression									
BASELINE	229		1.9 (0.91)	2.0	1.0, 4.0				
Low dose	125		1.8 (0.91)	2.0	1.0, 4.0				
High dose	104		2.0 (0.90)	2.0	1.0, 4.0				
WEEK 6	175	1.8 (0.89)	1.7 (0.83)	2.0	1.0, 5.0	-0.1 (1.02)	0.0	-2.0, 4.0	0.1853
Low dose	93	1.7 (0.85)	1.7 (0.88)	2.0	1.0, 5.0	0.0 (1.07)	0.0	-2.0, 4.0	0.7715
High dose	82	1.9 (0.93)	1.7 (0.77)	2.0	1.0, 4.0	-0.3 (0.95)	0.0	-2.0, 3.0	0.0172*
WEEK 13	146	1.8 (0.90)	1.7 (0.81)	2.0	1.0, 5.0	-0.1 (0.93)	0.0	-2.0, 4.0	0.0919
Low dose	80	1.8 (0.88)	1.8 (0.87)	2.0	1.0, 5.0	0.0 (0.89)	0.0	-2.0, 4.0	0.9007
High dose	66	1.9 (0.93)	1.6 (0.74)	1.5	1.0, 4.0	-0.3 (0.94)	0.0	-2.0, 2.0	0.0113*
WEEK 26	128	1.9 (0.92)	1.7 (0.86)	2.0	1.0, 5.0	-0.2 (0.88)	0.0	-2.0, 2.0	0.0132*
Low dose	70	1.8 (0.89)	1.8 (0.92)	2.0	1.0, 5.0	-0.0 (0.87)	0.0	-2.0, 2.0	0.7837
High dose	58	2.1 (0.93)	1.7 (0.80)	1.0	1.0, 4.0	-0.4 (0.86)	0.0	-2.0, 1.0	<=0.001***
WEEK 39	116	1.9 (0.88)	1.7 (0.71)	2.0	1.0, 4.0	-0.1 (0.96)	0.0	-3.0, 2.0	0.1242
Low dose	69	1.8 (0.85)	1.7 (0.68)	2.0	1.0, 3.0	-0.1 (0.87)	0.0	-2.0, 2.0	0.2704
High dose	47	1.9 (0.92)	1.8 (0.76)	2.0	1.0, 4.0	-0.2 (1.09)	0.0	-3.0, 2.0	0.2899
WEEK 52	111	1.8 (0.87)	1.7 (0.72)	2.0	1.0, 4.0	-0.1 (0.88)	0.0	-2.0, 2.0	0.2400
Low dose	64	1.8 (0.85)	1.8 (0.73)	2.0	1.0, 4.0	0.0 (0.85)	0.0	-2.0, 1.0	>0.999
High dose	47	1.9 (0.89)	1.7 (0.72)	2.0	1.0, 4.0	-0.2 (0.91)	0.0	-2.0, 2.0	0.0858

&: 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__5

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 (SD)	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 VAS									
BASELINE	229		57.0 (22.21)	60.0	8.0, 100.0				
Low dose	125		57.9 (22.75)	60.0	8.0, 100.0				
High dose	104		55.9 (21.61)	59.0	9.0, 99.0				
WEEK 6	175	58.5 (21.99)	68.4 (18.20)	70.0	1.0, 99.0	9.9 (24.87)	10.0	-90.0, 79.0	<=0.001***
Low dose	93	58.9 (22.42)	66.3 (19.74)	70.0	1.0, 95.0	7.5 (26.35)	9.0	-90.0, 67.0	0.0076**
High dose	82	58.2 (21.62)	70.8 (16.08)	70.0	21.0, 99.0	12.6 (22.91)	11.0	-34.0, 79.0	<=0.001***
WEEK 13	146	58.6 (22.12)	69.3 (18.90)	73.5	10.0, 100.0	10.7 (24.32)	10.0	-65.0, 90.0	<=0.001***
Low dose	80	58.7 (22.79)	67.6 (20.15)	72.5	10.0, 97.0	8.9 (25.06)	8.5	-65.0, 70.0	0.0021**
High dose	66	58.5 (21.46)	71.3 (17.18)	74.0	28.0, 100.0	12.8 (23.41)	11.0	-40.0, 90.0	<=0.001***
WEEK 26	128	58.5 (22.64)	71.4 (16.61)	75.0	10.0, 99.0	12.9 (22.30)	10.0	-39.0, 72.0	<=0.001***
Low dose	70	58.2 (23.31)	69.9 (17.32)	72.0	10.0, 94.0	11.7 (22.41)	10.0	-35.0, 72.0	<=0.001***
High dose	58	58.9 (22.00)	73.3 (15.65)	76.5	29.0, 99.0	14.3 (22.29)	14.5	-39.0, 71.0	<=0.001***
WEEK 39	116	59.0 (23.01)	71.1 (16.40)	75.0	18.0, 96.0	12.0 (23.65)	9.0	-49.0, 77.0	<=0.001***
Low dose	69	59.1 (22.80)	71.5 (16.46)	75.0	35.0, 96.0	12.4 (23.09)	10.0	-29.0, 77.0	<=0.001***
High dose	47	58.9 (23.56)	70.5 (16.48)	73.0	18.0, 93.0	11.6 (24.70)	5.0	-49.0, 63.0	0.0024**
WEEK 52	111	58.9 (22.27)	71.9 (16.27)	75.0	20.0, 100.0	13.0 (24.72)	8.0	-60.0, 71.0	<=0.001***
Low dose	64	59.4 (22.09)	73.0 (15.86)	75.0	20.0, 96.0	13.7 (25.34)	8.0	-60.0, 71.0	<=0.001***
High dose	47	58.3 (22.74)	70.4 (16.87)	73.0	30.0, 100.0	12.1 (24.08)	7.0	-35.0, 68.0	0.0012**

&: 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__5

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 (SD)	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	229		0.644 (0.1745)	0.666	-0.037, 1.000				
Low dose	125		0.654 (0.1854)	0.689	-0.024, 1.000				
High dose	104		0.631 (0.1604)	0.646	-0.037, 0.888				
WEEK 6	175	0.657 (0.1685)	0.742 (0.1506)	0.748	0.145, 1.000	0.085 (0.1870)	0.073	-0.592, 0.769	<=0.001***
Low dose	93	0.673 (0.1751)	0.732 (0.1689)	0.730	0.145, 1.000	0.060 (0.1921)	0.045	-0.592, 0.640	0.0035**
High dose	82	0.640 (0.1600)	0.753 (0.1269)	0.754	0.163, 1.000	0.113 (0.1780)	0.089	-0.446, 0.769	<=0.001***
WEEK 13	146	0.656 (0.1732)	0.746 (0.1678)	0.738	0.127, 1.000	0.090 (0.2092)	0.060	-0.683, 1.037	<=0.001***
Low dose	80	0.668 (0.1837)	0.732 (0.1831)	0.740	0.127, 1.000	0.064 (0.2153)	0.047	-0.683, 0.753	0.0098**
High dose	66	0.640 (0.1595)	0.762 (0.1468)	0.738	0.425, 1.000	0.122 (0.1984)	0.083	-0.242, 1.037	<=0.001***
WEEK 26	128	0.649 (0.1819)	0.745 (0.1439)	0.765	0.178, 1.000	0.096 (0.1795)	0.081	-0.322, 0.836	<=0.001***
Low dose	70	0.657 (0.1921)	0.731 (0.1568)	0.754	0.178, 1.000	0.074 (0.1771)	0.055	-0.322, 0.748	<=0.001***
High dose	58	0.640 (0.1700)	0.762 (0.1256)	0.777	0.393, 1.000	0.122 (0.1803)	0.097	-0.178, 0.836	<=0.001***
WEEK 39	116	0.651 (0.1851)	0.747 (0.1348)	0.756	0.178, 1.000	0.096 (0.1938)	0.044	-0.236, 0.890	<=0.001***
Low dose	69	0.661 (0.1945)	0.735 (0.1396)	0.756	0.178, 1.000	0.074 (0.1872)	0.027	-0.236, 0.660	0.0016**
High dose	47	0.637 (0.1713)	0.766 (0.1266)	0.756	0.540, 1.000	0.129 (0.2006)	0.076	-0.144, 0.890	<=0.001***
WEEK 52	111	0.661 (0.1868)	0.753 (0.1512)	0.756	0.126, 1.000	0.092 (0.2139)	0.059	-0.447, 1.037	<=0.001***
Low dose	64	0.666 (0.1971)	0.742 (0.1431)	0.746	0.306, 1.000	0.077 (0.2079)	0.042	-0.234, 0.748	0.0045**
High dose	47	0.655 (0.1737)	0.768 (0.1619)	0.778	0.126, 1.000	0.113 (0.2222)	0.097	-0.447, 1.037	0.0010**

&: 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32　PDQ-39スコア（FAS，日本人部分集団）：M15-741試験

[redacted]20[redacted] 10:50 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 4.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 (SD)	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-39 Summary Index Total Score									
BASELINE	27		34.9 (13.29)	34.0	12.8, 57.7				
Low dose	22		32.0 (12.18)	34.0	12.8, 57.7				
High dose	5		47.7 (10.93)	52.6	31.4, 56.4				
WEEK 6	19	34.0 (13.02)	33.2 (20.18)	29.5	1.9, 76.3	-0.8 (14.14)	-5.8	-15.8, 34.0	0.8007
Low dose	16	32.3 (12.74)	32.8 (21.02)	28.8	1.9, 76.3	0.5 (14.89)	-4.8	-15.8, 34.0	0.8875
High dose	3	43.2 (12.57)	35.0 (18.58)	29.5	19.9, 55.8	-8.1 (6.48)	-11.5	-12.2, -0.6	0.1624
WEEK 13	17	33.9 (13.41)	34.9 (17.78)	42.3	5.1, 69.9	1.0 (15.83)	-4.5	-21.8, 42.9	0.7890
Low dose	14	31.9 (13.14)	35.7 (17.88)	42.3	5.1, 69.9	3.8 (15.80)	-0.3	-14.7, 42.9	0.3806
High dose	3	43.2 (12.57)	31.2 (20.60)	33.3	9.6, 50.6	-12.0 (8.61)	-8.3	-21.8, -5.8	0.1377
WEEK 26	15	35.2 (13.18)	31.9 (16.64)	33.6	3.2, 56.4	-3.3 (11.78)	-4.5	-20.5, 19.2	0.2961
Low dose	12	33.3 (13.07)	32.4 (15.83)	34.1	3.2, 56.4	-0.9 (11.00)	-2.9	-17.3, 19.2	0.7897
High dose	3	43.2 (12.57)	30.1 (23.56)	23.1	10.9, 56.4	-13.0 (11.33)	-18.6	-20.5, 0.0	0.1845
WEEK 39	12	33.3 (13.93)	29.1 (18.68)	27.0	1.9, 64.1	-4.2 (12.22)	-5.4	-23.7, 14.7	0.2602
Low dose	9	30.0 (13.37)	28.1 (16.30)	29.6	1.9, 50.6	-1.9 (10.61)	-3.8	-18.6, 14.7	0.6094
High dose	3	43.2 (12.57)	32.1 (28.98)	24.4	7.7, 64.1	-11.1 (16.60)	-17.3	-23.7, 7.7	0.3659
WEEK 52	12	33.3 (13.93)	30.3 (20.46)	31.1	3.2, 76.9	-3.0 (13.38)	-2.9	-24.4, 20.5	0.4512
Low dose	9	30.0 (13.37)	27.1 (14.85)	27.6	3.2, 44.9	-3.0 (10.91)	0.0	-17.3, 9.0	0.4401
High dose	3	43.2 (12.57)	40.0 (35.11)	35.9	7.1, 76.9	-3.2 (22.55)	-5.8	-24.4, 20.5	0.8285

&: 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__4.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 (SD)	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-39 Mobility Domain Score									
BASELINE	27		50.0 (19.99)	47.5	7.5, 82.5				
Low dose	22		47.0 (19.92)	46.3	7.5, 80.0				
High dose	5		63.0 (15.95)	60.0	40.0, 82.5				
WEEK 6	19	49.5 (18.64)	47.6 (30.75)	42.5	0.0, 100.0	-1.8 (21.13)	-7.5	-25.0, 52.5	0.7084
Low dose	16	47.3 (18.06)	46.7 (31.61)	37.5	0.0, 100.0	-0.6 (22.52)	-6.3	-25.0, 52.5	0.9131
High dose	3	60.8 (21.26)	52.5 (31.22)	42.5	27.5, 87.5	-8.3 (11.81)	-12.5	-17.5, 5.0	0.3463
WEEK 13	17	49.4 (19.75)	52.9 (29.70)	55.0	5.0, 95.0	3.5 (22.66)	-2.5	-22.5, 67.5	0.5298
Low dose	14	47.0 (19.34)	53.2 (29.68)	57.5	5.0, 95.0	6.3 (23.47)	0.0	-22.5, 67.5	0.3372
High dose	3	60.8 (21.26)	51.7 (36.43)	47.5	17.5, 90.0	-9.2 (15.28)	-12.5	-22.5, 7.5	0.4078
WEEK 26	15	51.0 (19.13)	48.8 (26.12)	55.0	5.0, 87.5	-2.2 (17.42)	-5.0	-32.5, 22.5	0.6374
Low dose	12	48.5 (18.72)	50.6 (26.20)	56.3	5.0, 87.5	2.1 (16.54)	5.0	-32.5, 22.5	0.6711
High dose	3	60.8 (21.26)	41.7 (30.03)	40.0	12.5, 72.5	-19.2 (8.78)	-20.0	-27.5, -10.0	0.0634
WEEK 39	12	46.9 (19.10)	43.1 (26.57)	37.5	5.0, 82.5	-3.8 (18.14)	-3.8	-32.5, 22.5	0.4888
Low dose	9	42.2 (17.07)	42.5 (26.19)	40.0	5.0, 80.0	0.3 (18.22)	0.0	-32.5, 22.5	0.9646
High dose	3	60.8 (21.26)	45.0 (33.63)	35.0	17.5, 82.5	-15.8 (13.77)	-22.5	-25.0, 0.0	0.1846
WEEK 52	12	46.9 (19.10)	41.5 (30.55)	42.5	0.0, 100.0	-5.4 (19.85)	-8.8	-35.0, 20.0	0.3649
Low dose	9	42.2 (17.07)	38.9 (26.10)	42.5	0.0, 75.0	-3.3 (18.54)	-5.0	-32.5, 20.0	0.6043
High dose	3	60.8 (21.26)	49.2 (47.85)	42.5	5.0, 100.0	-11.7 (26.73)	-17.5	-35.0, 17.5	0.5286

&: 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__4.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 (SD)	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-39 Activities of Daily Living Domain Score									
BASELINE	27		38.7 (26.35)	29.2	0.0, 100.0				
Low dose	22		32.2 (24.34)	25.0	0.0, 100.0				
High dose	5		67.5 (11.56)	62.5	54.2, 83.3				
WEEK 6	19	34.6 (20.70)	41.0 (26.51)	37.5	0.0, 100.0	6.4 (23.99)	4.2	-29.2, 75.0	0.2630
Low dose	16	28.6 (16.24)	39.1 (27.76)	37.5	0.0, 100.0	10.4 (22.87)	6.2	-20.8, 75.0	0.0885
High dose	3	66.7 (7.22)	51.4 (18.79)	50.0	33.3, 70.8	-15.3 (20.55)	-25.0	-29.2, 8.3	0.3268
WEEK 13	17	36.3 (21.28)	42.4 (23.02)	41.7	4.2, 79.2	6.1 (26.73)	4.2	-50.0, 58.3	0.3585
Low dose	14	29.8 (17.05)	42.0 (21.89)	47.9	4.2, 75.0	12.2 (21.65)	8.3	-16.7, 58.3	0.0549
High dose	3	66.7 (7.22)	44.4 (33.42)	41.7	12.5, 79.2	-22.2 (34.69)	-33.3	-50.0, 16.7	0.3828
WEEK 26	15	39.4 (20.10)	35.0 (19.47)	37.5	8.3, 66.7	-4.4 (18.53)	0.0	-45.8, 20.8	0.3687
Low dose	12	32.6 (15.87)	33.0 (18.92)	35.4	8.3, 66.7	0.3 (14.70)	4.2	-29.2, 20.8	0.9363
High dose	3	66.7 (7.22)	43.1 (23.69)	50.0	16.7, 62.5	-23.6 (22.95)	-25.0	-45.8, 0.0	0.2167
WEEK 39	12	38.9 (22.43)	36.8 (25.43)	35.4	0.0, 79.2	-2.1 (28.29)	2.1	-58.3, 33.3	0.8033
Low dose	9	29.6 (17.11)	36.6 (22.90)	41.7	0.0, 62.5	6.9 (18.16)	4.2	-25.0, 33.3	0.2845
High dose	3	66.7 (7.22)	37.5 (38.19)	29.2	4.2, 79.2	-29.2 (40.18)	-45.8	-58.3, 16.7	0.3356
WEEK 52	12	38.9 (22.43)	38.5 (24.88)	43.8	0.0, 87.5	-0.3 (26.20)	-2.1	-54.2, 25.0	0.9642
Low dose	9	29.6 (17.11)	34.3 (19.18)	41.7	0.0, 54.2	4.6 (20.98)	8.3	-20.8, 25.0	0.5266
High dose	3	66.7 (7.22)	51.4 (40.04)	58.3	8.3, 87.5	-15.3 (39.60)	-16.7	-54.2, 25.0	0.5728

&: 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__4.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 (SD)	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-39 Emotional Well-being Domain Score									
BASELINE	27		31.6 (19.03)	25.0	12.5, 87.5				
Low dose	22		31.8 (19.27)	25.0	12.5, 87.5				
High dose	5		30.8 (20.11)	25.0	12.5, 62.5				
WEEK 6	19	33.1 (19.22)	35.1 (23.25)	37.5	0.0, 87.5	2.0 (26.55)	0.0	-50.0, 66.7	0.7496
Low dose	16	34.6 (20.17)	35.4 (24.01)	37.5	0.0, 87.5	0.8 (28.15)	-4.2	-50.0, 66.7	0.9131
High dose	3	25.0 (12.50)	33.3 (23.20)	29.2	12.5, 58.3	8.3 (18.16)	16.7	-12.5, 20.8	0.5101
WEEK 13	17	33.3 (20.25)	33.1 (22.89)	20.8	0.0, 83.3	-0.2 (19.40)	0.0	-45.8, 41.7	0.9591
Low dose	14	35.1 (21.48)	34.8 (23.89)	27.1	0.0, 83.3	-0.3 (20.77)	0.0	-45.8, 41.7	0.9581
High dose	3	25.0 (12.50)	25.0 (19.09)	20.8	8.3, 45.8	0.0 (14.43)	8.3	-16.7, 8.3	>0.999
WEEK 26	15	33.3 (21.42)	30.0 (25.16)	29.2	0.0, 91.7	-3.3 (22.72)	-8.3	-50.0, 33.3	0.5789
Low dose	12	35.4 (23.06)	32.3 (26.24)	33.3	0.0, 91.7	-3.1 (25.20)	-6.2	-50.0, 33.3	0.6758
High dose	3	25.0 (12.50)	20.8 (22.05)	12.5	4.2, 45.8	-4.2 (11.02)	-8.3	-12.5, 8.3	0.5799
WEEK 39	12	33.0 (22.51)	22.2 (18.32)	16.7	0.0, 50.0	-10.8 (19.01)	-12.5	-45.8, 16.7	0.0756
Low dose	9	35.6 (25.01)	22.7 (17.32)	20.8	0.0, 50.0	-13.0 (20.14)	-12.5	-45.8, 16.7	0.0896
High dose	3	25.0 (12.50)	20.8 (25.34)	8.3	4.2, 50.0	-4.2 (16.67)	-4.2	-20.8, 12.5	0.7072
WEEK 52	12	33.0 (22.51)	29.2 (23.30)	25.0	0.0, 75.0	-3.8 (23.06)	-4.2	-54.2, 33.3	0.5777
Low dose	9	35.6 (25.01)	26.4 (22.05)	25.0	0.0, 75.0	-9.3 (21.53)	-12.5	-54.2, 12.5	0.2330
High dose	3	25.0 (12.50)	37.5 (30.05)	29.2	12.5, 70.8	12.5 (23.20)	16.7	-12.5, 33.3	0.4492

&: 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__4.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 (SD)	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-39 Stigma Domain Score									
BASELINE	27		25.7 (19.87)	18.8	0.0, 75.0				
Low dose	22		21.9 (18.37)	18.8	0.0, 75.0				
High dose	5		42.5 (18.96)	50.0	12.5, 62.5				
WEEK 6	19	24.7 (21.70)	18.1 (18.39)	12.5	0.0, 75.0	-6.6 (21.09)	-6.3	-56.3, 50.0	0.1907
Low dose	16	22.3 (21.04)	16.8 (19.73)	12.5	0.0, 75.0	-5.5 (21.88)	-6.3	-56.3, 50.0	0.3332
High dose	3	37.5 (25.00)	25.0 (6.25)	25.0	18.8, 31.3	-12.5 (18.75)	-12.5	-31.3, 6.3	0.3675
WEEK 13	17	22.1 (19.02)	16.2 (20.14)	12.5	0.0, 75.0	-5.9 (27.82)	-6.3	-62.5, 56.3	0.3962
Low dose	14	18.8 (16.81)	17.9 (21.21)	12.5	0.0, 75.0	-0.9 (25.93)	-6.3	-56.3, 56.3	0.8994
High dose	3	37.5 (25.00)	8.3 (14.43)	0.0	0.0, 25.0	-29.2 (28.87)	-12.5	-62.5, -12.5	0.2222
WEEK 26	15	25.0 (18.30)	22.1 (25.32)	12.5	0.0, 87.5	-2.9 (22.89)	-6.3	-31.3, 50.0	0.6293
Low dose	12	21.9 (16.10)	19.8 (18.81)	15.6	0.0, 56.3	-2.1 (22.67)	-6.3	-31.3, 50.0	0.7561
High dose	3	37.5 (25.00)	31.3 (48.81)	6.3	0.0, 87.5	-6.3 (28.64)	-12.5	-31.3, 25.0	0.7418
WEEK 39	12	26.6 (19.06)	19.8 (22.43)	18.8	0.0, 81.3	-6.8 (17.57)	-6.3	-31.3, 25.0	0.2088
Low dose	9	22.9 (16.83)	16.7 (11.69)	18.8	0.0, 31.3	-6.3 (16.24)	-6.3	-31.3, 25.0	0.2815
High dose	3	37.5 (25.00)	29.2 (45.21)	6.3	0.0, 81.3	-8.3 (25.26)	-12.5	-31.3, 18.8	0.6254
WEEK 52	12	26.6 (19.06)	18.2 (20.55)	15.6	0.0, 75.0	-8.3 (13.93)	-6.3	-37.5, 12.5	0.0626
Low dose	9	22.9 (16.83)	14.6 (10.83)	18.8	0.0, 31.3	-8.3 (13.26)	-6.3	-37.5, 6.3	0.0961
High dose	3	37.5 (25.00)	29.2 (40.18)	12.5	0.0, 75.0	-8.3 (19.09)	-12.5	-25.0, 12.5	0.5286

&: 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__4.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 (SD)	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-39 Social Support Domain Score									
BASELINE	23		11.6 (16.43)	0.0	0.0, 58.3				
Low dose	19		10.5 (17.09)	0.0	0.0, 58.3				
High dose	4		16.7 (13.61)	16.7	0.0, 33.3				
WEEK 6	18	12.0 (17.20)	8.3 (11.79)	0.0	0.0, 33.3	-3.7 (9.14)	0.0	-25.0, 8.3	0.1037
Low dose	15	12.2 (18.60)	8.9 (12.78)	0.0	0.0, 33.3	-3.3 (9.86)	0.0	-25.0, 8.3	0.2115
High dose	3	11.1 (9.62)	5.6 (4.81)	8.3	0.0, 8.3	-5.6 (4.81)	-8.3	-8.3, 0.0	0.1835
WEEK 13	16	13.5 (17.71)	14.1 (21.24)	0.0	0.0, 66.7	0.5 (16.52)	0.0	-16.7, 50.0	0.9013
Low dose	13	14.1 (19.36)	17.3 (22.43)	16.7	0.0, 66.7	3.2 (16.85)	0.0	-16.7, 50.0	0.5059
High dose	3	11.1 (9.62)	0.0 (0.00)	0.0	0.0, 0.0	-11.1 (9.62)	-16.7	-16.7, 0.0	0.1835
WEEK 26	14	13.1 (17.82)	11.3 (12.49)	8.3	0.0, 33.3	-1.8 (16.72)	0.0	-33.3, 33.3	0.6960
Low dose	11	13.6 (19.82)	12.9 (13.62)	8.3	0.0, 33.3	-0.8 (18.05)	0.0	-33.3, 33.3	0.8920
High dose	3	11.1 (9.62)	5.6 (4.81)	8.3	0.0, 8.3	-5.6 (12.73)	-8.3	-16.7, 8.3	0.5286
WEEK 39	11	9.1 (12.61)	6.8 (10.42)	0.0	0.0, 25.0	-2.3 (11.24)	0.0	-25.0, 16.7	0.5175
Low dose	8	8.3 (14.09)	6.3 (9.71)	0.0	0.0, 25.0	-2.1 (11.57)	0.0	-25.0, 16.7	0.6263
High dose	3	11.1 (9.62)	8.3 (14.43)	0.0	0.0, 25.0	-2.8 (12.73)	0.0	-16.7, 8.3	0.7418
WEEK 52	11	9.1 (12.61)	11.4 (11.35)	8.3	0.0, 33.3	2.3 (15.85)	0.0	-25.0, 33.3	0.6446
Low dose	8	8.3 (14.09)	11.5 (11.73)	12.5	0.0, 33.3	3.1 (17.22)	0.0	-25.0, 33.3	0.6235
High dose	3	11.1 (9.62)	11.1 (12.73)	8.3	0.0, 25.0	-0.0 (14.43)	8.3	-16.7, 8.3	>0.999

&: 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__4.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 (SD)	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-39 Cognition Domain Score									
BASELINE	27		28.9 (14.10)	31.3	6.3, 62.5				
Low dose	22		26.7 (12.53)	25.0	6.3, 50.0				
High dose	5		38.8 (17.90)	37.5	12.5, 62.5				
WEEK 6	19	26.6 (12.98)	31.6 (23.52)	25.0	0.0, 81.3	4.9 (22.49)	-6.3	-25.0, 50.0	0.3517
Low dose	16	25.8 (12.68)	32.8 (25.46)	21.9	0.0, 81.3	7.0 (23.59)	-3.1	-25.0, 50.0	0.2517
High dose	3	31.3 (16.54)	25.0 (6.25)	25.0	18.8, 31.3	-6.3 (12.50)	-6.3	-18.8, 6.3	0.4778
WEEK 13	17	27.6 (12.71)	34.9 (21.20)	25.0	12.5, 75.0	7.4 (20.76)	6.3	-25.0, 50.0	0.1635
Low dose	14	26.8 (12.36)	38.4 (21.77)	31.3	18.8, 75.0	11.6 (20.04)	9.4	-25.0, 50.0	0.0494*
High dose	3	31.3 (16.54)	18.8 (6.25)	18.8	12.5, 25.0	-12.5 (10.83)	-18.8	-18.8, 0.0	0.1835
WEEK 26	15	26.3 (12.09)	30.4 (19.46)	25.0	6.3, 75.0	4.2 (16.14)	0.0	-18.8, 43.8	0.3343
Low dose	12	25.0 (11.31)	31.3 (21.49)	25.0	6.3, 75.0	6.3 (16.64)	3.1	-12.5, 43.8	0.2199
High dose	3	31.3 (16.54)	27.1 (9.55)	25.0	18.8, 37.5	-4.2 (13.01)	0.0	-18.8, 6.3	0.6349
WEEK 39	12	24.5 (12.35)	27.6 (16.09)	25.0	6.3, 62.5	3.1 (10.15)	3.1	-12.5, 25.0	0.3089
Low dose	9	22.2 (10.88)	22.9 (9.38)	25.0	6.3, 37.5	0.7 (8.53)	0.0	-12.5, 12.5	0.8131
High dose	3	31.3 (16.54)	41.7 (26.02)	50.0	12.5, 62.5	10.4 (13.01)	6.3	0.0, 25.0	0.2999
WEEK 52	12	24.5 (12.35)	24.5 (14.22)	21.9	0.0, 50.0	0.0 (9.61)	0.0	-18.8, 12.5	>0.999
Low dose	9	22.2 (10.88)	20.8 (10.83)	18.8	0.0, 37.5	-1.4 (10.26)	-6.3	-18.8, 12.5	0.6953
High dose	3	31.3 (16.54)	35.4 (20.09)	43.8	12.5, 50.0	4.2 (7.22)	0.0	0.0, 12.5	0.4226

&: 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__4.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 (SD)	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-39 Communication Domain Score									
BASELINE	27		23.5 (21.06)	16.7	0.0, 66.7				
Low dose	22		20.8 (19.54)	16.7	0.0, 66.7				
High dose	5		35.0 (25.95)	25.0	8.3, 66.7				
WEEK 6	19	25.0 (21.15)	21.5 (26.40)	16.7	0.0, 75.0	-3.5 (23.29)	0.0	-66.7, 41.7	0.5197
Low dose	16	24.0 (21.05)	21.4 (27.38)	12.5	0.0, 75.0	-2.6 (25.41)	0.0	-66.7, 41.7	0.6876
High dose	3	30.6 (25.46)	22.2 (25.46)	16.7	0.0, 50.0	-8.3 (0.00)	-8.3	-8.3, -8.3	<=0.001***
WEEK 13	17	25.0 (20.62)	18.6 (21.15)	16.7	0.0, 75.0	-6.4 (20.94)	0.0	-58.3, 25.0	0.2277
Low dose	14	23.8 (20.37)	14.3 (16.16)	12.5	0.0, 58.3	-9.5 (20.11)	0.0	-58.3, 25.0	0.0998
High dose	3	30.6 (25.46)	38.9 (33.68)	33.3	8.3, 75.0	8.3 (22.05)	16.7	-16.7, 25.0	0.5799
WEEK 26	15	27.2 (20.77)	17.8 (20.38)	8.3	0.0, 66.7	-9.4 (21.56)	-8.3	-66.7, 25.0	0.1119
Low dose	12	26.4 (20.67)	16.0 (16.46)	12.5	0.0, 58.3	-10.4 (23.60)	-8.3	-66.7, 25.0	0.1546
High dose	3	30.6 (25.46)	25.0 (36.32)	8.3	0.0, 66.7	-5.6 (12.73)	-8.3	-16.7, 8.3	0.5286
WEEK 39	12	27.1 (23.33)	22.9 (27.55)	12.5	0.0, 91.7	-4.2 (23.70)	0.0	-66.7, 33.3	0.5549
Low dose	9	25.9 (24.10)	22.2 (28.87)	16.7	0.0, 91.7	-3.7 (27.36)	0.0	-66.7, 33.3	0.6953
High dose	3	30.6 (25.46)	25.0 (28.87)	8.3	8.3, 58.3	-5.6 (9.62)	0.0	-16.7, 0.0	0.4226
WEEK 52	12	27.1 (23.33)	27.8 (28.28)	16.7	0.0, 83.3	0.7 (25.74)	4.2	-66.7, 33.3	0.9272
Low dose	9	25.9 (24.10)	24.1 (25.50)	16.7	0.0, 66.7	-1.9 (27.57)	0.0	-66.7, 33.3	0.8453
High dose	3	30.6 (25.46)	38.9 (39.38)	25.0	8.3, 83.3	8.3 (22.05)	16.7	-16.7, 25.0	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__4.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 (SD)	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-39 Bodily Discomfort Domain Score									
BASELINE	27		37.0 (24.93)	33.3	0.0, 100.0				
Low dose	22		34.1 (25.96)	33.3	0.0, 100.0				
High dose	5		50.0 (15.59)	50.0	33.3, 75.0				
WEEK 6	19	35.1 (24.78)	24.1 (21.50)	25.0	0.0, 66.7	-11.0 (20.61)	-8.3	-50.0, 25.0	0.0324*
Low dose	16	33.9 (26.78)	25.5 (22.66)	25.0	0.0, 66.7	-8.3 (21.30)	0.0	-50.0, 25.0	0.1385
High dose	3	41.7 (8.33)	16.7 (14.43)	8.3	8.3, 33.3	-25.0 (8.33)	-25.0	-33.3, -16.7	0.0351*
WEEK 13	17	30.9 (20.15)	25.5 (23.47)	16.7	0.0, 66.7	-5.4 (31.31)	0.0	-50.0, 50.0	0.4879
Low dose	14	28.6 (21.36)	26.8 (23.61)	25.0	0.0, 66.7	-1.8 (30.87)	0.0	-50.0, 50.0	0.8320
High dose	3	41.7 (8.33)	19.4 (26.79)	8.3	0.0, 50.0	-22.2 (33.68)	-41.7	-41.7, 16.7	0.3715
WEEK 26	15	32.8 (19.79)	23.3 (18.15)	25.0	0.0, 58.3	-9.4 (18.06)	-16.7	-41.7, 16.7	0.0623
Low dose	12	30.6 (21.42)	25.0 (18.80)	25.0	0.0, 58.3	-5.6 (17.16)	0.0	-33.3, 16.7	0.2861
High dose	3	41.7 (8.33)	16.7 (16.67)	16.7	0.0, 33.3	-25.0 (14.43)	-16.7	-41.7, -16.7	0.0955
WEEK 39	12	27.1 (17.45)	23.6 (23.79)	25.0	0.0, 75.0	-3.5 (27.17)	-12.5	-41.7, 58.3	0.6665
Low dose	9	22.2 (17.18)	24.1 (25.83)	25.0	0.0, 75.0	1.9 (26.93)	-8.3	-25.0, 58.3	0.8417
High dose	3	41.7 (8.33)	22.2 (20.97)	25.0	0.0, 41.7	-19.4 (25.46)	-25.0	-41.7, 8.3	0.3169
WEEK 52	12	27.1 (17.45)	24.3 (24.48)	20.8	0.0, 75.0	-2.8 (24.45)	0.0	-41.7, 33.3	0.7014
Low dose	9	22.2 (17.18)	18.5 (17.57)	16.7	0.0, 41.7	-3.7 (22.09)	0.0	-41.7, 33.3	0.6285
High dose	3	41.7 (8.33)	41.7 (38.19)	50.0	0.0, 75.0	0.0 (36.32)	16.7	-41.7, 25.0	>0.999

&: 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33　EQ-5D-5Lスコア（FAS，日本人部分集団）：M15-741試験

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ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.2 5.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 (SD)	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	26		3.5 (1.14)	4.0	1.0, 5.0				
Low dose	21		3.6 (1.08)	4.0	1.0, 5.0				
High dose	5		3.2 (1.48)	3.0	1.0, 5.0				
WEEK 6	18	3.4 (1.15)	2.6 (1.09)	3.0	1.0, 5.0	-0.8 (1.34)	-1.0	-3.0, 1.0	0.0172*
Low dose	15	3.7 (1.05)	2.7 (1.18)	3.0	1.0, 5.0	-1.0 (1.36)	-1.0	-3.0, 1.0	0.0131*
High dose	3	2.3 (1.15)	2.3 (0.58)	2.0	2.0, 3.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 13	17	3.5 (1.12)	2.8 (1.03)	3.0	1.0, 5.0	-0.8 (1.39)	-1.0	-3.0, 2.0	0.0379*
Low dose	14	3.8 (0.97)	2.9 (1.03)	3.0	1.0, 5.0	-0.9 (1.49)	-1.5	-3.0, 2.0	0.0366*
High dose	3	2.3 (1.15)	2.3 (1.15)	3.0	1.0, 3.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 26	15	3.7 (0.98)	2.2 (0.86)	2.0	1.0, 4.0	-1.5 (1.30)	-2.0	-3.0, 1.0	<=0.001***
Low dose	12	4.0 (0.60)	2.2 (0.94)	2.0	1.0, 4.0	-1.8 (1.11)	-2.0	-3.0, 0.0	<=0.001***
High dose	3	2.3 (1.15)	2.3 (0.58)	2.0	2.0, 3.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 39	12	3.7 (1.07)	2.6 (1.24)	2.5	1.0, 4.0	-1.1 (1.62)	-1.5	-3.0, 1.0	0.0410*
Low dose	9	4.1 (0.60)	2.4 (1.13)	2.0	1.0, 4.0	-1.7 (1.41)	-2.0	-3.0, 1.0	0.0077**
High dose	3	2.3 (1.15)	3.0 (1.73)	4.0	1.0, 4.0	0.7 (0.58)	1.0	0.0, 1.0	0.1835
WEEK 52	12	3.7 (1.07)	2.3 (1.36)	2.0	1.0, 5.0	-1.4 (1.78)	-1.5	-4.0, 2.0	0.0187*
Low dose	9	4.1 (0.60)	2.1 (1.17)	2.0	1.0, 4.0	-2.0 (1.50)	-2.0	-4.0, 1.0	0.0039**
High dose	3	2.3 (1.15)	2.7 (2.08)	2.0	1.0, 5.0	0.3 (1.53)	0.0	-1.0, 2.0	0.7418

&: 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__5.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 (SD)	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 Self-care									
BASELINE	26		3.0 (1.31)	3.0	1.0, 5.0				
Low dose	21		3.0 (1.32)	3.0	1.0, 5.0				
High dose	5		3.0 (1.41)	3.0	1.0, 5.0				
WEEK 6	18	2.9 (1.28)	2.3 (1.13)	2.0	1.0, 5.0	-0.6 (1.58)	0.0	-3.0, 2.0	0.1185
Low dose	15	3.0 (1.31)	2.3 (1.23)	2.0	1.0, 5.0	-0.7 (1.68)	0.0	-3.0, 2.0	0.1458
High dose	3	2.3 (1.15)	2.0 (0.00)	2.0	2.0, 2.0	-0.3 (1.15)	-1.0	-1.0, 1.0	0.6667
WEEK 13	17	3.0 (1.22)	2.6 (1.06)	3.0	1.0, 4.0	-0.4 (1.54)	0.0	-3.0, 2.0	0.2876
Low dose	14	3.1 (1.23)	2.6 (1.02)	2.5	1.0, 4.0	-0.6 (1.65)	-0.5	-3.0, 2.0	0.2178
High dose	3	2.3 (1.15)	2.7 (1.53)	3.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 26	15	3.2 (1.15)	1.9 (0.59)	2.0	1.0, 3.0	-1.3 (1.53)	-1.0	-4.0, 1.0	0.0064**
Low dose	12	3.4 (1.08)	1.8 (0.58)	2.0	1.0, 3.0	-1.6 (1.51)	-1.5	-4.0, 1.0	0.0039**
High dose	3	2.3 (1.15)	2.3 (0.58)	2.0	2.0, 3.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 39	12	3.4 (1.16)	2.3 (1.06)	2.0	1.0, 4.0	-1.2 (1.40)	-1.5	-3.0, 1.0	0.0150*
Low dose	9	3.8 (0.97)	2.1 (0.93)	2.0	1.0, 4.0	-1.7 (1.22)	-2.0	-3.0, 1.0	0.0035**
High dose	3	2.3 (1.15)	2.7 (1.53)	3.0	1.0, 4.0	0.3 (0.58)	0.0	0.0, 1.0	0.4226
WEEK 52	12	3.4 (1.16)	2.1 (1.00)	2.0	1.0, 4.0	-1.3 (1.44)	-1.5	-3.0, 1.0	0.0082**
Low dose	9	3.8 (0.97)	2.0 (0.87)	2.0	1.0, 3.0	-1.8 (1.30)	-2.0	-3.0, 1.0	0.0035**
High dose	3	2.3 (1.15)	2.3 (1.53)	2.0	1.0, 4.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999

&: 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__5.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 (SD)	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 Usual Activities									
BASELINE	26		3.5 (1.21)	4.0	1.0, 5.0				
Low dose	21		3.4 (1.28)	4.0	1.0, 5.0				
High dose	5		4.0 (0.71)	4.0	3.0, 5.0				
WEEK 6	18	3.6 (1.25)	2.6 (1.20)	2.0	1.0, 5.0	-1.0 (1.24)	-1.0	-3.0, 1.0	0.0032**
Low dose	15	3.5 (1.30)	2.5 (1.25)	2.0	1.0, 5.0	-0.9 (1.33)	-1.0	-3.0, 1.0	0.0170*
High dose	3	4.0 (1.00)	2.7 (1.15)	2.0	2.0, 4.0	-1.3 (0.58)	-1.0	-2.0, -1.0	0.0572
WEEK 13	17	3.6 (1.22)	2.6 (1.32)	2.0	1.0, 5.0	-1.0 (1.66)	-1.0	-3.0, 3.0	0.0243*
Low dose	14	3.6 (1.28)	2.6 (1.34)	2.0	1.0, 5.0	-0.9 (1.82)	-1.0	-3.0, 3.0	0.0782
High dose	3	4.0 (1.00)	2.7 (1.53)	3.0	1.0, 4.0	-1.3 (0.58)	-1.0	-2.0, -1.0	0.0572
WEEK 26	15	3.8 (1.08)	2.6 (1.06)	3.0	1.0, 4.0	-1.2 (1.37)	-1.0	-3.0, 2.0	0.0044**
Low dose	12	3.8 (1.14)	2.5 (1.17)	2.5	1.0, 4.0	-1.3 (1.48)	-1.0	-3.0, 2.0	0.0140*
High dose	3	4.0 (1.00)	3.0 (0.00)	3.0	3.0, 3.0	-1.0 (1.00)	-1.0	-2.0, 0.0	0.2254
WEEK 39	12	4.0 (0.74)	2.3 (0.97)	2.0	1.0, 4.0	-1.8 (0.97)	-2.0	-3.0, 0.0	<=0.001***
Low dose	9	4.0 (0.71)	2.2 (0.83)	2.0	1.0, 3.0	-1.8 (1.09)	-2.0	-3.0, 0.0	0.0012**
High dose	3	4.0 (1.00)	2.3 (1.53)	2.0	1.0, 4.0	-1.7 (0.58)	-2.0	-2.0, -1.0	0.0377*
WEEK 52	12	4.0 (0.74)	2.3 (1.23)	2.0	1.0, 5.0	-1.7 (1.30)	-2.0	-3.0, 1.0	0.0010**
Low dose	9	4.0 (0.71)	2.2 (0.97)	2.0	1.0, 4.0	-1.8 (1.39)	-2.0	-3.0, 1.0	0.0051**
High dose	3	4.0 (1.00)	2.7 (2.08)	2.0	1.0, 5.0	-1.3 (1.15)	-2.0	-2.0, 0.0	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__5.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 (SD)	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	26		2.8 (1.13)	3.0	1.0, 5.0				
Low dose	21		2.9 (1.15)	3.0	1.0, 5.0				
High dose	5		2.6 (1.14)	3.0	1.0, 4.0				
WEEK 6	18	3.0 (1.19)	2.0 (0.84)	2.0	1.0, 3.0	-1.0 (1.08)	-1.0	-4.0, 1.0	0.0011**
Low dose	15	3.1 (1.13)	1.9 (0.80)	2.0	1.0, 3.0	-1.2 (1.01)	-1.0	-4.0, 0.0	<=0.001***
High dose	3	2.3 (1.53)	2.3 (1.15)	3.0	1.0, 3.0	0.0 (1.00)	0.0	-1.0, 1.0	>0.999
WEEK 13	17	3.1 (1.20)	2.3 (1.10)	2.0	1.0, 4.0	-0.8 (1.64)	-1.0	-4.0, 2.0	0.0726
Low dose	14	3.2 (1.12)	2.2 (1.05)	2.0	1.0, 4.0	-1.0 (1.62)	-1.0	-4.0, 2.0	0.0377*
High dose	3	2.3 (1.53)	2.7 (1.53)	3.0	1.0, 4.0	0.3 (1.53)	0.0	-1.0, 2.0	0.7418
WEEK 26	15	3.2 (1.15)	2.4 (0.99)	2.0	1.0, 5.0	-0.8 (1.47)	-1.0	-4.0, 1.0	0.0541
Low dose	12	3.4 (1.00)	2.5 (1.00)	2.0	1.0, 5.0	-0.9 (1.31)	-1.0	-4.0, 1.0	0.0339*
High dose	3	2.3 (1.53)	2.0 (1.00)	2.0	1.0, 3.0	-0.3 (2.31)	1.0	-3.0, 1.0	0.8259
WEEK 39	12	3.3 (1.23)	2.2 (0.72)	2.0	1.0, 3.0	-1.2 (1.47)	-1.0	-4.0, 2.0	0.0187*
Low dose	9	3.7 (1.00)	2.1 (0.78)	2.0	1.0, 3.0	-1.6 (1.13)	-1.0	-4.0, 0.0	0.0033**
High dose	3	2.3 (1.53)	2.3 (0.58)	2.0	2.0, 3.0	0.0 (2.00)	0.0	-2.0, 2.0	>0.999
WEEK 52	12	3.3 (1.23)	2.1 (0.90)	2.0	1.0, 4.0	-1.3 (1.82)	-1.0	-4.0, 3.0	0.0362*
Low dose	9	3.7 (1.00)	2.0 (0.71)	2.0	1.0, 3.0	-1.7 (1.41)	-1.0	-4.0, 0.0	0.0077**
High dose	3	2.3 (1.53)	2.3 (1.53)	2.0	1.0, 4.0	0.0 (2.65)	-1.0	-2.0, 3.0	>0.999

&: 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__5.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 (SD)	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 Anxiety/Depression									
BASELINE	26		1.7 (0.96)	1.0	1.0, 4.0				
Low dose	21		1.8 (1.00)	1.0	1.0, 4.0				
High dose	5		1.6 (0.89)	1.0	1.0, 3.0				
WEEK 6	18	1.8 (1.06)	1.7 (1.08)	1.0	1.0, 5.0	-0.1 (1.60)	0.0	-2.0, 4.0	0.7725
Low dose	15	1.9 (1.10)	1.8 (1.15)	1.0	1.0, 5.0	-0.1 (1.77)	0.0	-2.0, 4.0	0.7744
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 13	17	1.8 (1.07)	1.9 (1.05)	2.0	1.0, 4.0	0.1 (0.97)	0.0	-2.0, 1.0	0.8050
Low dose	14	2.0 (1.11)	2.1 (1.07)	2.0	1.0, 4.0	0.1 (1.07)	0.0	-2.0, 1.0	0.8069
High dose	3	1.0 (0.00)	1.0 (0.00)	1.0	1.0, 1.0	0.0 (0.00)	0.0	0.0, 0.0	
WEEK 26	15	1.8 (1.08)	2.0 (1.07)	2.0	1.0, 4.0	0.2 (1.08)	0.0	-2.0, 2.0	0.4860
Low dose	12	2.0 (1.13)	2.1 (1.16)	2.0	1.0, 4.0	0.1 (1.16)	0.0	-2.0, 2.0	0.8088
High dose	3	1.0 (0.00)	1.7 (0.58)	2.0	1.0, 2.0	0.7 (0.58)	1.0	0.0, 1.0	0.1835
WEEK 39	12	1.7 (1.07)	1.5 (0.52)	1.5	1.0, 2.0	-0.2 (1.27)	0.0	-2.0, 1.0	0.6576
Low dose	9	1.9 (1.17)	1.3 (0.50)	1.0	1.0, 2.0	-0.6 (1.24)	0.0	-2.0, 1.0	0.2145
High dose	3	1.0 (0.00)	2.0 (0.00)	2.0	2.0, 2.0	1.0 (0.00)	1.0	1.0, 1.0	<=0.001***
WEEK 52	12	1.7 (1.07)	1.7 (0.78)	1.5	1.0, 3.0	0.0 (1.28)	0.0	-2.0, 2.0	>0.999
Low dose	9	1.9 (1.17)	1.6 (0.73)	1.0	1.0, 3.0	-0.3 (1.22)	0.0	-2.0, 1.0	0.4379
High dose	3	1.0 (0.00)	2.0 (1.00)	2.0	1.0, 3.0	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]

TABLE 14.2__5.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 (SD)	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 VAS									
BASELINE	26		43.7 (23.08)	39.5	8.0, 80.0				
Low dose	21		44.2 (23.26)	40.0	8.0, 80.0				
High dose	5		41.2 (24.75)	35.0	10.0, 78.0				
WEEK 6	18	42.7 (22.27)	60.4 (26.48)	65.0	8.0, 91.0	17.8 (29.10)	10.5	-20.0, 67.0	0.0190*
Low dose	15	40.5 (22.40)	60.0 (28.14)	70.0	8.0, 91.0	19.5 (31.69)	13.0	-20.0, 67.0	0.0316*
High dose	3	53.7 (22.05)	62.7 (20.23)	52.0	50.0, 86.0	9.0 (5.57)	8.0	4.0, 15.0	0.1074
WEEK 13	17	41.1 (21.85)	60.6 (23.41)	60.0	13.0, 95.0	19.5 (27.72)	17.0	-23.0, 70.0	0.0103*
Low dose	14	38.4 (21.64)	59.3 (23.89)	66.5	13.0, 88.0	20.9 (30.32)	15.0	-23.0, 70.0	0.0227*
High dose	3	53.7 (22.05)	66.7 (24.66)	55.0	50.0, 95.0	13.0 (9.64)	17.0	2.0, 20.0	0.1447
WEEK 26	15	39.9 (22.77)	64.9 (24.14)	70.0	10.0, 90.0	24.9 (32.93)	25.0	-39.0, 72.0	0.0109*
Low dose	12	36.5 (22.52)	67.0 (25.19)	73.0	10.0, 90.0	30.5 (29.84)	27.5	-20.0, 72.0	0.0046**
High dose	3	53.7 (22.05)	56.3 (21.22)	50.0	39.0, 80.0	2.7 (42.00)	2.0	-39.0, 45.0	0.9225
WEEK 39	12	39.9 (20.58)	70.9 (18.89)	75.0	35.0, 95.0	31.0 (31.78)	21.5	-15.0, 77.0	0.0062**
Low dose	9	35.3 (19.14)	72.0 (20.65)	75.0	35.0, 95.0	36.7 (33.43)	28.0	-15.0, 77.0	0.0110*
High dose	3	53.7 (22.05)	67.7 (15.37)	75.0	50.0, 78.0	14.0 (22.54)	2.0	0.0, 40.0	0.3945
WEEK 52	12	39.9 (20.58)	71.3 (20.58)	79.5	40.0, 96.0	31.4 (32.33)	28.5	-8.0, 71.0	0.0063**
Low dose	9	35.3 (19.14)	76.2 (16.32)	80.0	46.0, 96.0	40.9 (31.74)	50.0	-4.0, 71.0	0.0048**
High dose	3	53.7 (22.05)	56.7 (28.87)	40.0	40.0, 90.0	3.0 (10.15)	5.0	-8.0, 12.0	0.6596

&: 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__5.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 (SD)	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	26		0.515 (0.2449)	0.540	-0.024, 1.000				
Low dose	21		0.514 (0.2510)	0.540	-0.024, 1.000				
High dose	5		0.520 (0.2445)	0.540	0.142, 0.825				
WEEK 6	18	0.529 (0.2523)	0.680 (0.1879)	0.721	0.145, 0.888	0.151 (0.2480)	0.107	-0.202, 0.640	0.0192*
Low dose	15	0.506 (0.2652)	0.671 (0.2060)	0.717	0.145, 0.888	0.165 (0.2641)	0.067	-0.202, 0.640	0.0298*
High dose	3	0.639 (0.1630)	0.722 (0.0023)	0.723	0.719, 0.723	0.082 (0.1622)	0.146	-0.102, 0.203	0.4719
WEEK 13	17	0.512 (0.2503)	0.636 (0.2050)	0.630	0.320, 1.000	0.123 (0.3250)	0.057	-0.301, 0.753	0.1371
Low dose	14	0.485 (0.2617)	0.619 (0.2003)	0.638	0.320, 1.000	0.133 (0.3579)	0.041	-0.301, 0.753	0.1864
High dose	3	0.639 (0.1630)	0.716 (0.2526)	0.630	0.517, 1.000	0.076 (0.0906)	0.057	-0.003, 0.175	0.2817
WEEK 26	15	0.478 (0.2308)	0.668 (0.1459)	0.647	0.446, 1.000	0.190 (0.2655)	0.180	-0.178, 0.748	0.0151*
Low dose	12	0.438 (0.2326)	0.661 (0.1606)	0.608	0.446, 1.000	0.223 (0.2732)	0.199	-0.171, 0.748	0.0163*
High dose	3	0.639 (0.1630)	0.694 (0.0760)	0.654	0.647, 0.782	0.055 (0.2211)	0.081	-0.178, 0.262	0.7086
WEEK 39	12	0.450 (0.2492)	0.705 (0.1258)	0.729	0.540, 0.880	0.255 (0.2646)	0.260	-0.113, 0.660	0.0066**
Low dose	9	0.386 (0.2464)	0.725 (0.1181)	0.729	0.561, 0.880	0.339 (0.2535)	0.286	-0.113, 0.660	0.0039**
High dose	3	0.639 (0.1630)	0.643 (0.1537)	0.570	0.540, 0.820	0.004 (0.0422)	-0.005	-0.033, 0.050	0.8848
WEEK 52	12	0.450 (0.2492)	0.720 (0.2414)	0.728	0.126, 1.000	0.270 (0.3471)	0.247	-0.447, 0.748	0.0207*
Low dose	9	0.386 (0.2464)	0.759 (0.1557)	0.738	0.559, 1.000	0.373 (0.2945)	0.298	-0.145, 0.748	0.0052**
High dose	3	0.639 (0.1630)	0.601 (0.4420)	0.678	0.126, 1.000	-0.038 (0.3543)	0.158	-0.447, 0.175	0.8698

&: 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34　有害事象の概要（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:57 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period	N=132	N=112	N=244
Subjects with:			
Any TEAE	122 (92.4)	108 (96.4)	230 (94.3)
Any severe TEAE	27 (20.5)	36 (32.1)	63 (25.8)
Any TEAE that is considered associated with study drug$	118 (89.4)	106 (94.6)	224 (91.8)
Any TEAE that is considered associated with product complaint$	91 (68.9)	82 (73.2)	173 (70.9)
ABBV-951	52 (39.4)	44 (39.3)	96 (39.3)
Infusion pump	9 (6.8)	9 (8.0)	18 (7.4)
Vial adapter	0	1 (0.9)	1 (0.4)
Syringes	0	0	0
[redacted] infusion set (total)	51 (38.6)	41 (36.6)	92 (37.7)
[redacted] infusion set 6 mm	37 (28.0)	26 (23.2)	63 (25.8)
[redacted] infusion set 9 mm	25 (18.9)	24 (21.4)	49 (20.1)
Neria guard infusion set (total)	14 (10.6)	18 (16.1)	32 (13.1)
Neria guard infusion set 6 mm	8 (6.1)	9 (8.0)	17 (7.0)
Neria guard infusion set 9 mm	9 (6.8)	14 (12.5)	23 (9.4)
[redacted]	3 (2.3)	4 (3.6)	7 (2.9)
Any TEAE that is considered associated with loading dose$	2 (1.5)	5 (4.5)	7 (2.9)
Any TEAE that is considered associated with rescue dose$	4 (3.0)	8 (7.1)	12 (4.9)
Any TEAE that is considered associated with COVID-19 infection	2 (1.5)	1 (0.9)	3 (1.2)
Any TEAE leading to prematurely discontinuation of study drug	33 (25.0)	30 (26.8)	63 (25.8)
Any TEAE leading to death (fatal TEAE)	0	3 (2.7)	3 (1.2)
Any serious TEAE	33 (25.0)	30 (26.8)	63 (25.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	14 (10.6)	8 (7.1)	22 (9.0)
Possible	6 (4.5)	5 (4.5)	11 (4.5)
Probable	5 (3.8)	3 (2.7)	8 (3.3)
Causal relationship	7 (5.3)	2 (1.8)	9 (3.7)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.8)	1 (0.9)	2 (0.8)
Possible	1 (0.8)	1 (0.9)	2 (0.8)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (1.5)	1 (0.9)	3 (1.2)
Possible	1 (0.8)	1 (0.9)	2 (0.8)
Probable	0	0	0
Causal relationship	1 (0.8)	0	1 (0.4)
Any SAE that is considered associated with product complaint$	11 (8.3)	9 (8.0)	20 (8.2)
ABBV-951	4 (3.0)	4 (3.6)	8 (3.3)
Infusion pump	2 (1.5)	2 (1.8)	4 (1.6)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (2.3)	2 (1.8)	5 (2.0)
[redacted] infusion set 6 mm	2 (1.5)	1 (0.9)	3 (1.2)
[redacted] infusion set 9 mm	1 (0.8)	1 (0.9)	2 (0.8)
Neria guard infusion set (total)	2 (1.5)	1 (0.9)	3 (1.2)
Neria guard infusion set 6 mm	2 (1.5)	1 (0.9)	3 (1.2)
Neria guard infusion set 9 mm	0	0	0
[redacted]	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	2 (1.8)	2 (0.8)
Possible	0	2 (1.8)	2 (0.8)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	0	2 (1.8)	2 (0.8)
Possible	0	2 (1.8)	2 (0.8)
Probable	0	0	0
Causal relationship	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
& For subjects with AE onset date later than [redacted], 20[redacted].

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	5 (4.5)	5 (2.0)
All TE-deaths	0	3 (2.7)	3 (1.2)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (1.5)	6 (5.4)	8 (3.3)
AESI: weight loss	12 (9.1)	15 (13.4)	27 (11.1)
AESI: hallucinations/psychosis	32 (24.2)	29 (25.9)	61 (25.0)
AESI: somnolence	9 (6.8)	3 (2.7)	12 (4.9)
AESI: infusion site related infections	42 (31.8)	44 (39.3)	86 (35.2)
AESI: infusion site related non infection reactions	104 (78.8)	96 (85.7)	200 (82.0)
AESI: falls and associated injuries	36 (27.3)	37 (33.0)	73 (29.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period	N=132	N=112	N=244
Subjects with:			
Any TEAE	106 (80.3)	97 (86.6)	203 (83.2)
Any severe TEAE	11 (8.3)	10 (8.9)	21 (8.6)
Any TEAE that is considered associated with study drug$	97 (73.5)	95 (84.8)	192 (78.7)
Any TEAE that is considered associated with product complaint$	67 (50.8)	63 (56.3)	130 (53.3)
ABBV-951	38 (28.8)	32 (28.6)	70 (28.7)
Infusion pump	3 (2.3)	2 (1.8)	5 (2.0)
Vial adapter	0	1 (0.9)	1 (0.4)
Syringes	0	0	0
[redacted] infusion set (total)	37 (28.0)	31 (27.7)	68 (27.9)
[redacted] infusion set 6 mm	27 (20.5)	15 (13.4)	42 (17.2)
[redacted] infusion set 9 mm	15 (11.4)	17 (15.2)	32 (13.1)
Neria guard infusion set (total)	6 (4.5)	7 (6.3)	13 (5.3)
Neria guard infusion set 6 mm	3 (2.3)	5 (4.5)	8 (3.3)
Neria guard infusion set 9 mm	3 (2.3)	4 (3.6)	7 (2.9)
[redacted]	2 (1.5)	2 (1.8)	4 (1.6)
Any TEAE that is considered associated with loading dose$	2 (1.5)	3 (2.7)	5 (2.0)
Any TEAE that is considered associated with rescue dose$	2 (1.5)	2 (1.8)	4 (1.6)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	17 (12.9)	10 (8.9)	27 (11.1)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	11 (8.3)	6 (5.4)	17 (7.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	6 (4.5)	2 (1.8)	8 (3.3)
Possible	3 (2.3)	1 (0.9)	4 (1.6)
Probable	0	1 (0.9)	1 (0.4)
Causal relationship	3 (2.3)	0	3 (1.2)
Any SAE that is considered associated with [redacted] infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	3 (2.3)	2 (1.8)	5 (2.0)
ABBV-951	2 (1.5)	0	2 (0.8)
Infusion pump	1 (0.8)	0	1 (0.4)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	2 (1.8)	2 (0.8)
[redacted] infusion set 6 mm	0	1 (0.9)	1 (0.4)
[redacted] infusion set 9 mm	0	1 (0.9)	1 (0.4)
Neria guard infusion set (total)	0	0	0
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	0	0	0
[redacted]	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
& For subjects with AE onset date later than [redacted], 20[redacted].

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	0	0
All TE-deaths	0	0	0
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (0.8)	1 (0.9)	2 (0.8)
AESI: hallucinations/psychosis	17 (12.9)	8 (7.1)	25 (10.2)
AESI: somnolence	2 (1.5)	2 (1.8)	4 (1.6)
AESI: infusion site related infections	11 (8.3)	18 (16.1)	29 (11.9)
AESI: infusion site related non infection reactions	88 (66.7)	82 (73.2)	170 (69.7)
AESI: falls and associated injuries	19 (14.4)	19 (17.0)	38 (15.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Subjects with:			
Any TEAE	100 (90.1)	89 (93.7)	189 (91.7)
Any severe TEAE	19 (17.1)	29 (30.5)	48 (23.3)
Any TEAE that is considered associated with study drug$	90 (81.1)	84 (88.4)	174 (84.5)
Any TEAE that is considered associated with product complaint$	65 (58.6)	64 (67.4)	129 (62.6)
ABBV-951	31 (27.9)	36 (37.9)	67 (32.5)
Infusion pump	6 (5.4)	7 (7.4)	13 (6.3)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	33 (29.7)	29 (30.5)	62 (30.1)
[redacted] infusion set 6 mm	20 (18.0)	16 (16.8)	36 (17.5)
[redacted] infusion set 9 mm	18 (16.2)	17 (17.9)	35 (17.0)
Neria guard infusion set (total)	13 (11.7)	15 (15.8)	28 (13.6)
Neria guard infusion set 6 mm	6 (5.4)	7 (7.4)	13 (6.3)
Neria guard infusion set 9 mm	8 (7.2)	12 (12.6)	20 (9.7)
[redacted]	1 (0.9)	2 (2.1)	3 (1.5)
Any TEAE that is considered associated with loading dose$	0	2 (2.1)	2 (1.0)
Any TEAE that is considered associated with rescue dose$	2 (1.8)	6 (6.3)	8 (3.9)
Any TEAE that is considered associated with COVID-19 infection	2 (1.8)	1 (1.1)	3 (1.5)
Any TEAE leading to prematurely discontinuation of study drug	17 (15.3)	20 (21.1)	37 (18.0)
Any TEAE leading to death (fatal TEAE)	0	3 (3.2)	3 (1.5)
Any serious TEAE	23 (20.7)	26 (27.4)	49 (23.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	8 (7.2)	7 (7.4)	15 (7.3)
Possible	3 (2.7)	4 (4.2)	7 (3.4)
Probable	5 (4.5)	2 (2.1)	7 (3.4)
Causal relationship	4 (3.6)	2 (2.1)	6 (2.9)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.9)	1 (1.1)	2 (1.0)
Possible	1 (0.9)	1 (1.1)	2 (1.0)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (1.8)	1 (1.1)	3 (1.5)
Possible	1 (0.9)	1 (1.1)	2 (1.0)
Probable	0	0	0
Causal relationship	1 (0.9)	0	1 (0.5)
Any SAE that is considered associated with product complaint$	8 (7.2)	7 (7.4)	15 (7.3)
ABBV-951	2 (1.8)	4 (4.2)	6 (2.9)
Infusion pump	1 (0.9)	2 (2.1)	3 (1.5)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (2.7)	0	3 (1.5)
[redacted] infusion set 6 mm	2 (1.8)	0	2 (1.0)
[redacted] infusion set 9 mm	1 (0.9)	0	1 (0.5)
Neria guard infusion set (total)	2 (1.8)	1 (1.1)	3 (1.5)
Neria guard infusion set 6 mm	2 (1.8)	1 (1.1)	3 (1.5)
Neria guard infusion set 9 mm	0	0	0
[redacted]	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	2 (2.1)	2 (1.0)
Possible	0	2 (2.1)	2 (1.0)
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	0	2 (2.1)	2 (1.0)
Possible	0	2 (2.1)	2 (1.0)
Probable	0	0	0
Causal relationship	0	0	0

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
$ As assessed by investigator.
& For subjects with AE onset date later than [redacted], 20[redacted].

Program Source Code: [redacted]

TABLE 14.3__1.1

Overview of Treatment-Emergent Adverse Events and All Deaths by Time Interval
(Safety Analysis Set)

	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	3 (3.2)	3 (1.5)
All TE-deaths	0	3 (3.2)	3 (1.5)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (1.8)	6 (6.3)	8 (3.9)
AESI: weight loss	11 (9.9)	14 (14.7)	25 (12.1)
AESI: hallucinations/psychosis	23 (20.7)	23 (24.2)	46 (22.3)
AESI: somnolence	8 (7.2)	1 (1.1)	9 (4.4)
AESI: infusion site related infections	34 (30.6)	34 (35.8)	68 (33.0)
AESI: infusion site related non infection reactions	64 (57.7)	71 (74.7)	135 (65.5)
AESI: falls and associated injuries	22 (19.8)	25 (26.3)	47 (22.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.
Includes non treatment-emergent deaths.

Program Source Code: [redacted]

表35　すべての有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 10:56 <[redacted]>
ABBV-951
STUDY M15-741 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0153 - CLINICAL/STATISTICAL

TABLE 14.3 1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=132	N=112	N=244
Any adverse event	122 (92.4)	108 (96.4)	230 (94.3)
血液およびリンパ系障害	1 (0.8)	3 (2.7)	4 (1.6)
大球性貧血	0	1 (0.9)	1 (0.4)
凝血異常	0	1 (0.9)	1 (0.4)
リンパ節症	1 (0.8)	0	1 (0.4)
縦隔リンパ節腫脹	0	1 (0.9)	1 (0.4)
心臓障害	5 (3.8)	8 (7.1)	13 (5.3)
急性心筋梗塞	1 (0.8)	0	1 (0.4)
狭心症	1 (0.8)	0	1 (0.4)
心房細動	0	2 (1.8)	2 (0.8)
徐脈	0	1 (0.9)	1 (0.4)
心停止	1 (0.8)	0	1 (0.4)
心肺停止	0	1 (0.9)	1 (0.4)
冠動脈疾患	1 (0.8)	1 (0.9)	2 (0.8)
冠動脈狭窄	1 (0.8)	0	1 (0.4)
期外収縮	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
心臓障害 (Cont.)			
左室肥大	0	1 (0.9)	1 (0.4)
心筋梗塞	1 (0.8)	0	1 (0.4)
動悸	0	2 (1.8)	2 (0.8)
頻脈	1 (0.8)	0	1 (0.4)
耳および迷路障害	4 (3.0)	4 (3.6)	8 (3.3)
感音性難聴	1 (0.8)	0	1 (0.4)
乗物酔い	0	1 (0.9)	1 (0.4)
回転性めまい	3 (2.3)	2 (1.8)	5 (2.0)
頭位性回転性めまい	0	1 (0.9)	1 (0.4)
眼障害	8 (6.1)	8 (7.1)	16 (6.6)
白内障	2 (1.5)	2 (1.8)	4 (1.6)
複視	3 (2.3)	1 (0.9)	4 (1.6)
ドライアイ	1 (0.8)	3 (2.7)	4 (1.6)
緑内障	1 (0.8)	1 (0.9)	2 (0.8)
眼窩周囲痛	0	1 (0.9)	1 (0.4)
眼窩周囲腫脹	0	2 (1.8)	2 (0.8)
網膜裂孔	2 (1.5)	0	2 (0.8)
霧視	1 (0.8)	0	1 (0.4)
視野欠損	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害	27 (20.5)	29 (25.9)	56 (23.0)
腹部膨満	1 (0.8)	3 (2.7)	4 (1.6)
腹痛	2 (1.5)	1 (0.9)	3 (1.2)
上腹部痛	1 (0.8)	1 (0.9)	2 (0.8)
アフタ性潰瘍	1 (0.8)	0	1 (0.4)
呼気臭	2 (1.5)	1 (0.9)	3 (1.2)
虚血性大腸炎	1 (0.8)	0	1 (0.4)
便秘	8 (6.1)	12 (10.7)	20 (8.2)
齲歯	1 (0.8)	0	1 (0.4)
下痢	6 (4.5)	3 (2.7)	9 (3.7)
口内乾燥	3 (2.3)	5 (4.5)	8 (3.3)
消化不良	1 (0.8)	0	1 (0.4)
嚥下障害	0	1 (0.9)	1 (0.4)
糞塊	0	1 (0.9)	1 (0.4)
排便回数増加	0	1 (0.9)	1 (0.4)
胃食道逆流性疾患	1 (0.8)	1 (0.9)	2 (0.8)
舌炎	1 (0.8)	0	1 (0.4)
舌痛	1 (0.8)	0	1 (0.4)
吐血	1 (0.8)	0	1 (0.4)
痔核	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
裂孔ヘルニア	1 (0.8)	0	1 (0.4)
胃排出不全	1 (0.8)	0	1 (0.4)
鼠径ヘルニア	1 (0.8)	0	1 (0.4)
腸出血	1 (0.8)	0	1 (0.4)
過敏性腸症候群	1 (0.8)	1 (0.9)	2 (0.8)
大腸ポリープ	0	1 (0.9)	1 (0.4)
口唇乾燥	1 (0.8)	0	1 (0.4)
メレナ	2 (1.5)	0	2 (0.8)
口腔腫脹	1 (0.8)	0	1 (0.4)
悪心	8 (6.1)	11 (9.8)	19 (7.8)
口腔内不快感	1 (0.8)	0	1 (0.4)
口腔内痛	1 (0.8)	0	1 (0.4)
口の錯感覚	1 (0.8)	1 (0.9)	2 (0.8)
直腸出血	0	1 (0.9)	1 (0.4)
歯痛	0	1 (0.9)	1 (0.4)
嘔吐	3 (2.3)	3 (2.7)	6 (2.5)
一般・全身障害および投与部位の状態	107 (81.1)	96 (85.7)	203 (83.2)
投与部位内出血	0	1 (0.9)	1 (0.4)
投与部位紅斑	1 (0.8)	0	1 (0.4)
投与部位漏出	0	1 (0.9)	1 (0.4)
無力症	3 (2.3)	0	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
カテーテル留置部位紅斑	1 (0.8)	1 (0.9)	2 (0.8)
カテーテル留置部位漏出	1 (0.8)	0	1 (0.4)
カテーテル留置部位出血	0	1 (0.9)	1 (0.4)
カテーテル留置部位炎症	0	1 (0.9)	1 (0.4)
カテーテル留置部位刺激感	0	1 (0.9)	1 (0.4)
カテーテル留置部位浮腫	0	1 (0.9)	1 (0.4)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
胸部不快感	0	1 (0.9)	1 (0.4)
胸痛	1 (0.8)	1 (0.9)	2 (0.8)
泣き	1 (0.8)	0	1 (0.4)
不快感	1 (0.8)	0	1 (0.4)
薬効欠如	0	1 (0.9)	1 (0.4)
薬剤離脱症候群	1 (0.8)	1 (0.9)	2 (0.8)
疲労	6 (4.5)	3 (2.7)	9 (3.7)
異常感	1 (0.8)	1 (0.9)	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
冷感	0	1 (0.9)	1 (0.4)
熱感	1 (0.8)	0	1 (0.4)
歩行障害	0	2 (1.8)	2 (0.8)
歩行不能	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	1 (0.9)	2 (0.8)
インフルエンザ様疾患	1 (0.8)	2 (1.8)	3 (1.2)
注入部位内出血	10 (7.6)	8 (7.1)	18 (7.4)
注入部位皮膚炎	2 (1.5)	2 (1.8)	4 (1.6)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
注入部位変色	2 (1.5)	0	2 (0.8)
注入部位不快感	3 (2.3)	1 (0.9)	4 (1.6)
注入部位びらん	1 (0.8)	1 (0.9)	2 (0.8)
注入部位紅斑	65 (49.2)	61 (54.5)	126 (51.6)
注入部位皮膚剥脱	3 (2.3)	3 (2.7)	6 (2.5)
注入部位血管外漏出	8 (6.1)	12 (10.7)	20 (8.2)
注入部位血腫	10 (7.6)	8 (7.1)	18 (7.4)
注入部位出血	4 (3.0)	5 (4.5)	9 (3.7)
注入部位硬結	7 (5.3)	3 (2.7)	10 (4.1)
注入部位炎症	3 (2.3)	6 (5.4)	9 (3.7)
注入部位損傷	0	2 (1.8)	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位刺激感	1 (0.8)	4 (3.6)	5 (2.0)
注入部位腫瘤	5 (3.8)	3 (2.7)	8 (3.3)
注入部位壊死	0	1 (0.9)	1 (0.4)
注入部位結節	35 (26.5)	34 (30.4)	69 (28.3)
注入部位浮腫	19 (14.4)	28 (25.0)	47 (19.3)
注入部位疼痛	18 (13.6)	20 (17.9)	38 (15.6)
注入部位蒼白	3 (2.3)	2 (1.8)	5 (2.0)
注入部位丘疹	7 (5.3)	11 (9.8)	18 (7.4)
注入部位異常感覚	0	2 (1.8)	2 (0.8)
注入部位そう痒感	5 (3.8)	2 (1.8)	7 (2.9)
注入部位発疹	3 (2.3)	4 (3.6)	7 (2.9)
注入部位反応	13 (9.8)	17 (15.2)	30 (12.3)
注入部位痂皮	0	1 (0.9)	1 (0.4)
注入部位腫脹	4 (3.0)	2 (1.8)	6 (2.5)
注入部位小水疱	0	2 (1.8)	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位熱感	0	1 (0.9)	1 (0.4)
注射部位内出血	2 (1.5)	1 (0.9)	3 (1.2)
注射部位変色	1 (0.8)	0	1 (0.4)
注射部位紅斑	6 (4.5)	8 (7.1)	14 (5.7)
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
注射部位血腫	0	1 (0.9)	1 (0.4)
注射部位出血	0	1 (0.9)	1 (0.4)
注射部位炎症	2 (1.5)	4 (3.6)	6 (2.5)
注射部位結節	3 (2.3)	6 (5.4)	9 (3.7)
注射部位浮腫	2 (1.5)	3 (2.7)	5 (2.0)
注射部位疼痛	2 (1.5)	6 (5.4)	8 (3.3)
注射部位丘疹	0	2 (1.8)	2 (0.8)
注射部位反応	1 (0.8)	1 (0.9)	2 (0.8)
注射部位腫脹	2 (1.5)	2 (1.8)	4 (1.6)
注射部位蕁麻疹	0	1 (0.9)	1 (0.4)
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
滴下投与部位痛	0	1 (0.9)	1 (0.4)
限局性浮腫	0	1 (0.9)	1 (0.4)
適用部位からの吸収不良	0	1 (0.9)	1 (0.4)
倦怠感	1 (0.8)	2 (1.8)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
医療機器使用部位刺激感	1 (0.8)	2 (1.8)	3 (1.2)
医療機器使用部位そう痒感	1 (0.8)	0	1 (0.4)
医療機器使用部位発疹	0	2 (1.8)	2 (0.8)
小結節	1 (0.8)	0	1 (0.4)
非心臓性胸痛	0	2 (1.8)	2 (0.8)
末梢性浮腫	5 (3.8)	4 (3.6)	9 (3.7)
疼痛	2 (1.5)	0	2 (0.8)
末梢腫脹	0	4 (3.6)	4 (1.6)
穿刺部位内出血	1 (0.8)	0	1 (0.4)
穿刺部位紅斑	0	3 (2.7)	3 (1.2)
穿刺部位出血	1 (0.8)	0	1 (0.4)
穿刺部位硬結	2 (1.5)	0	2 (0.8)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
発熱	2 (1.5)	2 (1.8)	4 (1.6)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
口渇	1 (0.8)	0	1 (0.4)
血管穿刺部位硬結	1 (0.8)	0	1 (0.4)
肝胆道系障害	2 (1.5)	1 (0.9)	3 (1.2)
肝嚢胞	1 (0.8)	0	1 (0.4)
脂肪肝	0	1 (0.9)	1 (0.4)
門脈血栓症	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	58 (43.9)	56 (50.0)	114 (46.7)
四肢膿瘍	0	1 (0.9)	1 (0.4)
無症候性COVID-19	0	1 (0.9)	1 (0.4)
細菌性疾患キャリアー	0	1 (0.9)	1 (0.4)
ボレリア感染	1 (0.8)	0	1 (0.4)
ウイルス性気管支炎	0	1 (0.9)	1 (0.4)
COVID-19	1 (0.8)	0	1 (0.4)
COVID-19肺炎	1 (0.8)	0	1 (0.4)
カテーテル留置部位感染	1 (0.8)	0	1 (0.4)
蜂巣炎	1 (0.8)	2 (1.8)	3 (1.2)
結膜炎	2 (1.5)	0	2 (0.8)
膀胱炎	1 (0.8)	1 (0.9)	2 (0.8)
爪の皮膚糸状菌症	0	1 (0.9)	1 (0.4)
真菌感染	1 (0.8)	0	1 (0.4)
胃腸炎	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
歯肉炎	1 (0.8)	0	1 (0.4)
麦粒腫	1 (0.8)	0	1 (0.4)
感染性皮膚潰瘍	0	1 (0.9)	1 (0.4)
インフルエンザ	0	1 (0.9)	1 (0.4)
注入部位膿瘍	14 (10.6)	13 (11.6)	27 (11.1)
注入部位蜂巣炎	29 (22.0)	27 (24.1)	56 (23.0)
注入部位感染	7 (5.3)	11 (9.8)	18 (7.4)
注入部位膿疱	0	1 (0.9)	1 (0.4)
注射部位蜂巣炎	0	3 (2.7)	3 (1.2)
リンパ管炎	0	1 (0.9)	1 (0.4)
上咽頭炎	5 (3.8)	5 (4.5)	10 (4.1)
爪真菌症	0	1 (0.9)	1 (0.4)
耳下腺膿瘍	0	1 (0.9)	1 (0.4)
肺炎	3 (2.3)	1 (0.9)	4 (1.6)
術後膿瘍	1 (0.8)	0	1 (0.4)
シュードモナス感染	0	1 (0.9)	1 (0.4)
膿疱性皮疹	1 (0.8)	0	1 (0.4)
気道感染	0	1 (0.9)	1 (0.4)
敗血症	3 (2.3)	0	3 (1.2)
敗血症性ショック	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
副鼻腔炎	1 (0.8)	0	1 (0.4)
ブドウ球菌感染	1 (0.8)	1 (0.9)	2 (0.8)
歯感染	1 (0.8)	1 (0.9)	2 (0.8)
上気道感染	1 (0.8)	0	1 (0.4)
尿路感染	8 (6.1)	11 (9.8)	19 (7.8)
水痘帯状疱疹ウイルス感染	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	21 (15.9)	27 (24.1)	48 (19.7)
足関節部骨折	0	1 (0.9)	1 (0.4)
節足動物咬傷	0	1 (0.9)	1 (0.4)
骨挫傷	1 (0.8)	1 (0.9)	2 (0.8)
脳挫傷	1 (0.8)	0	1 (0.4)
挫傷	2 (1.5)	6 (5.4)	8 (3.3)
医療機器設置の問題	1 (0.8)	0	1 (0.4)
医療機器による投与の欠落	1 (0.8)	0	1 (0.4)
期限切れの製品使用	1 (0.8)	0	1 (0.4)
眼挫傷	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
顔面損傷	0	1 (0.9)	1 (0.4)
顔面骨骨折	0	2 (1.8)	2 (0.8)
転倒	16 (12.1)	24 (21.4)	40 (16.4)
頭部損傷	2 (1.5)	3 (2.7)	5 (2.0)
注入に伴う反応	1 (0.8)	0	1 (0.4)
関節脱臼	0	1 (0.9)	1 (0.4)
靱帯捻挫	1 (0.8)	1 (0.9)	2 (0.8)
腰椎骨折	0	1 (0.9)	1 (0.4)
過量投与	0	1 (0.9)	1 (0.4)
処置後挫傷	1 (0.8)	0	1 (0.4)
処置によるめまい	0	1 (0.9)	1 (0.4)
肋骨骨折	1 (0.8)	2 (1.8)	3 (1.2)
皮膚擦過傷	1 (0.8)	2 (1.8)	3 (1.2)
皮膚損傷	1 (0.8)	0	1 (0.4)
皮膚裂傷	1 (0.8)	6 (5.4)	7 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
ストレス骨折	1 (0.8)	0	1 (0.4)
硬膜下血腫	0	1 (0.9)	1 (0.4)
サンバーン	0	1 (0.9)	1 (0.4)
腱断裂	1 (0.8)	1 (0.9)	2 (0.8)
過少量投与	0	1 (0.9)	1 (0.4)
創傷	1 (0.8)	0	1 (0.4)
臨床検査	24 (18.2)	24 (21.4)	48 (19.7)
血中クレアチンホスホキナーゼ増加	1 (0.8)	1 (0.9)	2 (0.8)
血中クレアチニン減少	0	1 (0.9)	1 (0.4)
血中葉酸異常	0	1 (0.9)	1 (0.4)
血中葉酸減少	1 (0.8)	1 (0.9)	2 (0.8)
血中ホモシステイン増加	1 (0.8)	2 (1.8)	3 (1.2)
血中リン減少	0	1 (0.9)	1 (0.4)
血圧上昇	1 (0.8)	1 (0.9)	2 (0.8)
起立血圧低下	1 (0.8)	0	1 (0.4)
血中ナトリウム減少	1 (0.8)	0	1 (0.4)
C-反応性蛋白増加	0	1 (0.9)	1 (0.4)
心雑音	1 (0.8)	0	1 (0.4)
握力低下	1 (0.8)	0	1 (0.4)
ヘモグロビン減少	1 (0.8)	1 (0.9)	2 (0.8)
リンパ球数減少	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
臨床検査 (Cont.)			
単球数増加	0	1 (0.9)	1 (0.4)
好中球数増加	0	2 (1.8)	2 (0.8)
プロトロンビン時間延長	0	1 (0.9)	1 (0.4)
赤血球数減少	0	1 (0.9)	1 (0.4)
ビタミンB12減少	1 (0.8)	1 (0.9)	2 (0.8)
ビタミンB6減少	5 (3.8)	6 (5.4)	11 (4.5)
ビタミンD減少	0	1 (0.9)	1 (0.4)
体重減少	10 (7.6)	14 (12.5)	24 (9.8)
体重増加	2 (1.5)	0	2 (0.8)
白血球数増加	0	2 (1.8)	2 (0.8)
代謝および栄養障害	11 (8.3)	19 (17.0)	30 (12.3)
悪液質	1 (0.8)	0	1 (0.4)
食欲減退	3 (2.3)	3 (2.7)	6 (2.5)
脱水	1 (0.8)	3 (2.7)	4 (1.6)
糖尿病	0	1 (0.9)	1 (0.4)
水分過負荷	0	1 (0.9)	1 (0.4)
体液貯留	1 (0.8)	1 (0.9)	2 (0.8)
葉酸欠乏	1 (0.8)	1 (0.9)	2 (0.8)
耐糖能障害	0	1 (0.9)	1 (0.4)
高コレステロール血症	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
代謝および栄養障害 (Cont.)			
高血糖	0	1 (0.9)	1 (0.4)
高ホモシステイン血症	0	1 (0.9)	1 (0.4)
低カルシウム血症	0	1 (0.9)	1 (0.4)
低カリウム血症	0	3 (2.7)	3 (1.2)
低ナトリウム血症	2 (1.5)	0	2 (0.8)
栄養障害	0	1 (0.9)	1 (0.4)
ビタミンB群欠乏	1 (0.8)	1 (0.9)	2 (0.8)
ビタミンB12欠乏	0	2 (1.8)	2 (0.8)
ビタミンB6欠乏	3 (2.3)	5 (4.5)	8 (3.3)
筋骨格系および結合組織障害	24 (18.2)	21 (18.8)	45 (18.4)
関節痛	3 (2.3)	5 (4.5)	8 (3.3)
反応性関節炎	1 (0.8)	1 (0.9)	2 (0.8)
背部痛	8 (6.1)	5 (4.5)	13 (5.3)
骨痛	0	1 (0.9)	1 (0.4)
滑液包炎	2 (1.5)	0	2 (0.8)
外骨腫	0	1 (0.9)	1 (0.4)
椎間関節症候群	0	1 (0.9)	1 (0.4)
椎間板変性症	1 (0.8)	0	1 (0.4)
椎間板突出	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
関節滲出液	0	2 (1.8)	2 (0.8)
関節腫脹	0	1 (0.9)	1 (0.4)
四肢不快感	0	1 (0.9)	1 (0.4)
筋萎縮	0	1 (0.9)	1 (0.4)
筋痙縮	2 (1.5)	3 (2.7)	5 (2.0)
筋力低下	4 (3.0)	1 (0.9)	5 (2.0)
筋骨格硬直	0	1 (0.9)	1 (0.4)
筋肉痛	2 (1.5)	1 (0.9)	3 (1.2)
頚部痛	2 (1.5)	0	2 (0.8)
骨炎	0	1 (0.9)	1 (0.4)
変形性関節症	1 (0.8)	4 (3.6)	5 (2.0)
骨減少症	1 (0.8)	0	1 (0.4)
四肢痛	3 (2.3)	3 (2.7)	6 (2.5)
関節周囲炎	0	1 (0.9)	1 (0.4)
姿勢異常	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害 (Cont.)			
横紋筋融解症	2 (1.5)	0	2 (0.8)
肩回旋筋腱板症候群	0	1 (0.9)	1 (0.4)
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
変形性脊椎症	1 (0.8)	0	1 (0.4)
腱障害	0	1 (0.9)	1 (0.4)
腱炎	1 (0.8)	0	1 (0.4)
斜頚	0	1 (0.9)	1 (0.4)
弾発指	1 (0.8)	0	1 (0.4)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.8)	4 (3.6)	5 (2.0)
基底細胞癌	0	2 (1.8)	2 (0.8)
直腸腺癌	1 (0.8)	0	1 (0.4)
脂漏性角化症	0	1 (0.9)	1 (0.4)
皮膚有棘細胞癌	0	1 (0.9)	1 (0.4)
神経系障害	62 (47.0)	48 (42.9)	110 (45.1)
アカシジア	1 (0.8)	0	1 (0.4)
健忘	1 (0.8)	0	1 (0.4)
失語症	0	1 (0.9)	1 (0.4)
運動失調	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
平衡障害	0	4 (3.6)	4 (1.6)
運動緩慢	1 (0.8)	1 (0.9)	2 (0.8)
手根管症候群	0	1 (0.9)	1 (0.4)
大脳萎縮	0	1 (0.9)	1 (0.4)
脳出血	0	1 (0.9)	1 (0.4)
脳圧排効果	0	1 (0.9)	1 (0.4)
脳血管発作	0	1 (0.9)	1 (0.4)
認知障害	4 (3.0)	2 (1.8)	6 (2.5)
振動覚低下	1 (0.8)	0	1 (0.4)
注意力障害	0	1 (0.9)	1 (0.4)
浮動性めまい	15 (11.4)	10 (8.9)	25 (10.2)
体位性めまい	5 (3.8)	0	5 (2.0)
構語障害	0	3 (2.7)	3 (1.2)
味覚不全	2 (1.5)	1 (0.9)	3 (1.2)
ジスキネジア	12 (9.1)	6 (5.4)	18 (7.4)
起立障害	1 (0.8)	0	1 (0.4)
ジストニア	2 (1.5)	5 (4.5)	7 (2.9)
脳症	0	1 (0.9)	1 (0.4)
てんかん	0	1 (0.9)	1 (0.4)
本態性振戦	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
伸展性足底反応	1 (0.8)	0	1 (0.4)
すくみ現象	4 (3.0)	0	4 (1.6)
全身性強直性間代性発作	0	1 (0.9)	1 (0.4)
頭部不快感	1 (0.8)	0	1 (0.4)
頭痛	7 (5.3)	7 (6.3)	14 (5.7)
片側感覚消失	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
知覚過敏	0	1 (0.9)	1 (0.4)
感覚鈍麻	1 (0.8)	2 (1.8)	3 (1.2)
反射減弱	2 (1.5)	1 (0.9)	3 (1.2)
不規則睡眠覚醒リズム障害	1 (0.8)	0	1 (0.4)
嗜眠	1 (0.8)	1 (0.9)	2 (0.8)
意識消失	1 (0.8)	1 (0.9)	2 (0.8)
腰仙部神経根障害	0	1 (0.9)	1 (0.4)
記憶障害	0	2 (1.8)	2 (0.8)
代謝性脳症	1 (0.8)	1 (0.9)	2 (0.8)
神経痛	0	1 (0.9)	1 (0.4)
末梢性ニューロパチー	1 (0.8)	1 (0.9)	2 (0.8)
オンオフ現象	4 (3.0)	5 (4.5)	9 (3.7)
錯感覚	4 (3.0)	3 (2.7)	7 (2.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
パーキンソン病	12 (9.1)	5 (4.5)	17 (7.0)
パーキンソニズム	0	3 (2.7)	3 (1.2)
末梢性感覚ニューロパチー	0	1 (0.9)	1 (0.4)
側反弓	1 (0.8)	2 (1.8)	3 (1.2)
多発ニューロパチー	0	2 (1.8)	2 (0.8)
失神寸前の状態	0	1 (0.9)	1 (0.4)
心因性発作	0	1 (0.9)	1 (0.4)
精神運動亢進	1 (0.8)	1 (0.9)	2 (0.8)
反射異常	0	1 (0.9)	1 (0.4)
安静時振戦	0	1 (0.9)	1 (0.4)
坐骨神経痛	0	3 (2.7)	3 (1.2)
痙攣発作	0	1 (0.9)	1 (0.4)
感覚障害	0	1 (0.9)	1 (0.4)
感覚消失	0	1 (0.9)	1 (0.4)
睡眠時麻痺	1 (0.8)	0	1 (0.4)
傾眠	9 (6.8)	3 (2.7)	12 (4.9)
失神	0	3 (2.7)	3 (1.2)
振戦	1 (0.8)	2 (1.8)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
製品の問題	2 (1.5)	1 (0.9)	3 (1.2)
医療機器送達システムの問題	1 (0.8)	0	1 (0.4)
医療機器位置異常	1 (0.8)	0	1 (0.4)
医療機器機能不良	0	1 (0.9)	1 (0.4)
精神障害	51 (38.6)	57 (50.9)	108 (44.3)
異常な夢	0	1 (0.9)	1 (0.4)
感情不安定	1 (0.8)	1 (0.9)	2 (0.8)
激越	0	1 (0.9)	1 (0.4)
不安	11 (8.3)	18 (16.1)	29 (11.9)
不安障害	0	1 (0.9)	1 (0.4)
無感情	1 (0.8)	0	1 (0.4)
歯ぎしり	2 (1.5)	0	2 (0.8)
強迫行為	0	1 (0.9)	1 (0.4)
強迫性性行動	1 (0.8)	0	1 (0.4)
錯乱状態	4 (3.0)	5 (4.5)	9 (3.7)
譫妄	1 (0.8)	4 (3.6)	5 (2.0)
妄想	8 (6.1)	2 (1.8)	10 (4.1)
寄生虫妄想	1 (0.8)	0	1 (0.4)
妄想性障害、詳細不明	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
抑うつ気分	2 (1.5)	2 (1.8)	4 (1.6)
うつ病	3 (2.3)	2 (1.8)	5 (2.0)
抑うつ症状	2 (1.5)	0	2 (0.8)
ドーパミン調節障害症候群	1 (0.8)	0	1 (0.4)
ディスフェミア	0	1 (0.9)	1 (0.4)
睡眠異常	1 (0.8)	0	1 (0.4)
情動障害	1 (0.8)	1 (0.9)	2 (0.8)
注射恐怖	0	1 (0.9)	1 (0.4)
幻覚	20 (15.2)	22 (19.6)	42 (17.2)
幻聴	3 (2.3)	3 (2.7)	6 (2.5)
幻嗅	0	1 (0.9)	1 (0.4)
幻視	10 (7.6)	5 (4.5)	15 (6.1)
混合性幻覚	1 (0.8)	0	1 (0.4)
性欲過剰	1 (0.8)	0	1 (0.4)
錯覚	1 (0.8)	1 (0.9)	2 (0.8)
衝動制御障害	0	4 (3.6)	4 (1.6)
衝動行為	0	1 (0.9)	1 (0.4)
不眠症	9 (6.8)	9 (8.0)	18 (7.4)
易刺激性	1 (0.8)	1 (0.9)	2 (0.8)
嫉妬妄想	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
躁病	0	1 (0.9)	1 (0.4)
気分変化	1 (0.8)	0	1 (0.4)
気分動揺	0	1 (0.9)	1 (0.4)
悪夢	1 (0.8)	1 (0.9)	2 (0.8)
強迫観念	1 (0.8)	0	1 (0.4)
パニック発作	0	3 (2.7)	3 (1.2)
パニック反応	0	1 (0.9)	1 (0.4)
妄想症	2 (1.5)	0	2 (0.8)
睡眠の質低下	1 (0.8)	0	1 (0.4)
処置に対する不安	0	1 (0.9)	1 (0.4)
精神病性障害	4 (3.0)	2 (1.8)	6 (2.5)
精神病症状	1 (0.8)	0	1 (0.4)
レム睡眠行動障害	1 (0.8)	1 (0.9)	2 (0.8)
レム睡眠異常	1 (0.8)	0	1 (0.4)
睡眠障害	2 (1.5)	1 (0.9)	3 (1.2)
ねごと	1 (0.8)	1 (0.9)	2 (0.8)
常同症	0	1 (0.9)	1 (0.4)
ストレス	0	1 (0.9)	1 (0.4)
自殺念慮	1 (0.8)	2 (1.8)	3 (1.2)
自殺企図	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
腎および尿路障害	13 (9.8)	7 (6.3)	20 (8.2)
膀胱痙縮	1 (0.8)	0	1 (0.4)
膀胱結石	1 (0.8)	0	1 (0.4)
尿路結石	1 (0.8)	0	1 (0.4)
排尿困難	1 (0.8)	2 (1.8)	3 (1.2)
緊張性膀胱	1 (0.8)	0	1 (0.4)
夜間頻尿	0	1 (0.9)	1 (0.4)
頻尿	1 (0.8)	0	1 (0.4)
多尿	0	1 (0.9)	1 (0.4)
腎機能障害	0	1 (0.9)	1 (0.4)
尿管結石症	0	1 (0.9)	1 (0.4)
切迫性尿失禁	3 (2.3)	0	3 (1.2)
尿失禁	3 (2.3)	2 (1.8)	5 (2.0)
尿閉	0	3 (2.7)	3 (1.2)
尿路障害	1 (0.8)	0	1 (0.4)
尿異常	0	1 (0.9)	1 (0.4)
尿臭異常	0	1 (0.9)	1 (0.4)
生殖系および乳房障害	2 (1.5)	5 (4.5)	7 (2.9)
良性前立腺肥大症	1 (0.8)	0	1 (0.4)
勃起不全	1 (0.8)	1 (0.9)	2 (0.8)
骨盤痛	0	1 (0.9)	1 (0.4)
ペイロニー病	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
生殖系および乳房障害 (Cont.)			
閉経後出血	0	1 (0.9)	1 (0.4)
前立腺腫大	0	1 (0.9)	1 (0.4)
腟脱	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	7 (5.3)	19 (17.0)	26 (10.7)
急性呼吸不全	0	1 (0.9)	1 (0.4)
気管支拡張症	1 (0.8)	0	1 (0.4)
咳嗽	1 (0.8)	2 (1.8)	3 (1.2)
発声障害	0	2 (1.8)	2 (0.8)
呼吸困難	2 (1.5)	6 (5.4)	8 (3.3)
労作性呼吸困難	1 (0.8)	0	1 (0.4)
鼻出血	0	1 (0.9)	1 (0.4)
過換気	0	2 (1.8)	2 (0.8)
口腔咽頭痛	1 (0.8)	1 (0.9)	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
呼吸器、胸郭および縦隔障害 (Cont.)			
誤嚥性肺炎	0	1 (0.9)	1 (0.4)
湿性咳嗽	0	1 (0.9)	1 (0.4)
肺塞栓症	0	2 (1.8)	2 (0.8)
ラ音	0	1 (0.9)	1 (0.4)
呼吸窮迫	1 (0.8)	0	1 (0.4)
鼻痛	0	1 (0.9)	1 (0.4)
鼻漏	0	2 (1.8)	2 (0.8)
咽喉刺激感	0	1 (0.9)	1 (0.4)
皮膚および皮下組織障害	14 (10.6)	16 (14.3)	30 (12.3)
脱毛症	2 (1.5)	1 (0.9)	3 (1.2)
褥瘡性潰瘍	0	1 (0.9)	1 (0.4)
皮膚嚢腫	1 (0.8)	1 (0.9)	2 (0.8)
皮膚炎	0	1 (0.9)	1 (0.4)
接触皮膚炎	2 (1.5)	0	2 (0.8)
おむつ皮膚炎	1 (0.8)	0	1 (0.4)
薬疹	1 (0.8)	0	1 (0.4)
皮膚乾燥	1 (0.8)	1 (0.9)	2 (0.8)
斑状出血	1 (0.8)	0	1 (0.4)
紅斑	1 (0.8)	3 (2.7)	4 (1.6)
爪の障害	1 (0.8)	0	1 (0.4)
脂肪織炎	0	1 (0.9)	1 (0.4)
丘疹	0	2 (1.8)	2 (0.8)
口囲皮膚炎	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
光線過敏性反応	0	1 (0.9)	1 (0.4)
そう痒症	2 (1.5)	2 (1.8)	4 (1.6)
乾癬	0	1 (0.9)	1 (0.4)
発疹	2 (1.5)	1 (0.9)	3 (1.2)
紅斑性皮疹	0	1 (0.9)	1 (0.4)
そう痒性皮疹	2 (1.5)	1 (0.9)	3 (1.2)
皮膚刺激	0	1 (0.9)	1 (0.4)
皮膚病変	0	1 (0.9)	1 (0.4)
皮膚潰瘍	1 (0.8)	1 (0.9)	2 (0.8)
蕁麻疹	2 (1.5)	0	2 (0.8)
社会環境	1 (0.8)	0	1 (0.4)
運動不能	1 (0.8)	0	1 (0.4)
外科および内科処置	0	1 (0.9)	1 (0.4)
抜歯	0	1 (0.9)	1 (0.4)
血管障害	12 (9.1)	15 (13.4)	27 (11.1)
深部静脈血栓症	0	1 (0.9)	1 (0.4)
血腫	0	1 (0.9)	1 (0.4)
出血	0	1 (0.9)	1 (0.4)
ほてり	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=132	N=112	N=244
血管障害 (Cont.)			
高血圧	3 (2.3)	3 (2.7)	6 (2.5)
高血圧クリーゼ	1 (0.8)	0	1 (0.4)
低血圧	2 (1.5)	4 (3.6)	6 (2.5)
不安定血圧	0	1 (0.9)	1 (0.4)
起立性高血圧	0	1 (0.9)	1 (0.4)
起立性低血圧	7 (5.3)	6 (5.4)	13 (5.3)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=132	N=112	N=244
Any adverse event	106 (80.3)	97 (86.6)	203 (83.2)
心臓障害	0	2 (1.8)	2 (0.8)
徐脈	0	1 (0.9)	1 (0.4)
動悸	0	1 (0.9)	1 (0.4)
耳および迷路障害	2 (1.5)	2 (1.8)	4 (1.6)
乗物酔い	0	1 (0.9)	1 (0.4)
回転性めまい	2 (1.5)	1 (0.9)	3 (1.2)
眼障害	2 (1.5)	2 (1.8)	4 (1.6)
複視	1 (0.8)	1 (0.9)	2 (0.8)
眼窩周囲腫脹	0	1 (0.9)	1 (0.4)
霧視	1 (0.8)	0	1 (0.4)
胃腸障害	13 (9.8)	15 (13.4)	28 (11.5)
腹部膨満	0	2 (1.8)	2 (0.8)
腹痛	1 (0.8)	0	1 (0.4)
上腹部痛	0	1 (0.9)	1 (0.4)
アフタ性潰瘍	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
胃腸障害 (Cont.)			
呼気臭	2 (1.5)	0	2 (0.8)
便秘	2 (1.5)	2 (1.8)	4 (1.6)
下痢	2 (1.5)	2 (1.8)	4 (1.6)
口内乾燥	2 (1.5)	3 (2.7)	5 (2.0)
消化不良	1 (0.8)	0	1 (0.4)
胃食道逆流性疾患	0	1 (0.9)	1 (0.4)
痔核	1 (0.8)	0	1 (0.4)
過敏性腸症候群	0	1 (0.9)	1 (0.4)
悪心	5 (3.8)	5 (4.5)	10 (4.1)
嘔吐	2 (1.5)	1 (0.9)	3 (1.2)
一般・全身障害および投与部位の状態	91 (68.9)	82 (73.2)	173 (70.9)
投与部位紅斑	1 (0.8)	0	1 (0.4)
無力症	1 (0.8)	0	1 (0.4)
カテーテル留置部位紅斑	0	1 (0.9)	1 (0.4)
カテーテル留置部位炎症	0	1 (0.9)	1 (0.4)
カテーテル留置部位疼痛	0	2 (1.8)	2 (0.8)
不快感	1 (0.8)	0	1 (0.4)
薬剤離脱症候群	1 (0.8)	0	1 (0.4)
疲労	3 (2.3)	2 (1.8)	5 (2.0)
異常感	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
熱感	1 (0.8)	0	1 (0.4)
歩行障害	0	1 (0.9)	1 (0.4)
歩行不能	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
インフルエンザ様疾患	1 (0.8)	1 (0.9)	2 (0.8)
注入部位内出血	3 (2.3)	7 (6.3)	10 (4.1)
注入部位分泌物	1 (0.8)	1 (0.9)	2 (0.8)
注入部位変色	2 (1.5)	0	2 (0.8)
注入部位不快感	2 (1.5)	1 (0.9)	3 (1.2)
注入部位びらん	0	1 (0.9)	1 (0.4)
注入部位紅斑	50 (37.9)	45 (40.2)	95 (38.9)
注入部位皮膚剥脱	0	1 (0.9)	1 (0.4)
注入部位血管外漏出	4 (3.0)	7 (6.3)	11 (4.5)
注入部位血腫	4 (3.0)	4 (3.6)	8 (3.3)
注入部位出血	0	3 (2.7)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注入部位硬結	4 (3.0)	1 (0.9)	5 (2.0)
注入部位炎症	1 (0.8)	3 (2.7)	4 (1.6)
注入部位腫瘤	4 (3.0)	1 (0.9)	5 (2.0)
注入部位壊死	0	1 (0.9)	1 (0.4)
注入部位結節	21 (15.9)	18 (16.1)	39 (16.0)
注入部位浮腫	14 (10.6)	16 (14.3)	30 (12.3)
注入部位疼痛	13 (9.8)	14 (12.5)	27 (11.1)
注入部位蒼白	2 (1.5)	1 (0.9)	3 (1.2)
注入部位丘疹	1 (0.8)	4 (3.6)	5 (2.0)
注入部位異常感覚	0	1 (0.9)	1 (0.4)
注入部位そう痒感	2 (1.5)	1 (0.9)	3 (1.2)
注入部位発疹	2 (1.5)	1 (0.9)	3 (1.2)
注入部位反応	9 (6.8)	11 (9.8)	20 (8.2)
注入部位腫脹	3 (2.3)	1 (0.9)	4 (1.6)
注射部位内出血	1 (0.8)	0	1 (0.4)
注射部位紅斑	5 (3.8)	5 (4.5)	10 (4.1)
注射部位漏出	1 (0.8)	1 (0.9)	2 (0.8)
注射部位血腫	0	1 (0.9)	1 (0.4)
注射部位炎症	1 (0.8)	2 (1.8)	3 (1.2)
注射部位結節	1 (0.8)	2 (1.8)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
注射部位浮腫	2 (1.5)	2 (1.8)	4 (1.6)
注射部位疼痛	2 (1.5)	4 (3.6)	6 (2.5)
注射部位反応	0	1 (0.9)	1 (0.4)
注射部位腫脹	1 (0.8)	0	1 (0.4)
滴下投与部位熱傷	0	1 (0.9)	1 (0.4)
限局性浮腫	0	1 (0.9)	1 (0.4)
適用部位からの吸収不良	0	1 (0.9)	1 (0.4)
倦怠感	1 (0.8)	1 (0.9)	2 (0.8)
医療機器使用部位刺激感	0	1 (0.9)	1 (0.4)
医療機器使用部位そう痒感	1 (0.8)	0	1 (0.4)
医療機器使用部位発疹	0	1 (0.9)	1 (0.4)
小結節	1 (0.8)	0	1 (0.4)
末梢性浮腫	1 (0.8)	3 (2.7)	4 (1.6)
末梢腫脹	0	2 (1.8)	2 (0.8)
穿刺部位内出血	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位紅斑	0	1 (0.9)	1 (0.4)
穿刺部位出血	1 (0.8)	0	1 (0.4)
穿刺部位硬結	1 (0.8)	0	1 (0.4)
穿刺部位浮腫	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
発熱	2 (1.5)	1 (0.9)	3 (1.2)
口渇	1 (0.8)	0	1 (0.4)
肝胆道系障害	1 (0.8)	0	1 (0.4)
門脈血栓症	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	17 (12.9)	27 (24.1)	44 (18.0)
ボレリア感染	1 (0.8)	0	1 (0.4)
膀胱炎	0	1 (0.9)	1 (0.4)
真菌感染	1 (0.8)	0	1 (0.4)
胃腸炎	0	1 (0.9)	1 (0.4)
注入部位膿瘍	3 (2.3)	5 (4.5)	8 (3.3)
注入部位蜂巣炎	10 (7.6)	13 (11.6)	23 (9.4)
注入部位感染	1 (0.8)	3 (2.7)	4 (1.6)
注射部位蜂巣炎	0	1 (0.9)	1 (0.4)
上咽頭炎	0	3 (2.7)	3 (1.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
感染症および寄生虫症 (Cont.)			
爪真菌症	0	1 (0.9)	1 (0.4)
肺炎	1 (0.8)	1 (0.9)	2 (0.8)
膿疱性皮疹	1 (0.8)	0	1 (0.4)
敗血症	1 (0.8)	0	1 (0.4)
敗血症性ショック	1 (0.8)	0	1 (0.4)
尿路感染	3 (2.3)	3 (2.7)	6 (2.5)
傷害、中毒および処置合併症	10 (7.6)	11 (9.8)	21 (8.6)
挫傷	1 (0.8)	0	1 (0.4)
医療機器設置の問題	1 (0.8)	0	1 (0.4)
医療機器による投与の欠落	1 (0.8)	0	1 (0.4)
顔面骨骨折	0	2 (1.8)	2 (0.8)
転倒	7 (5.3)	9 (8.0)	16 (6.6)
頭部損傷	1 (0.8)	0	1 (0.4)
注入に伴う反応	1 (0.8)	0	1 (0.4)
腰椎骨折	0	1 (0.9)	1 (0.4)
処置後挫傷	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
傷害、中毒および処置合併症 (Cont.)			
処置によるめまい	0	1 (0.9)	1 (0.4)
肋骨骨折	0	1 (0.9)	1 (0.4)
皮膚擦過傷	1 (0.8)	0	1 (0.4)
皮膚裂傷	0	2 (1.8)	2 (0.8)
臨床検査	3 (2.3)	5 (4.5)	8 (3.3)
血圧上昇	1 (0.8)	1 (0.9)	2 (0.8)
起立血圧低下	1 (0.8)	0	1 (0.4)
リンパ球数減少	0	1 (0.9)	1 (0.4)
単球数増加	0	1 (0.9)	1 (0.4)
好中球数増加	0	1 (0.9)	1 (0.4)
ビタミンB12減少	1 (0.8)	0	1 (0.4)
ビタミンB6減少	0	2 (1.8)	2 (0.8)
体重減少	0	1 (0.9)	1 (0.4)
白血球数増加	0	1 (0.9)	1 (0.4)
代謝および栄養障害	1 (0.8)	5 (4.5)	6 (2.5)
食欲減退	1 (0.8)	1 (0.9)	2 (0.8)
脱水	0	1 (0.9)	1 (0.4)
耐糖能障害	0	1 (0.9)	1 (0.4)
高血糖	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
筋骨格系および結合組織障害	10 (7.6)	8 (7.1)	18 (7.4)
関節痛	2 (1.5)	2 (1.8)	4 (1.6)
反応性関節炎	0	1 (0.9)	1 (0.4)
背部痛	3 (2.3)	1 (0.9)	4 (1.6)
関節腫脹	0	1 (0.9)	1 (0.4)
筋力低下	2 (1.5)	0	2 (0.8)
筋骨格硬直	0	1 (0.9)	1 (0.4)
筋肉痛	2 (1.5)	1 (0.9)	3 (1.2)
四肢痛	0	1 (0.9)	1 (0.4)
姿勢異常	0	1 (0.9)	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
仙腸関節機能障害	1 (0.8)	0	1 (0.4)
斜頚	0	1 (0.9)	1 (0.4)
神経系障害	36 (27.3)	26 (23.2)	62 (25.4)
運動失調	1 (0.8)	0	1 (0.4)
平衡障害	0	1 (0.9)	1 (0.4)
運動緩慢	1 (0.8)	0	1 (0.4)
認知障害	2 (1.5)	0	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
浮動性めまい	10 (7.6)	8 (7.1)	18 (7.4)
体位性めまい	3 (2.3)	0	3 (1.2)
構語障害	0	1 (0.9)	1 (0.4)
味覚不全	2 (1.5)	0	2 (0.8)
ジスキネジア	6 (4.5)	3 (2.7)	9 (3.7)
起立障害	1 (0.8)	0	1 (0.4)
ジストニア	1 (0.8)	1 (0.9)	2 (0.8)
本態性振戦	0	1 (0.9)	1 (0.4)
すくみ現象	3 (2.3)	0	3 (1.2)
頭部不快感	1 (0.8)	0	1 (0.4)
頭痛	4 (3.0)	2 (1.8)	6 (2.5)
片側感覚消失	0	1 (0.9)	1 (0.4)
不全片麻痺	0	1 (0.9)	1 (0.4)
代謝性脳症	0	1 (0.9)	1 (0.4)
オンオフ現象	3 (2.3)	3 (2.7)	6 (2.5)
錯感覚	0	1 (0.9)	1 (0.4)
パーキンソン病	5 (3.8)	3 (2.7)	8 (3.3)
パーキンソニズム	0	1 (0.9)	1 (0.4)
精神運動亢進	1 (0.8)	1 (0.9)	2 (0.8)
安静時振戦	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
神経系障害 (Cont.)			
坐骨神経痛	0	2 (1.8)	2 (0.8)
傾眠	2 (1.5)	2 (1.8)	4 (1.6)
振戦	0	2 (1.8)	2 (0.8)
製品の問題	0	1 (0.9)	1 (0.4)
医療機器機能不良	0	1 (0.9)	1 (0.4)
精神障害	31 (23.5)	24 (21.4)	55 (22.5)
異常な夢	0	1 (0.9)	1 (0.4)
感情不安定	1 (0.8)	0	1 (0.4)
不安	2 (1.5)	8 (7.1)	10 (4.1)
歯ぎしり	2 (1.5)	0	2 (0.8)
錯乱状態	1 (0.8)	1 (0.9)	2 (0.8)
譫妄	1 (0.8)	2 (1.8)	3 (1.2)
妄想	1 (0.8)	1 (0.9)	2 (0.8)
抑うつ気分	1 (0.8)	1 (0.9)	2 (0.8)
抑うつ症状	2 (1.5)	0	2 (0.8)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
精神障害 (Cont.)			
睡眠異常	1 (0.8)	0	1 (0.4)
情動障害	0	1 (0.9)	1 (0.4)
幻覚	13 (9.8)	5 (4.5)	18 (7.4)
幻聴	0	1 (0.9)	1 (0.4)
幻視	4 (3.0)	1 (0.9)	5 (2.0)
不眠症	7 (5.3)	3 (2.7)	10 (4.1)
易刺激性	1 (0.8)	0	1 (0.4)
嫉妬妄想	1 (0.8)	0	1 (0.4)
気分変化	1 (0.8)	0	1 (0.4)
強迫観念	1 (0.8)	0	1 (0.4)
パニック発作	0	3 (2.7)	3 (1.2)
精神病性障害	2 (1.5)	0	2 (0.8)
レム睡眠行動障害	1 (0.8)	0	1 (0.4)
睡眠障害	0	1 (0.9)	1 (0.4)
ねごと	0	1 (0.9)	1 (0.4)
腎および尿路障害	6 (4.5)	1 (0.9)	7 (2.9)
排尿困難	1 (0.8)	1 (0.9)	2 (0.8)
切迫性尿失禁	2 (1.5)	0	2 (0.8)
尿失禁	2 (1.5)	0	2 (0.8)
尿路障害	1 (0.8)	0	1 (0.4)
尿異常	0	1 (0.9)	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
生殖系および乳房障害	0	1 (0.9)	1 (0.4)
勃起不全	0	1 (0.9)	1 (0.4)
呼吸器、胸郭および縦隔障害	1 (0.8)	7 (6.3)	8 (3.3)
急性呼吸不全	0	1 (0.9)	1 (0.4)
咳嗽	1 (0.8)	1 (0.9)	2 (0.8)
呼吸困難	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)
口腔咽頭痛	0	1 (0.9)	1 (0.4)
鼻痛	0	1 (0.9)	1 (0.4)
鼻漏	0	1 (0.9)	1 (0.4)
皮膚および皮下組織障害	6 (4.5)	5 (4.5)	11 (4.5)
脱毛症	1 (0.8)	0	1 (0.4)
接触皮膚炎	1 (0.8)	0	1 (0.4)
皮膚乾燥	0	1 (0.9)	1 (0.4)
斑状出血	1 (0.8)	0	1 (0.4)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=132	N=112	N=244
皮膚および皮下組織障害 (Cont.)			
紅斑	0	1 (0.9)	1 (0.4)
光線過敏性反応	0	1 (0.9)	1 (0.4)
発疹	1 (0.8)	0	1 (0.4)
そう痒性皮疹	1 (0.8)	0	1 (0.4)
皮膚刺激	0	1 (0.9)	1 (0.4)
皮膚病変	0	1 (0.9)	1 (0.4)
皮膚潰瘍	1 (0.8)	0	1 (0.4)
社会環境	1 (0.8)	0	1 (0.4)
運動不能	1 (0.8)	0	1 (0.4)
血管障害	3 (2.3)	7 (6.3)	10 (4.1)
ほてり	0	1 (0.9)	1 (0.4)
高血圧	2 (1.5)	1 (0.9)	3 (1.2)
低血圧	0	2 (1.8)	2 (0.8)
不安定血圧	0	1 (0.9)	1 (0.4)
起立性低血圧	1 (0.8)	4 (3.6)	5 (2.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=111	N=95	N=206
Any adverse event	100 (90.1)	89 (93.7)	189 (91.7)
血液およびリンパ系障害	1 (0.9)	3 (3.2)	4 (1.9)
大球性貧血	0	1 (1.1)	1 (0.5)
凝血異常	0	1 (1.1)	1 (0.5)
リンパ節症	1 (0.9)	0	1 (0.5)
縦隔リンパ節腫脹	0	1 (1.1)	1 (0.5)
心臓障害	5 (4.5)	6 (6.3)	11 (5.3)
急性心筋梗塞	1 (0.9)	0	1 (0.5)
狭心症	1 (0.9)	0	1 (0.5)
心房細動	0	2 (2.1)	2 (1.0)
心停止	1 (0.9)	0	1 (0.5)
心肺停止	0	1 (1.1)	1 (0.5)
冠動脈疾患	1 (0.9)	1 (1.1)	2 (1.0)
冠動脈狭窄	1 (0.9)	0	1 (0.5)
期外収縮	0	1 (1.1)	1 (0.5)
左室肥大	0	1 (1.1)	1 (0.5)
心筋梗塞	1 (0.9)	0	1 (0.5)
動悸	0	1 (1.1)	1 (0.5)
頻脈	1 (0.9)	0	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
耳および迷路障害	2 (1.8)	2 (2.1)	4 (1.9)
感音性難聴	1 (0.9)	0	1 (0.5)
回転性めまい	1 (0.9)	1 (1.1)	2 (1.0)
頭位性回転性めまい	0	1 (1.1)	1 (0.5)
眼障害	7 (6.3)	6 (6.3)	13 (6.3)
白内障	2 (1.8)	2 (2.1)	4 (1.9)
複視	2 (1.8)	0	2 (1.0)
ドライアイ	1 (0.9)	3 (3.2)	4 (1.9)
緑内障	1 (0.9)	1 (1.1)	2 (1.0)
眼窩周囲痛	0	1 (1.1)	1 (0.5)
眼窩周囲腫脹	0	1 (1.1)	1 (0.5)
網膜裂孔	2 (1.8)	0	2 (1.0)
視野欠損	0	1 (1.1)	1 (0.5)
胃腸障害	17 (15.3)	21 (22.1)	38 (18.4)
腹部膨満	1 (0.9)	2 (2.1)	3 (1.5)
腹痛	1 (0.9)	1 (1.1)	2 (1.0)
上腹部痛	1 (0.9)	0	1 (0.5)
呼気臭	0	1 (1.1)	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
虚血性大腸炎	1 (0.9)	0	1 (0.5)
便秘	6 (5.4)	10 (10.5)	16 (7.8)
齲歯	1 (0.9)	0	1 (0.5)
下痢	4 (3.6)	1 (1.1)	5 (2.4)
口内乾燥	1 (0.9)	3 (3.2)	4 (1.9)
嚥下障害	0	1 (1.1)	1 (0.5)
糞塊	0	1 (1.1)	1 (0.5)
排便回数増加	0	1 (1.1)	1 (0.5)
胃食道逆流性疾患	1 (0.9)	0	1 (0.5)
舌炎	1 (0.9)	0	1 (0.5)
舌痛	1 (0.9)	0	1 (0.5)
吐血	1 (0.9)	0	1 (0.5)
裂孔ヘルニア	1 (0.9)	0	1 (0.5)
胃排出不全	1 (0.9)	0	1 (0.5)
鼠径ヘルニア	1 (0.9)	0	1 (0.5)
腸出血	1 (0.9)	0	1 (0.5)
過敏性腸症候群	1 (0.9)	1 (1.1)	2 (1.0)
大腸ポリープ	0	1 (1.1)	1 (0.5)
口唇乾燥	1 (0.9)	0	1 (0.5)
メレナ	2 (1.8)	0	2 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
胃腸障害 (Cont.)			
口腔腫脹	1 (0.9)	0	1 (0.5)
悪心	4 (3.6)	7 (7.4)	11 (5.3)
口腔内不快感	1 (0.9)	0	1 (0.5)
口腔内痛	1 (0.9)	0	1 (0.5)
口の錯感覚	1 (0.9)	1 (1.1)	2 (1.0)
直腸出血	0	1 (1.1)	1 (0.5)
歯痛	0	1 (1.1)	1 (0.5)
嘔吐	1 (0.9)	2 (2.1)	3 (1.5)
一般・全身障害および投与部位の状態	66 (59.5)	72 (75.8)	138 (67.0)
投与部位内出血	0	1 (1.1)	1 (0.5)
投与部位漏出	0	1 (1.1)	1 (0.5)
無力症	2 (1.8)	0	2 (1.0)
カテーテル留置部位紅斑	1 (0.9)	1 (1.1)	2 (1.0)
カテーテル留置部位漏出	1 (0.9)	0	1 (0.5)
カテーテル留置部位出血	0	1 (1.1)	1 (0.5)
カテーテル留置部位刺激感	0	1 (1.1)	1 (0.5)
カテーテル留置部位浮腫	0	1 (1.1)	1 (0.5)
カテーテル留置部位疼痛	0	1 (1.1)	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
胸部不快感	0	1 (1.1)	1 (0.5)
胸痛	1 (0.9)	1 (1.1)	2 (1.0)
泣き	1 (0.9)	0	1 (0.5)
薬効欠如	0	1 (1.1)	1 (0.5)
薬剤離脱症候群	0	1 (1.1)	1 (0.5)
疲労	3 (2.7)	1 (1.1)	4 (1.9)
異常感	0	1 (1.1)	1 (0.5)
冷感	0	1 (1.1)	1 (0.5)
歩行障害	0	1 (1.1)	1 (0.5)
低体温	1 (0.9)	1 (1.1)	2 (1.0)
インフルエンザ様疾患	1 (0.9)	2 (2.1)	3 (1.5)
注入部位内出血	7 (6.3)	2 (2.1)	9 (4.4)
注入部位皮膚炎	2 (1.8)	2 (2.1)	4 (1.9)
注入部位分泌物	0	1 (1.1)	1 (0.5)
注入部位不快感	1 (0.9)	0	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位びらん	1 (0.9)	0	1 (0.5)
注入部位紅斑	36 (32.4)	44 (46.3)	80 (38.8)
注入部位皮膚剥脱	3 (2.7)	2 (2.1)	5 (2.4)
注入部位血管外漏出	5 (4.5)	6 (6.3)	11 (5.3)
注入部位血腫	6 (5.4)	4 (4.2)	10 (4.9)
注入部位出血	4 (3.6)	2 (2.1)	6 (2.9)
注入部位硬結	5 (4.5)	2 (2.1)	7 (3.4)
注入部位炎症	2 (1.8)	6 (6.3)	8 (3.9)
注入部位損傷	0	2 (2.1)	2 (1.0)
注入部位刺激感	1 (0.9)	4 (4.2)	5 (2.4)
注入部位腫瘤	1 (0.9)	2 (2.1)	3 (1.5)
注入部位結節	20 (18.0)	25 (26.3)	45 (21.8)
注入部位浮腫	8 (7.2)	18 (18.9)	26 (12.6)
注入部位疼痛	8 (7.2)	11 (11.6)	19 (9.2)
注入部位蒼白	1 (0.9)	1 (1.1)	2 (1.0)
注入部位丘疹	6 (5.4)	8 (8.4)	14 (6.8)
注入部位異常感覚	0	2 (2.1)	2 (1.0)
注入部位そう痒感	3 (2.7)	1 (1.1)	4 (1.9)
注入部位発疹	1 (0.9)	3 (3.2)	4 (1.9)
注入部位反応	8 (7.2)	11 (11.6)	19 (9.2)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注入部位痂皮	0	1 (1.1)	1 (0.5)
注入部位腫脹	2 (1.8)	1 (1.1)	3 (1.5)
注入部位小水疱	0	2 (2.1)	2 (1.0)
注入部位熱感	0	1 (1.1)	1 (0.5)
注射部位内出血	1 (0.9)	1 (1.1)	2 (1.0)
注射部位変色	1 (0.9)	0	1 (0.5)
注射部位紅斑	5 (4.5)	5 (5.3)	10 (4.9)
注射部位出血	0	1 (1.1)	1 (0.5)
注射部位炎症	2 (1.8)	4 (4.2)	6 (2.9)
注射部位結節	3 (2.7)	5 (5.3)	8 (3.9)
注射部位浮腫	1 (0.9)	1 (1.1)	2 (1.0)
注射部位疼痛	0	2 (2.1)	2 (1.0)
注射部位丘疹	0	2 (2.1)	2 (1.0)
注射部位反応	1 (0.9)	0	1 (0.5)
注射部位腫脹	1 (0.9)	2 (2.1)	3 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
一般・全身障害および投与部位の状態 (Cont.)			
注射部位蕁麻疹	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	1 (1.1)	1 (0.5)
倦怠感	0	1 (1.1)	1 (0.5)
医療機器使用部位刺激感	1 (0.9)	1 (1.1)	2 (1.0)
医療機器使用部位発疹	0	1 (1.1)	1 (0.5)
非心臓性胸痛	0	2 (2.1)	2 (1.0)
末梢性浮腫	4 (3.6)	1 (1.1)	5 (2.4)
疼痛	2 (1.8)	0	2 (1.0)
末梢腫脹	0	3 (3.2)	3 (1.5)
穿刺部位紅斑	0	2 (2.1)	2 (1.0)
穿刺部位硬結	2 (1.8)	0	2 (1.0)
発熱	0	1 (1.1)	1 (0.5)
血管穿刺部位硬結	1 (0.9)	0	1 (0.5)
肝胆道系障害	1 (0.9)	1 (1.1)	2 (1.0)
肝嚢胞	1 (0.9)	0	1 (0.5)
脂肪肝	0	1 (1.1)	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症	46 (41.4)	45 (47.4)	91 (44.2)
四肢膿瘍	0	1 (1.1)	1 (0.5)
無症候性COVID-19	0	1 (1.1)	1 (0.5)
細菌性疾患キャリアー	0	1 (1.1)	1 (0.5)
ウイルス性気管支炎	0	1 (1.1)	1 (0.5)
COVID-19	1 (0.9)	0	1 (0.5)
COVID-19肺炎	1 (0.9)	0	1 (0.5)
カテーテル留置部位感染	1 (0.9)	0	1 (0.5)
蜂巣炎	1 (0.9)	2 (2.1)	3 (1.5)
結膜炎	2 (1.8)	0	2 (1.0)
膀胱炎	1 (0.9)	0	1 (0.5)
爪の皮膚糸状菌症	0	1 (1.1)	1 (0.5)
歯肉炎	1 (0.9)	0	1 (0.5)
麦粒腫	1 (0.9)	0	1 (0.5)
感染性皮膚潰瘍	0	1 (1.1)	1 (0.5)
インフルエンザ	0	1 (1.1)	1 (0.5)
注入部位膿瘍	11 (9.9)	9 (9.5)	20 (9.7)
注入部位蜂巣炎	21 (18.9)	19 (20.0)	40 (19.4)
注入部位感染	6 (5.4)	9 (9.5)	15 (7.3)
注入部位膿疱	0	1 (1.1)	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
感染症および寄生虫症 (Cont.)			
注射部位蜂巣炎	0	2 (2.1)	2 (1.0)
リンパ管炎	0	1 (1.1)	1 (0.5)
上咽頭炎	5 (4.5)	2 (2.1)	7 (3.4)
耳下腺膿瘍	0	1 (1.1)	1 (0.5)
肺炎	2 (1.8)	1 (1.1)	3 (1.5)
術後膿瘍	1 (0.9)	0	1 (0.5)
シュードモナス感染	0	1 (1.1)	1 (0.5)
気道感染	0	1 (1.1)	1 (0.5)
敗血症	2 (1.8)	0	2 (1.0)
副鼻腔炎	1 (0.9)	0	1 (0.5)
ブドウ球菌感染	1 (0.9)	1 (1.1)	2 (1.0)
歯感染	1 (0.9)	1 (1.1)	2 (1.0)
上気道感染	1 (0.9)	0	1 (0.5)
尿路感染	5 (4.5)	11 (11.6)	16 (7.8)
水痘帯状疱疹ウイルス感染	1 (0.9)	0	1 (0.5)
傷害、中毒および処置合併症	13 (11.7)	21 (22.1)	34 (16.5)
足関節部骨折	0	1 (1.1)	1 (0.5)
節足動物咬傷	0	1 (1.1)	1 (0.5)
骨挫傷	1 (0.9)	1 (1.1)	2 (1.0)
脳挫傷	1 (0.9)	0	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
傷害、中毒および処置合併症 (Cont.)			
挫傷	1 (0.9)	6 (6.3)	7 (3.4)
期限切れの製品使用	1 (0.9)	0	1 (0.5)
眼挫傷	0	1 (1.1)	1 (0.5)
顔面損傷	0	1 (1.1)	1 (0.5)
転倒	11 (9.9)	18 (18.9)	29 (14.1)
頭部損傷	1 (0.9)	3 (3.2)	4 (1.9)
関節脱臼	0	1 (1.1)	1 (0.5)
靭帯捻挫	1 (0.9)	1 (1.1)	2 (1.0)
過量投与	0	1 (1.1)	1 (0.5)
肋骨骨折	1 (0.9)	1 (1.1)	2 (1.0)
皮膚擦過傷	0	2 (2.1)	2 (1.0)
皮膚損傷	1 (0.9)	0	1 (0.5)
皮膚裂傷	1 (0.9)	4 (4.2)	5 (2.4)
ストレス骨折	1 (0.9)	0	1 (0.5)
硬膜下血腫	0	1 (1.1)	1 (0.5)
サンバーン	0	1 (1.1)	1 (0.5)
腱断裂	1 (0.9)	1 (1.1)	2 (1.0)
過少量投与	0	1 (1.1)	1 (0.5)
創傷	1 (0.9)	0	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査	21 (18.9)	19 (20.0)	40 (19.4)
血中クレアチンホスホキナーゼ増加	1 (0.9)	1 (1.1)	2 (1.0)
血中クレアチニン減少	0	1 (1.1)	1 (0.5)
血中葉酸異常	0	1 (1.1)	1 (0.5)
血中葉酸減少	1 (0.9)	1 (1.1)	2 (1.0)
血中ホモシステイン増加	1 (0.9)	2 (2.1)	3 (1.5)
血中リン減少	0	1 (1.1)	1 (0.5)
血中ナトリウム減少	1 (0.9)	0	1 (0.5)
C-反応性蛋白増加	0	1 (1.1)	1 (0.5)
心雑音	1 (0.9)	0	1 (0.5)
握力低下	1 (0.9)	0	1 (0.5)
ヘモグロビン減少	1 (0.9)	1 (1.1)	2 (1.0)
好中球数増加	0	1 (1.1)	1 (0.5)
プロトロンビン時間延長	0	1 (1.1)	1 (0.5)
赤血球数減少	0	1 (1.1)	1 (0.5)
ビタミンB12減少	0	1 (1.1)	1 (0.5)
ビタミンB6減少	5 (4.5)	4 (4.2)	9 (4.4)
ビタミンD減少	0	1 (1.1)	1 (0.5)
体重減少	10 (9.0)	13 (13.7)	23 (11.2)
体重増加	2 (1.8)	0	2 (1.0)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査 (Cont.)			
白血球数増加	0	1 (1.1)	1 (0.5)
代謝および栄養障害	10 (9.0)	16 (16.8)	26 (12.6)
悪液質	1 (0.9)	0	1 (0.5)
食欲減退	2 (1.8)	2 (2.1)	4 (1.9)
脱水	1 (0.9)	2 (2.1)	3 (1.5)
糖尿病	0	1 (1.1)	1 (0.5)
水分過負荷	0	1 (1.1)	1 (0.5)
体液貯留	1 (0.9)	1 (1.1)	2 (1.0)
葉酸欠乏	1 (0.9)	1 (1.1)	2 (1.0)
高コレステロール血症	0	1 (1.1)	1 (0.5)
高ホモシステイン血症	0	1 (1.1)	1 (0.5)
低カルシウム血症	0	1 (1.1)	1 (0.5)
低カリウム血症	0	2 (2.1)	2 (1.0)
低ナトリウム血症	2 (1.8)	0	2 (1.0)
栄養障害	0	1 (1.1)	1 (0.5)
ビタミンB群欠乏	1 (0.9)	1 (1.1)	2 (1.0)
ビタミンB12欠乏	0	2 (2.1)	2 (1.0)
ビタミンB6欠乏	3 (2.7)	5 (5.3)	8 (3.9)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害	17 (15.3)	15 (15.8)	32 (15.5)
関節痛	1 (0.9)	3 (3.2)	4 (1.9)
反応性関節炎	1 (0.9)	0	1 (0.5)
背部痛	5 (4.5)	4 (4.2)	9 (4.4)
骨痛	0	1 (1.1)	1 (0.5)
滑液包炎	2 (1.8)	0	2 (1.0)
外骨腫	0	1 (1.1)	1 (0.5)
椎間関節症候群	0	1 (1.1)	1 (0.5)
椎間板変性症	1 (0.9)	0	1 (0.5)
椎間板突出	0	1 (1.1)	1 (0.5)
関節滲出液	0	2 (2.1)	2 (1.0)
四肢不快感	0	1 (1.1)	1 (0.5)
筋萎縮	0	1 (1.1)	1 (0.5)
筋痙縮	2 (1.8)	3 (3.2)	5 (2.4)
筋力低下	2 (1.8)	1 (1.1)	3 (1.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3__1.2

Subjects with Treatment-Emergent Adverse Events
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
筋骨格系および結合組織障害 (Cont.)			
頚部痛	2 (1.8)	0	2 (1.0)
骨炎	0	1 (1.1)	1 (0.5)
変形性関節症	1 (0.9)	4 (4.2)	5 (2.4)
骨減少症	1 (0.9)	0	1 (0.5)
四肢痛	3 (2.7)	2 (2.1)	5 (2.4)
関節周囲炎	0	1 (1.1)	1 (0.5)
横紋筋融解症	1 (0.9)	0	1 (0.5)
肩回旋筋腱板症候群	0	1 (1.1)	1 (0.5)
変形性脊椎症	1 (0.9)	0	1 (0.5)
腱障害	0	1 (1.1)	1 (0.5)
腱炎	1 (0.9)	0	1 (0.5)
弾発指	1 (0.9)	0	1 (0.5)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	1 (0.9)	4 (4.2)	5 (2.4)
基底細胞癌	0	2 (2.1)	2 (1.0)
直腸腺癌	1 (0.9)	0	1 (0.5)
脂漏性角化症	0	1 (1.1)	1 (0.5)
皮膚有棘細胞癌	0	1 (1.1)	1 (0.5)

Note: Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]