TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
冷感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
歩行障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
低体温	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
インフルエンザ様疾患	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	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)
Reasonable possibility	7 (6.3)	2 (2.1)	9 (4.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
注入部位皮膚炎	2 (1.8)	2 (2.1)	4 (1.9)
Reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
注入部位分泌物	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位不快感	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
注入部位びらん	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注入部位紅斑	35 (31.5)	43 (45.3)	78 (37.9)
No reasonable possibility	4 (3.6)	1 (1.1)	5 (2.4)
Reasonable possibility	31 (27.9)	42 (44.2)	73 (35.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位皮膚剥脱	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	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)
Reasonable possibility	5 (4.5)	6 (6.3)	11 (5.3)
注入部位血腫	4 (3.6)	4 (4.2)	8 (3.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	3 (2.7)	4 (4.2)	7 (3.4)
注入部位出血	4 (3.6)	2 (2.1)	6 (2.9)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
注入部位硬結	5 (4.5)	2 (2.1)	7 (3.4)
Reasonable possibility	5 (4.5)	2 (2.1)	7 (3.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位炎症	2 (1.8)	6 (6.3)	8 (3.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	5 (5.3)	7 (3.4)
注入部位損傷	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
注入部位刺激感	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	3 (3.2)	4 (1.9)
注入部位腫瘤	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
注入部位結節	20 (18.0)	25 (26.3)	45 (21.8)
Reasonable possibility	20 (18.0)	25 (26.3)	45 (21.8)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位浮腫	8 (7.2)	18 (18.9)	26 (12.6)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	8 (7.2)	17 (17.9)	25 (12.1)
注入部位疼痛	8 (7.2)	11 (11.6)	19 (9.2)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	7 (6.3)	10 (10.5)	17 (8.3)
注入部位蒼白	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注入部位丘疹	6 (5.4)	8 (8.4)	14 (6.8)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	6 (5.4)	7 (7.4)	13 (6.3)
注入部位異常感覚	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位そう痒感	3 (2.7)	1 (1.1)	4 (1.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	3 (2.7)	0	3 (1.5)
注入部位発疹	1 (0.9)	3 (3.2)	4 (1.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注入部位反応	8 (7.2)	11 (11.6)	19 (9.2)
Reasonable possibility	8 (7.2)	11 (11.6)	19 (9.2)
注入部位痂皮	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位腫脹	2 (1.8)	1 (1.1)	3 (1.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位小水疱	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
注入部位熱感	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位内出血	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注射部位変色	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注射部位紅斑	5 (4.5)	5 (5.3)	10 (4.9)
Reasonable possibility	5 (4.5)	5 (5.3)	10 (4.9)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
注射部位出血	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位炎症	2 (1.8)	4 (4.2)	6 (2.9)
Reasonable possibility	2 (1.8)	4 (4.2)	6 (2.9)
注射部位結節	3 (2.7)	5 (5.3)	8 (3.9)
Reasonable possibility	3 (2.7)	5 (5.3)	8 (3.9)
注射部位浮腫	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
注射部位疼痛	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注射部位丘疹	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位反応	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
注射部位腫脹	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
注射部位蕁麻疹	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
倦怠感	0	1 (1.1)	1 (0.5)
Reasonable possibility	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)
No reasonable possibility	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)
No reasonable possibility	0	1 (1.1)	1 (0.5)
非心臓性胸痛	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
末梢性浮腫	4 (3.6)	1 (1.1)	5 (2.4)
No reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
疼痛	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
末梢腫脹	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	2 (2.1)	2 (1.0)
穿刺部位紅斑	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
穿刺部位硬結	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
発熱	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
血管穿刺部位硬結	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
肝胆道系障害	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
肝嚢胞	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
脂肪肝	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	46 (41.4)	45 (47.4)	91 (44.2)
No reasonable possibility	15 (13.5)	13 (13.7)	28 (13.6)
Reasonable possibility	31 (27.9)	32 (33.7)	63 (30.6)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
無症候性COVID-19	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
細菌性疾患キャリアー	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
ウイルス性気管支炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
COVID-19	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
COVID-19肺炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
カテーテル留置部位感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
蜂巣炎	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
結膜炎	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
爪の皮膚糸状菌症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
歯肉炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
麦粒腫	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
感染性皮膚潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
インフルエンザ	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
注入部位膿瘍	10 (9.0)	9 (9.5)	19 (9.2)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	10 (9.0)	8 (8.4)	18 (8.7)
注入部位蜂巣炎	21 (18.9)	19 (20.0)	40 (19.4)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	20 (18.0)	18 (18.9)	38 (18.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
注入部位感染	5 (4.5)	9 (9.5)	14 (6.8)
No reasonable possibility	2 (1.8)	0	2 (1.0)
Reasonable possibility	3 (2.7)	9 (9.5)	12 (5.8)
注入部位膿疱	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
注射部位蜂巣炎	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
上咽頭炎	5 (4.5)	2 (2.1)	7 (3.4)
No reasonable possibility	5 (4.5)	2 (2.1)	7 (3.4)
耳下腺膿瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
肺炎	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
術後膿瘍	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
シュードモナス感染	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
気道感染	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
敗血症	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	0	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
副鼻腔炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ブドウ球菌感染	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
歯感染	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
上気道感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
尿路感染	5 (4.5)	11 (11.6)	16 (7.8)
No reasonable possibility	5 (4.5)	11 (11.6)	16 (7.8)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
水痘帯状疱疹ウイルス感染	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
傷害、中毒および処置合併症	13 (11.7)	20 (21.1)	33 (16.0)
No reasonable possibility	9 (8.1)	15 (15.8)	24 (11.7)
Reasonable possibility	4 (3.6)	5 (5.3)	9 (4.4)
足関節部骨折	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
節足動物咬傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
骨挫傷	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
脳挫傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
挫傷	1 (0.9)	6 (6.3)	7 (3.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
Reasonable possibility	0	2 (2.1)	2 (1.0)
期限切れの製品使用	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
眼挫傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
顔面損傷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
転倒	11 (9.9)	17 (17.9)	28 (13.6)
No reasonable possibility	8 (7.2)	14 (14.7)	22 (10.7)
Reasonable possibility	3 (2.7)	3 (3.2)	6 (2.9)
頭部損傷	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
関節脱臼	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
靭帯捻挫	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
過量投与	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
肋骨骨折	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
皮膚擦過傷	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
皮膚損傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚裂傷	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
ストレス骨折	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
硬膜下血腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
サンバーン	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
腱断裂	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
過少量投与	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
創傷	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
臨床検査	20 (18.0)	17 (17.9)	37 (18.0)
No reasonable possibility	9 (8.1)	4 (4.2)	13 (6.3)
Reasonable possibility	11 (9.9)	13 (13.7)	24 (11.7)
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)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
血中クレアチニン減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
血中葉酸減少	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
血中ホモシステイン増加	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
血中リン減少	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
血中ナトリウム減少	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
C-反応性蛋白増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
握力低下	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ヘモグロビン減少	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
好中球数増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	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)
No reasonable possibility	0	1 (1.1)	1 (0.5)
赤血球数減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ビタミンB12減少	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ビタミンB6減少	5 (4.5)	4 (4.2)	9 (4.4)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (2.9)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
ビタミンD減少	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
体重減少	10 (9.0)	11 (11.6)	21 (10.2)
No reasonable possibility	6 (5.4)	1 (1.1)	7 (3.4)
Reasonable possibility	4 (3.6)	10 (10.5)	14 (6.8)
体重増加	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
白血球数増加	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
代謝および栄養障害	10 (9.0)	14 (14.7)	24 (11.7)
No reasonable possibility	7 (6.3)	8 (8.4)	15 (7.3)
Reasonable possibility	3 (2.7)	6 (6.3)	9 (4.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
悪液質	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
食欲減退	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
脱水	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
糖尿病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
水分過負荷	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
体液貯留	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
葉酸欠乏	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
高コレステロール血症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
高ホモシステイン血症	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
低カリウム血症	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
代謝および栄養障害 (Cont.)			
低ナトリウム血症	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
栄養障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
ビタミンB群欠乏	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
ビタミンB12欠乏	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
ビタミンB6欠乏	3 (2.7)	5 (5.3)	8 (3.9)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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)	14 (14.7)	31 (15.0)
No reasonable possibility	14 (12.6)	12 (12.6)	26 (12.6)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
関節痛	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
反応性関節炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
背部痛	5 (4.5)	3 (3.2)	8 (3.9)
No reasonable possibility	5 (4.5)	3 (3.2)	8 (3.9)
骨痛	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
滑液包炎	2 (1.8)	0	2 (1.0)
No reasonable possibility	2 (1.8)	0	2 (1.0)
外骨腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
椎間関節症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
椎間板変性症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
椎間板突出	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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.)			
関節滲出液	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
四肢不快感	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
筋萎縮	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
筋痙縮	2 (1.8)	3 (3.2)	5 (2.4)
No reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
筋力低下	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	0	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category 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)
No reasonable possibility	2 (1.8)	0	2 (1.0)
骨炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
変形性関節症	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
骨減少症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
四肢痛	3 (2.7)	2 (2.1)	5 (2.4)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
関節周囲炎	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
横紋筋融解症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
肩回旋筋腱板症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
変形性脊椎症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
腱障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	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.)			
腱炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
弾発指	1 (0.9)	0	1 (0.5)
No reasonable possibility	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）	0	4 (4.2)	4 (1.9)
No reasonable possibility	0	4 (4.2)	4 (1.9)
基底細胞癌	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
脂漏性角化症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
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）(Cont.)			
皮膚有棘細胞癌	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
神経系障害	37 (33.3)	34 (35.8)	71 (34.5)
No reasonable possibility	18 (16.2)	17 (17.9)	35 (17.0)
Reasonable possibility	19 (17.1)	17 (17.9)	36 (17.5)
アカシジア	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
健忘	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
失語症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
平衡障害	0	4 (4.2)	4 (1.9)
No reasonable possibility	0	3 (3.2)	3 (1.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
運動緩慢	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
手根管症候群	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
大脳萎縮	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
脳出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
脳圧排効果	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
認知障害	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
振動覚低下	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
注意力障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
浮動性めまい	6 (5.4)	2 (2.1)	8 (3.9)
No reasonable possibility	3 (2.7)	0	3 (1.5)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
体位性めまい	3 (2.7)	0	3 (1.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	2 (1.8)	0	2 (1.0)
構語障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
味覚不全	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ジスキネジア	7 (6.3)	3 (3.2)	10 (4.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	6 (5.4)	3 (3.2)	9 (4.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
ジストニア	1 (0.9)	4 (4.2)	5 (2.4)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
脳症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
てんかん	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
伸展性足底反応	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
すくみ現象	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
全身性強直性間代性発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
頭痛	3 (2.7)	6 (6.3)	9 (4.4)
No reasonable possibility	1 (0.9)	4 (4.2)	5 (2.4)
Reasonable possibility	2 (1.8)	2 (2.1)	4 (1.9)
感覚鈍麻	1 (0.9)	2 (2.1)	3 (1.5)
Reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
反射減弱	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
不規則睡眠覚醒リズム障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
嗜眠	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
意識消失	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
腰仙部神経根障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
記憶障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
代謝性脳症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
神経痛	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
末梢性ニューロパチー	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
オンオフ現象	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
錯感覚	4 (3.6)	2 (2.1)	6 (2.9)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
パーキンソン病	7 (6.3)	2 (2.1)	9 (4.4)
No reasonable possibility	4 (3.6)	0	4 (1.9)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
パーキンソニズム	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
側反弓	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
多発ニューロパチー	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
失神寸前の状態	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
心因性発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
反射異常	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
坐骨神経痛	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
痙攣発作	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感覚障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
感覚消失	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
神経系障害 (Cont.)			
睡眠時麻痺	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
傾眠	8 (7.2)	1 (1.1)	9 (4.4)
No reasonable possibility	5 (4.5)	0	5 (2.4)
Reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
失神	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
振戦	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
製品の問題	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
製品の問題 (Cont.)			
医療機器送達システムの問題	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
医療機器位置異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
精神障害	36 (32.4)	39 (41.1)	75 (36.4)
No reasonable possibility	8 (7.2)	12 (12.6)	20 (9.7)
Reasonable possibility	28 (25.2)	27 (28.4)	55 (26.7)
感情不安定	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
激越	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
不安	9 (8.1)	12 (12.6)	21 (10.2)
No reasonable possibility	7 (6.3)	7 (7.4)	14 (6.8)
Reasonable possibility	2 (1.8)	5 (5.3)	7 (3.4)
不安障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
無感情	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
強迫行為	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
強迫性性行動	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
錯乱状態	4 (3.6)	3 (3.2)	7 (3.4)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (2.9)
譫妄	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)
妄想	7 (6.3)	1 (1.1)	8 (3.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	7 (6.3)	0	7 (3.4)
寄生虫妄想	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
妄想性障害、詳細不明	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
抑うつ気分	2 (1.8)	0	2 (1.0)
No reasonable possibility	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
うつ病	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ドーパミン調節障害症候群	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
ディスフェミア	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
睡眠異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
情動障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
注射恐怖	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
幻覚	12 (10.8)	18 (18.9)	30 (14.6)
No reasonable possibility	0	4 (4.2)	4 (1.9)
Reasonable possibility	12 (10.8)	14 (14.7)	26 (12.6)
幻聴	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
幻嗅	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
幻視	6 (5.4)	4 (4.2)	10 (4.9)
Reasonable possibility	6 (5.4)	4 (4.2)	10 (4.9)
混合性幻覚	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
性欲過剰	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
錯覚	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
衝動制御障害	0	4 (4.2)	4 (1.9)
No reasonable possibility	0	2 (2.1)	2 (1.0)
Reasonable possibility	0	2 (2.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
衝動行為	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
不眠症	2 (1.8)	6 (6.3)	8 (3.9)
No reasonable possibility	0	3 (3.2)	3 (1.5)
Reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
易刺激性	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
躁病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
気分動揺	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
悪夢	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
パニック発作	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
パニック反応	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
妄想症	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
睡眠の質低下	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
処置に対する不安	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
精神病性障害	3 (2.7)	2 (2.1)	5 (2.4)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)
精神病症状	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
レム睡眠行動障害	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
レム睡眠異常	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
睡眠障害	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
ねごと	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
常同症	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
ストレス	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
精神障害 (Cont.)			
自殺念慮	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
自殺企図	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
腎および尿路障害	5 (4.5)	7 (7.4)	12 (5.8)
No reasonable possibility	5 (4.5)	5 (5.3)	10 (4.9)
Reasonable possibility	0	2 (2.1)	2 (1.0)
膀胱痙縮	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
膀胱結石	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
腎および尿路障害 (Cont.)			
排尿困難	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
緊張性膀胱	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
夜間頻尿	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
多尿	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
腎機能障害	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
腎および尿路障害 (Cont.)			
尿管結石症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
切迫性尿失禁	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
尿失禁	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
尿閉	0	3 (3.2)	3 (1.5)
No reasonable possibility	0	3 (3.2)	3 (1.5)
尿臭異常	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
生殖系および乳房障害	2 (1.8)	3 (3.2)	5 (2.4)
No reasonable possibility	1 (0.9)	3 (3.2)	4 (1.9)
Reasonable possibility	1 (0.9)	0	1 (0.5)
良性前立腺肥大症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
勃起不全	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
ペイロニー病	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
前立腺腫大	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
生殖系および乳房障害 (Cont.)			
腟脱	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
呼吸器、胸郭および縦隔障害	5 (4.5)	13 (13.7)	18 (8.7)
No reasonable possibility	5 (4.5)	11 (11.6)	16 (7.8)
Reasonable possibility	0	2 (2.1)	2 (1.0)
気管支拡張症	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
咳嗽	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
発声障害	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
呼吸困難	2 (1.8)	5 (5.3)	7 (3.4)
No reasonable possibility	2 (1.8)	3 (3.2)	5 (2.4)
Reasonable possibility	0	2 (2.1)	2 (1.0)
労作性呼吸困難	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
鼻出血	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
過換気	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
口腔咽頭痛	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
誤嚥性肺炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
湿性咳嗽	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
肺塞栓症	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	2 (2.1)	2 (1.0)
ラ音	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
鼻漏	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
呼吸器、胸郭および縦隔障害 (Cont.)			
咽喉刺激感	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	10 (9.0)	10 (10.5)	20 (9.7)
No reasonable possibility	6 (5.4)	8 (8.4)	14 (6.8)
Reasonable possibility	4 (3.6)	2 (2.1)	6 (2.9)
脱毛症	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
褥瘡性潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
皮膚嚢腫	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
皮膚炎	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
接触皮膚炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
おむつ皮膚炎	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
薬疹	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚乾燥	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
紅斑	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	2 (2.1)	3 (1.5)
爪の障害	1 (0.9)	0	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
脂肪織炎	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
丘疹	0	2 (2.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	0	1 (1.1)	1 (0.5)
そう痒症	2 (1.8)	1 (1.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	1 (0.9)	0	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
乾癬	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
発疹	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
紅斑性皮疹	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
そう痒性皮疹	1 (0.9)	1 (1.1)	2 (1.0)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	1 (0.9)	0	1 (0.5)
皮膚潰瘍	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
皮膚および皮下組織障害 (Cont.)			
蕁麻疹	2 (1.8)	0	2 (1.0)
Reasonable possibility	2 (1.8)	0	2 (1.0)
外科および内科処置	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
抜歯	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
血管障害	10 (9.0)	9 (9.5)	19 (9.2)
No reasonable possibility	5 (4.5)	6 (6.3)	11 (5.3)
Reasonable possibility	5 (4.5)	3 (3.2)	8 (3.9)
深部静脈血栓症	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害 (Cont.)			
血腫	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
出血	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
高血圧	1 (0.9)	2 (2.1)	3 (1.5)
No reasonable possibility	1 (0.9)	1 (1.1)	2 (1.0)
Reasonable possibility	0	1 (1.1)	1 (0.5)
高血圧クリーゼ	1 (0.9)	0	1 (0.5)
No reasonable possibility	1 (0.9)	0	1 (0.5)
低血圧	2 (1.8)	2 (2.1)	4 (1.9)
No reasonable possibility	0	1 (1.1)	1 (0.5)
Reasonable possibility	2 (1.8)	1 (1.1)	3 (1.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Maintenance period (Cont.)	N=111	N=95	N=206
血管障害 (Cont.)			
起立性高血圧	0	1 (1.1)	1 (0.5)
No reasonable possibility	0	1 (1.1)	1 (0.5)
起立性低血圧	6 (5.4)	3 (3.2)	9 (4.4)
No reasonable possibility	3 (2.7)	1 (1.1)	4 (1.9)
Reasonable possibility	3 (2.7)	2 (2.1)	5 (2.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表37　死亡した被験者一覧：M15-741試験

[redacted]20[redacted] 04:28 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE [redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 5[redacted].[redacted] kg								
	FU	57 TO 63	119	R: MULTIPLE ORGAN FAILURE S: 一般・全身障害および投与部位の状態 P: 多臓器機能不全症候群 L: Multiple organ failure	E: 119 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DOSE NOT CHANGED O: NONE	S: Yes, Death of subject R: UNLIKELY O: GENERAL IMPAIRMENT, PROGRESS IN PARKINSON'S DISEASE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted] [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 108	108	108	R: CARDIORESPIRATORY ARREST S: 心臓障害 P: 心肺停止 L: Cardio-respiratory arrest	E: 108 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Death of subject R: NOT RELATED O: DETERIORATION OF THE GENERAL STATE OF HEALTH A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Epoch Name	Epoch Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE [redacted]# Age: 7[redacted] Sex: Female Race: WHITE Weight: 6[redacted].[redacted] kg							
	FU	275 TO	37 311	R: CAQUEXIA. S: 代謝および栄養障害 P: 悪液質 L: Cachexia	E: 322 L: 12 Days	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG INTERRUPTED	S: Yes, Life threatening, Death of subject, Hospitalization or prolonged hospitalization, Other medically important serious event, Persistent or significant disability/incapacity R: NOT RELATED O: IT HAS BEEN IN THE CONTEXT OF URINARY INFECTION, 2 RESPIRATORY INFECTIONS AND PROLONGED BEDDING. A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE								
[redacted]# Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 289	289	289	R: ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA S: 傷害、中毒および処置合併症 P: 硬膜下血腫 L: Acute subdural hematoma	E: 289 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Life threatening, Death of subject R: NOT RELATED O: PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE									
[redacted]#	Age: 6[redacted] Sex: Female Race: WHITE Weight: 4[redacted].[redacted] kg								
	TRT	1 TO 289	289	289		R: CEREBRAL MARKED MASS EFFECT S: 神経系障害 P: 脳圧排効果 L: Cerebral mass effect	E: 289 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN	S: Yes, Life threatening, Death of subject R: NOT RELATED O: PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

TABLE 14.3 2.1

Listing of All Deaths
(All Screened Subjects)

Subject Number	Name	Epoch	Interval	Rx Day of Onset	Day	R: Reported Term S: System Organ Class P: MedDRA 24.0 Preferred Term L: Lower Level Term	E: Rx Day Ended O: Ongoing at the End of Study? L: Length I: Intermittent?	S: Severity ----- Relationship to ----- R1: ABBV-951 R2: Loading Dose Drug R3: Rescue Dose Drug R4: COVID-19 Infection A1: Action Taken with ABBV-951 A2: Action Taken with Rescue Dose Treatment O: Other Actions Taken	S: Serious AE? R: Relationship to Infusion Pump? O: Other Cause of Event A: AbbVie Opinion of Causality
INV: [redacted], [redacted] ([redacted]) TRT: ABBV-951 HIGH DOSE									
[redacted]# Age: 6[redacted] Sex: Male Race: WHITE Weight: 10[redacted].[redacted] kg									
	TRT	1 TO 117	117	117		R: CEREBRAL VASCULAR ACCIDENT S: 神経系障害 P: 脳血管発作 L: Cerebrovascular accident	E: 117 L: 1 Day	S: SEVERE R1: NO REASONABLE POSSIBILITY R4: No A1: DRUG WITHDRAWN O: NONE	S: Yes, Life threatening, Death of subject, Other medically important serious event, Persistent or significant disability/incapacity R: NOT RELATED O: MEDICAL HISTORY OF: CAD, INFERIOR MI [redacted]/[redacted]/20[redacted], INFRARENAL ABDOMINAL AORTIC ANEURYSM, BILATERAL LOWER LOBE CAP, EMPHYSEMA/COPD A: NO REASONABLE POSSIBILITY

Subject prematurely discontinued.

Program Source Code: [redacted]

表38　重篤な有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 04:28 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1

Subjects with Treatment-Emergent Serious 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	31 (23.5)	30 (26.8)	61 (25.0)
心臓障害	1 (0.8)	2 (1.8)	3 (1.2)
急性心筋梗塞	1 (0.8)	0	1 (0.4)
心房細動	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)
眼障害	0	1 (0.9)	1 (0.4)
眼窩周囲痛	0	1 (0.9)	1 (0.4)
眼窩周囲腫脹	0	1 (0.9)	1 (0.4)
胃腸障害	1 (0.8)	0	1 (0.4)
虚血性大腸炎	1 (0.8)	0	1 (0.4)
腸出血	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 1.11.1

Subjects with Treatment-Emergent Serious 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	4 (3.0)	3 (2.7)	7 (2.9)
無力症	1 (0.8)	0	1 (0.4)
胸部不快感	0	1 (0.9)	1 (0.4)
胸痛	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
注入部位血腫	0	1 (0.9)	1 (0.4)
注入部位損傷	1 (0.8)	1 (0.9)	2 (0.8)
感染症および寄生虫症	11 (8.3)	13 (11.6)	24 (9.8)
COVID-19	1 (0.8)	0	1 (0.4)
蜂巣炎	0	1 (0.9)	1 (0.4)
注入部位膿瘍	5 (3.8)	3 (2.7)	8 (3.3)
注入部位蜂巣炎	4 (3.0)	6 (5.4)	10 (4.1)
注入部位感染	0	1 (0.9)	1 (0.4)
耳下腺膿瘍	0	1 (0.9)	1 (0.4)
肺炎	2 (1.5)	1 (0.9)	3 (1.2)
敗血症	3 (2.3)	1 (0.9)	4 (1.6)
敗血症性ショック	1 (0.8)	0	1 (0.4)
尿路感染	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 1.11.1

Subjects with Treatment-Emergent Serious 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	1 (0.8)	2 (1.8)	3 (1.2)
顔面損傷	0	1 (0.9)	1 (0.4)
転倒	1 (0.8)	1 (0.9)	2 (0.8)
硬膜下血腫	0	1 (0.9)	1 (0.4)
臨床検査	1 (0.8)	0	1 (0.4)
血中ナトリウム減少	1 (0.8)	0	1 (0.4)
代謝および栄養障害	2 (1.5)	1 (0.9)	3 (1.2)
脱水	1 (0.8)	0	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
低ナトリウム血症	1 (0.8)	0	1 (0.4)
筋骨格系および結合組織障害	3 (2.3)	1 (0.9)	4 (1.6)
反応性関節炎	1 (0.8)	0	1 (0.4)
変形性関節症	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)
神経系障害	9 (6.8)	12 (10.7)	21 (8.6)
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	1 (0.8)	1 (0.9)	2 (0.8)
浮動性めまい	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 1.11.1

Subjects with Treatment-Emergent Serious 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.)			
構語障害	0	1 (0.9)	1 (0.4)
ジストニア	0	2 (1.8)	2 (0.8)
全身性強直性間代性発作	0	1 (0.9)	1 (0.4)
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)
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)
オンオフ現象	1 (0.8)	0	1 (0.4)
錯感覚	0	1 (0.9)	1 (0.4)
パーキンソン病	5 (3.8)	1 (0.9)	6 (2.5)
パーキンソニズム	0	1 (0.9)	1 (0.4)
心因性発作	0	1 (0.9)	1 (0.4)
精神障害	11 (8.3)	6 (5.4)	17 (7.0)
錯乱状態	0	1 (0.9)	1 (0.4)
譫妄	1 (0.8)	1 (0.9)	2 (0.8)
妄想	1 (0.8)	1 (0.9)	2 (0.8)
妄想性障害、詳細不明	0	1 (0.9)	1 (0.4)
ドーパミン調節障害症候群	1 (0.8)	0	1 (0.4)
幻覚	6 (4.5)	1 (0.9)	7 (2.9)
精神病性障害	4 (3.0)	2 (1.8)	6 (2.5)
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 1.11.1

Subjects with Treatment-Emergent Serious 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
呼吸器、胸郭および縦隔障害	1 (0.8)	3 (2.7)	4 (1.6)
気管支拡張症	1 (0.8)	0	1 (0.4)
呼吸困難	0	1 (0.9)	1 (0.4)
過換気	0	1 (0.9)	1 (0.4)
肺塞栓症	0	1 (0.9)	1 (0.4)
血管障害	1 (0.8)	2 (1.8)	3 (1.2)
血腫	0	1 (0.9)	1 (0.4)
出血	0	1 (0.9)	1 (0.4)
起立性低血圧	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 1.11.1

Subjects with Treatment-Emergent Serious 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	11 (8.3)	6 (5.4)	17 (7.0)
一般・全身障害および投与部位の状態	1 (0.8)	0	1 (0.4)
低体温	1 (0.8)	0	1 (0.4)
感染症および寄生虫症	3 (2.3)	3 (2.7)	6 (2.5)
注入部位膿瘍	1 (0.8)	1 (0.9)	2 (0.8)
注入部位蜂巣炎	0	2 (1.8)	2 (0.8)
肺炎	1 (0.8)	1 (0.9)	2 (0.8)
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	1 (0.8)	0	1 (0.4)
傷害、中毒および処置合併症	1 (0.8)	0	1 (0.4)
転倒	1 (0.8)	0	1 (0.4)
代謝および栄養障害	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 1.11.1

Subjects with Treatment-Emergent Serious 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	2 (1.5)	0	2 (0.8)
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)
神経系障害	5 (3.8)	3 (2.7)	8 (3.3)
認知障害	1 (0.8)	0	1 (0.4)
浮動性めまい	1 (0.8)	0	1 (0.4)
構語障害	0	1 (0.9)	1 (0.4)
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)
錯感覚	0	1 (0.9)	1 (0.4)
パーキンソン病	3 (2.3)	1 (0.9)	4 (1.6)
精神障害	6 (4.5)	1 (0.9)	7 (2.9)
錯乱状態	0	1 (0.9)	1 (0.4)
譫妄	1 (0.8)	1 (0.9)	2 (0.8)
妄想	1 (0.8)	0	1 (0.4)
幻覚	4 (3.0)	0	4 (1.6)
精神病性障害	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 1.11.1

Subjects with Treatment-Emergent Serious 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
呼吸器、胸郭および縦隔障害	0	1 (0.9)	1 (0.4)
過換気	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 1.11.1

Subjects with Treatment-Emergent Serious 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	21 (18.9)	26 (27.4)	47 (22.8)
心臓障害	1 (0.9)	2 (2.1)	3 (1.5)
急性心筋梗塞	1 (0.9)	0	1 (0.5)
心房細動	0	1 (1.1)	1 (0.5)
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)
眼障害	0	1 (1.1)	1 (0.5)
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)
胃腸障害	1 (0.9)	0	1 (0.5)
虚血性大腸炎	1 (0.9)	0	1 (0.5)
腸出血	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 1.11.1

Subjects with Treatment-Emergent Serious 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	3 (2.7)	3 (3.2)	6 (2.9)
無力症	1 (0.9)	0	1 (0.5)
胸部不快感	0	1 (1.1)	1 (0.5)
胸痛	1 (0.9)	0	1 (0.5)
注入部位血腫	0	1 (1.1)	1 (0.5)
注入部位損傷	1 (0.9)	1 (1.1)	2 (1.0)
感染症および寄生虫症	8 (7.2)	11 (11.6)	19 (9.2)
COVID-19	1 (0.9)	0	1 (0.5)
蜂巣炎	0	1 (1.1)	1 (0.5)
注入部位膿瘍	4 (3.6)	2 (2.1)	6 (2.9)
注入部位蜂巣炎	4 (3.6)	4 (4.2)	8 (3.9)
注入部位感染	0	1 (1.1)	1 (0.5)
耳下腺膿瘍	0	1 (1.1)	1 (0.5)
肺炎	1 (0.9)	1 (1.1)	2 (1.0)
敗血症	2 (1.8)	1 (1.1)	3 (1.5)
尿路感染	1 (0.9)	2 (2.1)	3 (1.5)
傷害、中毒および処置合併症	0	2 (2.1)	2 (1.0)
顔面損傷	0	1 (1.1)	1 (0.5)
転倒	0	1 (1.1)	1 (0.5)
硬膜下血腫	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 1.11.1

Subjects with Treatment-Emergent Serious 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	1 (0.9)	0	1 (0.5)
血中ナトリウム減少	1 (0.9)	0	1 (0.5)
代謝および栄養障害	2 (1.8)	0	2 (1.0)
脱水	1 (0.9)	0	1 (0.5)
低ナトリウム血症	1 (0.9)	0	1 (0.5)
筋骨格系および結合組織障害	1 (0.9)	1 (1.1)	2 (1.0)
反応性関節炎	1 (0.9)	0	1 (0.5)
変形性関節症	0	1 (1.1)	1 (0.5)
神経系障害	4 (3.6)	9 (9.5)	13 (6.3)
脳圧排効果	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
認知障害	0	1 (1.1)	1 (0.5)
ジストニア	0	2 (2.1)	2 (1.0)
全身性強直性間代性発作	0	1 (1.1)	1 (0.5)
意識消失	1 (0.9)	1 (1.1)	2 (1.0)
腰仙部神経根障害	0	1 (1.1)	1 (0.5)
オンオフ現象	1 (0.9)	0	1 (0.5)
パーキンソン病	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 1.11.1

Subjects with Treatment-Emergent Serious 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
神経系障害 (Cont.)			
パーキンソニズム	0	1 (1.1)	1 (0.5)
心因性発作	0	1 (1.1)	1 (0.5)
精神障害	6 (5.4)	5 (5.3)	11 (5.3)
妄想	0	1 (1.1)	1 (0.5)
妄想性障害、詳細不明	0	1 (1.1)	1 (0.5)
ドーパミン調節障害症候群	1 (0.9)	0	1 (0.5)
幻覚	2 (1.8)	1 (1.1)	3 (1.5)
精神病性障害	2 (1.8)	2 (2.1)	4 (1.9)
自殺企図	1 (0.9)	0	1 (0.5)
呼吸器、胸郭および縦隔障害	1 (0.9)	2 (2.1)	3 (1.5)
気管支拡張症	1 (0.9)	0	1 (0.5)
呼吸困難	0	1 (1.1)	1 (0.5)
肺塞栓症	0	1 (1.1)	1 (0.5)
血管障害	1 (0.9)	2 (2.1)	3 (1.5)
血腫	0	1 (1.1)	1 (0.5)
出血	0	1 (1.1)	1 (0.5)
起立性低血圧	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]

表39　中止に至った有害事象（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 04:28 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	32 (24.2)	30 (26.8)	62 (25.4)
心臓障害	0	1 (0.9)	1 (0.4)
心肺停止	0	1 (0.9)	1 (0.4)
胃腸障害	1 (0.8)	0	1 (0.4)
舌炎	1 (0.8)	0	1 (0.4)
舌痛	1 (0.8)	0	1 (0.4)
口の錯感覚	1 (0.8)	0	1 (0.4)
一般・全身障害および投与部位の状態	14 (10.6)	7 (6.3)	21 (8.6)
不快感	1 (0.8)	0	1 (0.4)
注入部位紅斑	6 (4.5)	3 (2.7)	9 (3.7)
注入部位血管外漏出	0	1 (0.9)	1 (0.4)
注入部位硬結	1 (0.8)	0	1 (0.4)
注入部位損傷	1 (0.8)	0	1 (0.4)
注入部位腫瘤	1 (0.8)	0	1 (0.4)
注入部位結節	1 (0.8)	3 (2.7)	4 (1.6)
注入部位浮腫	2 (1.5)	2 (1.8)	4 (1.6)
注入部位疼痛	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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.)			
注入部位丘疹	0	1 (0.9)	1 (0.4)
注入部位発疹	1 (0.8)	0	1 (0.4)
注入部位反応	2 (1.5)	1 (0.9)	3 (1.2)
注射部位炎症	1 (0.8)	0	1 (0.4)
注射部位疼痛	0	1 (0.9)	1 (0.4)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
感染症および寄生虫症	5 (3.8)	8 (7.1)	13 (5.3)
注入部位膿瘍	1 (0.8)	2 (1.8)	3 (1.2)
注入部位蜂巣炎	4 (3.0)	5 (4.5)	9 (3.7)
注入部位感染	0	1 (0.9)	1 (0.4)
尿路感染	0	1 (0.9)	1 (0.4)
傷害、中毒および処置合併症	1 (0.8)	1 (0.9)	2 (0.8)
注入に伴う反応	1 (0.8)	0	1 (0.4)
硬膜下血腫	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	0	1 (0.9)	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)
白血球数増加	0	1 (0.9)	1 (0.4)
代謝および栄養障害	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
筋骨格系および結合組織障害	2 (1.5)	0	2 (0.8)
筋力低下	1 (0.8)	0	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
神経系障害	10 (7.6)	8 (7.1)	18 (7.4)
運動緩慢	1 (0.8)	0	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	0	1 (0.9)	1 (0.4)
ジスキネジア	5 (3.8)	0	5 (2.0)
すくみ現象	2 (1.5)	0	2 (0.8)
代謝性脳症	0	1 (0.9)	1 (0.4)
オンオフ現象	2 (1.5)	1 (0.9)	3 (1.2)
パーキンソン病	2 (1.5)	1 (0.9)	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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.)			
パーキンソニズム	0	2 (1.8)	2 (0.8)
精神障害	7 (5.3)	8 (7.1)	15 (6.1)
感情不安定	1 (0.8)	0	1 (0.4)
不安	1 (0.8)	1 (0.9)	2 (0.8)
錯乱状態	0	2 (1.8)	2 (0.8)
妄想	1 (0.8)	0	1 (0.4)
寄生虫妄想	1 (0.8)	0	1 (0.4)
注射恐怖	0	1 (0.9)	1 (0.4)
幻覚	5 (3.8)	5 (4.5)	10 (4.1)
幻視	2 (1.5)	0	2 (0.8)
処置に対する不安	0	1 (0.9)	1 (0.4)
精神病性障害	1 (0.8)	1 (0.9)	2 (0.8)
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	0	1 (0.9)	1 (0.4)
過換気	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	1 (0.8)	0	1 (0.4)
蕁麻疹	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	16 (12.1)	10 (8.9)	26 (10.7)
一般・全身障害および投与部位の状態	7 (5.3)	2 (1.8)	9 (3.7)
不快感	1 (0.8)	0	1 (0.4)
注入部位紅斑	2 (1.5)	0	2 (0.8)
注入部位血管外漏出	0	1 (0.9)	1 (0.4)
注入部位腫瘤	1 (0.8)	0	1 (0.4)
注入部位浮腫	1 (0.8)	0	1 (0.4)
注入部位発疹	1 (0.8)	0	1 (0.4)
注入部位反応	2 (1.5)	0	2 (0.8)
穿刺部位腫脹	0	1 (0.9)	1 (0.4)
感染症および寄生虫症	3 (2.3)	3 (2.7)	6 (2.5)
注入部位膿瘍	0	1 (0.9)	1 (0.4)
注入部位蜂巣炎	3 (2.3)	3 (2.7)	6 (2.5)
傷害、中毒および処置合併症	1 (0.8)	0	1 (0.4)
注入に伴う反応	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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
臨床検査	0	1 (0.9)	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)
白血球数増加	0	1 (0.9)	1 (0.4)
代謝および栄養障害	0	1 (0.9)	1 (0.4)
低カリウム血症	0	1 (0.9)	1 (0.4)
筋骨格系および結合組織障害	2 (1.5)	0	2 (0.8)
筋力低下	1 (0.8)	0	1 (0.4)
横紋筋融解症	1 (0.8)	0	1 (0.4)
神経系障害	7 (5.3)	4 (3.6)	11 (4.5)
運動緩慢	1 (0.8)	0	1 (0.4)
ジスキネジア	3 (2.3)	0	3 (1.2)
すくみ現象	2 (1.5)	0	2 (0.8)
代謝性脳症	0	1 (0.9)	1 (0.4)
オンオフ現象	1 (0.8)	1 (0.9)	2 (0.8)
パーキンソン病	2 (1.5)	1 (0.9)	3 (1.2)
パーキンソニズム	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	3 (2.3)	2 (1.8)	5 (2.0)
感情不安定	1 (0.8)	0	1 (0.4)
不安	1 (0.8)	1 (0.9)	2 (0.8)
錯乱状態	0	1 (0.9)	1 (0.4)
幻覚	3 (2.3)	1 (0.9)	4 (1.6)
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	0	1 (0.9)	1 (0.4)
過換気	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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	16 (14.4)	20 (21.1)	36 (17.5)
心臓障害	0	1 (1.1)	1 (0.5)
心肺停止	0	1 (1.1)	1 (0.5)
胃腸障害	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)
口の錯感覚	1 (0.9)	0	1 (0.5)
一般・全身障害および投与部位の状態	7 (6.3)	5 (5.3)	12 (5.8)
注入部位紅斑	4 (3.6)	3 (3.2)	7 (3.4)
注入部位硬結	1 (0.9)	0	1 (0.5)
注入部位損傷	1 (0.9)	0	1 (0.5)
注入部位結節	1 (0.9)	3 (3.2)	4 (1.9)
注入部位浮腫	1 (0.9)	2 (2.1)	3 (1.5)
注入部位疼痛	1 (0.9)	0	1 (0.5)
注入部位丘疹	0	1 (1.1)	1 (0.5)
注入部位反応	0	1 (1.1)	1 (0.5)
注射部位炎症	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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.)			
注射部位疼痛	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	2 (1.8)	5 (5.3)	7 (3.4)
注入部位膿瘍	1 (0.9)	1 (1.1)	2 (1.0)
注入部位蜂巣炎	1 (0.9)	2 (2.1)	3 (1.5)
注入部位感染	0	1 (1.1)	1 (0.5)
尿路感染	0	1 (1.1)	1 (0.5)
傷害、中毒および処置合併症	0	1 (1.1)	1 (0.5)
硬膜下血腫	0	1 (1.1)	1 (0.5)
神経系障害	3 (2.7)	4 (4.2)	7 (3.4)
脳圧排効果	0	1 (1.1)	1 (0.5)
脳血管発作	0	1 (1.1)	1 (0.5)
認知障害	0	1 (1.1)	1 (0.5)
ジスキネジア	2 (1.8)	0	2 (1.0)
オンオフ現象	1 (0.9)	0	1 (0.5)
パーキンソニズム	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 1.8.1

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) 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
精神障害	4 (3.6)	6 (6.3)	10 (4.9)
錯乱状態	0	1 (1.1)	1 (0.5)
妄想	1 (0.9)	0	1 (0.5)
寄生虫妄想	1 (0.9)	0	1 (0.5)
注射恐怖	0	1 (1.1)	1 (0.5)
幻覚	2 (1.8)	4 (4.2)	6 (2.9)
幻視	2 (1.8)	0	2 (1.0)
処置に対する不安	0	1 (1.1)	1 (0.5)
精神病性障害	1 (0.9)	1 (1.1)	2 (1.0)
皮膚および皮下組織障害	1 (0.9)	0	1 (0.5)
蕁麻疹	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]

表40　有害事象の90日間ごとの初回発現割合の推移（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 04:29 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N eval (%)	 Days 91 to 180 (N=182) n/N eval (%)	 Days 181 to 270 (N=149) n/N eval (%)	 Days 271 to 360 (N=128) n/N eval (%)
Total (Any Dose)				
Any adverse event	225/244 (92.2)	3/13 (23.1)	1/8 (12.5)	1/7 (14.3)
血液およびリンパ系障害	2/244 (0.8)	1/181 (0.6)	0/147	1/126 (0.8)
大球性貧血	0/244	0/182	0/149	1/128 (0.8)
凝血異常	1/244 (0.4)	0/182	0/149	0/128
リンパ節症	1/244 (0.4)	0/181	0/148	0/127
縦隔リンパ節腫脹	0/244	1/182 (0.5)	0/148	0/127
心臓障害	5/244 (2.0)	2/179 (1.1)	2/146 (1.4)	2/123 (1.6)
急性心筋梗塞	0/244	0/182	0/149	1/128 (0.8)
狭心症	0/244	1/182 (0.5)	0/148	0/127
心房細動	0/244	0/182	1/149 (0.7)	0/127
徐脈	1/244 (0.4)	0/181	0/148	0/127
心停止	0/244	0/182	0/149	1/128 (0.8)
心肺停止	0/244	1/182 (0.5)	0/149	0/128
冠動脈疾患	0/244	0/182	1/149 (0.7)	1/127 (0.8)
冠動脈狭窄	0/244	0/182	0/149	1/128 (0.8)
期外収縮	1/244 (0.4)	0/181	0/148	0/127
左室肥大	1/244 (0.4)	0/182	0/149	0/128
心筋梗塞	1/244 (0.4)	0/181	0/149	0/128
動悸	1/244 (0.4)	0/182	1/149 (0.7)	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
Any adverse event	0/4	0/0	0/0	230/244 (94.3)
血液およびリンパ系障害	0/111	0/1	0/0	4/244 (1.6)
大球性貧血	0/113	0/1	0/0	1/244 (0.4)
凝血異常	0/114	0/1	0/0	1/244 (0.4)
リンパ節症	0/113	0/1	0/0	1/244 (0.4)
縦隔リンパ節腫脹	0/113	0/1	0/0	1/244 (0.4)
心臓障害	0/107	0/1	0/0	11/244 (4.5)
急性心筋梗塞	0/113	0/1	0/0	1/244 (0.4)
狭心症	0/113	0/1	0/0	1/244 (0.4)
心房細動	0/113	0/1	0/0	1/244 (0.4)
徐脈	0/113	0/1	0/0	1/244 (0.4)
心停止	0/113	0/1	0/0	1/244 (0.4)
心肺停止	0/114	0/1	0/0	1/244 (0.4)
冠動脈疾患	0/112	0/1	0/0	2/244 (0.8)
冠動脈狭窄	0/113	0/1	0/0	1/244 (0.4)
期外収縮	0/113	0/1	0/0	1/244 (0.4)
左室肥大	0/114	0/1	0/0	1/244 (0.4)
心筋梗塞	0/114	0/1	0/0	1/244 (0.4)
動悸	0/113	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
耳および迷路障害	6/244 (2.5)	1/177 (0.6)	1/144 (0.7)	0/123
感音性難聴	0/244	0/182	1/149 (0.7)	0/127
乗物酔い	1/244 (0.4)	0/181	0/148	0/127
回転性めまい	4/244 (1.6)	1/179 (0.6)	0/146	0/126
頭位性回転性めまい	1/244 (0.4)	0/181	0/148	0/127
眼障害	5/244 (2.0)	6/179 (3.4)	2/141 (1.4)	2/120 (1.7)
白内障	1/244 (0.4)	0/181	2/148 (1.4)	1/125 (0.8)
複視	3/244 (1.2)	0/181	0/148	0/127
ドライアイ	2/244 (0.8)	1/181 (0.6)	1/147 (0.7)	0/126
緑内障	0/244	1/182 (0.5)	0/148	1/127 (0.8)
眼窩周囲痛	0/244	1/182 (0.5)	0/148	0/127
眼窩周囲腫脹	1/244 (0.4)	1/181 (0.6)	0/148	0/127
網膜裂孔	0/244	2/182 (1.1)	0/147	0/126
霧視	1/244 (0.4)	0/182	0/149	0/128
視野欠損	0/244	1/182 (0.5)	0/148	0/128
胃腸障害	41/244 (16.8)	8/150 (5.3)	5/116 (4.3)	2/98 (2.0)
腹部膨満	3/244 (1.2)	1/179 (0.6)	0/145	0/126
腹痛	1/244 (0.4)	1/182 (0.5)	0/148	1/128 (0.8)
上腹部痛	1/244 (0.4)	1/182 (0.5)	0/148	0/127
アフタ性潰瘍	1/244 (0.4)	0/181	0/148	0/127
呼気臭	3/244 (1.2)	0/179	0/147	0/126
虚血性大腸炎	0/244	1/182 (0.5)	0/148	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
耳および迷路障害	0/111	0/1	0/0	8/244 (3.3)
感音性難聴	0/113	0/1	0/0	1/244 (0.4)
乗物酔い	0/113	0/1	0/0	1/244 (0.4)
回転性めまい	0/113	0/1	0/0	5/244 (2.0)
頭位性回転性めまい	0/114	0/1	0/0	1/244 (0.4)
眼障害	0/104	0/1	0/0	15/244 (6.1)
白内障	0/110	0/1	0/0	4/244 (1.6)
複視	0/113	0/1	0/0	3/244 (1.2)
ドライアイ	0/112	0/1	0/0	4/244 (1.6)
緑内障	0/112	0/1	0/0	2/244 (0.8)
眼窩周囲痛	0/113	0/1	0/0	1/244 (0.4)
眼窩周囲腫脹	0/113	0/1	0/0	2/244 (0.8)
網膜裂孔	0/112	0/1	0/0	2/244 (0.8)
霧視	0/114	0/1	0/0	1/244 (0.4)
視野欠損	0/114	0/1	0/0	1/244 (0.4)
胃腸障害	0/84	0/1	0/0	56/244 (23.0)
腹部膨満	0/112	0/1	0/0	4/244 (1.6)
腹痛	0/113	0/1	0/0	3/244 (1.2)
上腹部痛	0/114	0/1	0/0	2/244 (0.8)
アフタ性潰瘍	0/113	0/1	0/0	1/244 (0.4)
呼気臭	0/112	0/1	0/0	3/244 (1.2)
虚血性大腸炎	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	11/244 (4.5)	6/175 (3.4)	2/138 (1.4)	1/118 (0.8)
齲歯	0/244	0/182	1/149 (0.7)	0/128
下痢	5/244 (2.0)	2/178 (1.1)	2/143 (1.4)	0/123
口内乾燥	8/244 (3.3)	0/174	0/144	0/124
消化不良	1/244 (0.4)	0/181	0/148	0/127
嚥下障害	1/244 (0.4)	0/181	0/149	0/128
糞塊	1/244 (0.4)	0/182	0/149	0/128
排便回数増加	0/244	1/182 (0.5)	0/149	0/128
胃食道逆流性疾患	1/244 (0.4)	0/181	1/148 (0.7)	0/126
舌炎	0/244	1/182 (0.5)	0/148	0/128
舌痛	0/244	1/182 (0.5)	0/148	0/128
吐血	0/244	0/182	0/149	1/128 (0.8)
痔核	1/244 (0.4)	0/182	0/149	0/128
裂孔ヘルニア	0/244	0/182	0/149	1/128 (0.8)
胃排出不全	0/244	0/182	0/149	1/128 (0.8)
腸出血	0/244	1/182 (0.5)	0/148	0/128
過敏性腸症候群	2/244 (0.8)	0/180	0/147	0/126
大腸ポリープ	0/244	0/182	0/149	1/128 (0.8)
口唇乾燥	0/244	1/182 (0.5)	0/148	0/127
メレナ	1/244 (0.4)	1/181 (0.6)	0/147	0/127
口腔腫脹	0/244	1/182 (0.5)	0/148	0/128
悪心	13/244 (5.3)	3/174 (1.7)	2/139 (1.4)	1/118 (0.8)
口腔内不快感	0/244	1/182 (0.5)	0/148	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	0/104	0/1	0/0	20/244 (8.2)
齲歯	0/114	0/1	0/0	1/244 (0.4)
下痢	0/110	0/1	0/0	9/244 (3.7)
口内乾燥	0/110	0/1	0/0	8/244 (3.3)
消化不良	0/113	0/1	0/0	1/244 (0.4)
嚥下障害	0/114	0/1	0/0	1/244 (0.4)
糞塊	0/114	0/1	0/0	1/244 (0.4)
排便回数増加	0/114	0/1	0/0	1/244 (0.4)
胃食道逆流性疾患	0/112	0/1	0/0	2/244 (0.8)
舌炎	0/114	0/1	0/0	1/244 (0.4)
舌痛	0/114	0/1	0/0	1/244 (0.4)
吐血	0/113	0/1	0/0	1/244 (0.4)
痔核	0/114	0/1	0/0	1/244 (0.4)
裂孔ヘルニア	0/113	0/1	0/0	1/244 (0.4)
胃排出不全	0/113	0/1	0/0	1/244 (0.4)
腸出血	0/114	0/1	0/0	1/244 (0.4)
過敏性腸症候群	0/112	0/1	0/0	2/244 (0.8)
大腸ポリープ	0/113	0/1	0/0	1/244 (0.4)
口唇乾燥	0/113	0/1	0/0	1/244 (0.4)
メレナ	0/113	0/1	0/0	2/244 (0.8)
口腔腫脹	0/114	0/1	0/0	1/244 (0.4)
悪心	0/103	0/1	0/0	19/244 (7.8)
口腔内不快感	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内痛	0/244	0/182	1/149 (0.7)	0/128
口の錯感覚	1/244 (0.4)	0/181	1/148 (0.7)	0/127
直腸出血	0/244	1/182 (0.5)	1/148 (0.7)	0/127
歯痛	1/244 (0.4)	0/181	0/148	0/127
嘔吐	4/244 (1.6)	1/180 (0.6)	1/146 (0.7)	0/124
一般・全身障害および投与部位の状態	194/244 (79.5)	3/35 (8.6)	5/25 (20.0)	0/17
投与部位内出血	0/244	0/182	0/149	1/128 (0.8)
投与部位紅斑	1/244 (0.4)	0/182	0/149	0/128
投与部位漏出	2/244 (0.8)	0/180	0/147	0/127
無力症	1/244 (0.4)	1/182 (0.5)	1/148 (0.7)	0/126
カテーテル留置部位紅斑	2/244 (0.8)	0/180	0/147	0/127
カテーテル留置部位漏出	0/244	0/182	1/149 (0.7)	0/127
カテーテル留置部位出血	1/244 (0.4)	0/181	0/148	0/127
カテーテル留置部位炎症	1/244 (0.4)	0/181	0/148	0/128
カテーテル留置部位刺激感	1/244 (0.4)	0/181	0/148	0/127
カテーテル留置部位浮腫	1/244 (0.4)	0/181	0/148	0/128
カテーテル留置部位疼痛	2/244 (0.8)	0/180	0/147	0/127
胸部不快感	0/244	1/182 (0.5)	0/148	0/127
胸痛	1/244 (0.4)	0/181	0/148	1/127 (0.8)
泣き	0/244	1/182 (0.5)	0/148	0/128
不快感	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内痛	0/114	0/1	0/0	1/244 (0.4)
口の錯感覚	0/113	0/1	0/0	2/244 (0.8)
直腸出血	0/114	0/1	0/0	2/244 (0.8)
歯痛	0/113	0/1	0/0	1/244 (0.4)
嘔吐	0/111	0/1	0/0	6/244 (2.5)
一般・全身障害および投与部位の状態	0/12	0/1	0/0	202/244 (82.8)
投与部位内出血	0/113	0/1	0/0	1/244 (0.4)
投与部位紅斑	0/114	0/1	0/0	1/244 (0.4)
投与部位漏出	0/113	0/1	0/0	2/244 (0.8)
無力症	0/112	0/1	0/0	3/244 (1.2)
カテーテル留置部位紅斑	0/113	0/1	0/0	2/244 (0.8)
カテーテル留置部位漏出	0/113	0/1	0/0	1/244 (0.4)
カテーテル留置部位出血	0/113	0/1	0/0	1/244 (0.4)
カテーテル留置部位炎症	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位刺激感	0/113	0/1	0/0	1/244 (0.4)
カテーテル留置部位浮腫	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位疼痛	0/113	0/1	0/0	2/244 (0.8)
胸部不快感	0/113	0/1	0/0	1/244 (0.4)
胸痛	0/112	0/1	0/0	2/244 (0.8)
泣き	0/114	0/1	0/0	1/244 (0.4)
不快感	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
薬効欠如	0/244	1/182 (0.5)	0/148	0/127
薬剤離脱症候群	2/244 (0.8)	0/181	0/148	0/127
疲労	7/244 (2.9)	0/178	1/146 (0.7)	1/125 (0.8)
異常感	2/244 (0.8)	0/180	0/149	0/128
冷感	0/244	0/182	1/149 (0.7)	0/127
熱感	1/244 (0.4)	0/182	0/149	0/128
歩行障害	1/244 (0.4)	1/182 (0.5)	0/148	0/128
歩行不能	1/244 (0.4)	0/181	0/149	0/128
低体温	1/244 (0.4)	0/181	0/148	1/127 (0.8)
インフルエンザ様疾患	3/244 (1.2)	0/179	0/146	0/125
注入部位内出血	14/244 (5.7)	2/169 (1.2)	2/137 (1.5)	0/115
注入部位皮膚炎	1/244 (0.4)	1/181 (0.6)	0/147	2/127 (1.6)
注入部位分泌物	2/244 (0.8)	0/180	0/147	0/126
注入部位変色	2/244 (0.8)	0/180	0/147	0/126
注入部位不快感	3/244 (1.2)	1/179 (0.6)	0/145	0/125
注入部位びらん	2/244 (0.8)	0/180	0/148	0/127
注入部位紅斑	113/244 (46.3)	4/91 (4.4)	5/75 (6.7)	2/62 (3.2)
注入部位皮膚剥脱	3/244 (1.2)	0/180	1/148 (0.7)	2/126 (1.6)
注入部位血管外漏出	17/244 (7.0)	1/170 (0.6)	1/139 (0.7)	1/119 (0.8)
注入部位血腫	12/244 (4.9)	1/172 (0.6)	1/140 (0.7)	2/121 (1.7)
注入部位出血	6/244 (2.5)	2/177 (1.1)	0/142	1/123 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
薬効欠如	0/113	0/1	0/0	1/244 (0.4)
薬剤離脱症候群	0/113	0/1	0/0	2/244 (0.8)
疲労	0/110	0/1	0/0	9/244 (3.7)
異常感	0/114	0/1	0/0	2/244 (0.8)
冷感	0/113	0/1	0/0	1/244 (0.4)
熱感	0/114	0/1	0/0	1/244 (0.4)
歩行障害	0/114	0/1	0/0	2/244 (0.8)
歩行不能	0/114	0/1	0/0	1/244 (0.4)
低体温	0/112	0/1	0/0	2/244 (0.8)
インフルエンザ様疾患	0/111	0/1	0/0	3/244 (1.2)
注入部位内出血	0/101	0/1	0/0	18/244 (7.4)
注入部位皮膚炎	0/111	0/1	0/0	4/244 (1.6)
注入部位分泌物	0/112	0/1	0/0	2/244 (0.8)
注入部位変色	0/112	0/1	0/0	2/244 (0.8)
注入部位不快感	0/111	0/1	0/0	4/244 (1.6)
注入部位びらん	0/113	0/1	0/0	2/244 (0.8)
注入部位紅斑	1/51 (2.0)	0/1	0/0	125/244 (51.2)
注入部位皮膚剥脱	0/110	0/1	0/0	6/244 (2.5)
注入部位血管外漏出	0/105	0/1	0/0	20/244 (8.2)
注入部位血腫	0/105	0/1	0/0	16/244 (6.6)
注入部位出血	0/109	0/1	0/0	9/244 (3.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位硬結	8/244 (3.3)	0/177	1/147 (0.7)	1/125 (0.8)
注入部位炎症	5/244 (2.0)	0/178	1/147 (0.7)	1/127 (0.8)
注入部位損傷	2/244 (0.8)	0/181	1/149 (0.7)	0/127
注入部位刺激感	3/244 (1.2)	1/179 (0.6)	1/145 (0.7)	0/125
注入部位腫瘤	8/244 (3.3)	0/177	0/145	0/125
注入部位壊死	1/244 (0.4)	0/181	0/149	0/128
注入部位結節	53/244 (21.7)	9/131 (6.9)	3/95 (3.2)	2/77 (2.6)
注入部位浮腫	36/244 (14.8)	5/159 (3.1)	2/124 (1.6)	3/106 (2.8)
注入部位疼痛	32/244 (13.1)	4/156 (2.6)	1/123 (0.8)	1/107 (0.9)
注入部位蒼白	3/244 (1.2)	1/180 (0.6)	0/147	0/126
注入部位丘疹	8/244 (3.3)	4/177 (2.3)	2/141 (1.4)	1/120 (0.8)
注入部位異常感覚	2/244 (0.8)	0/180	0/147	0/126
注入部位そう痒感	4/244 (1.6)	2/179 (1.1)	1/144 (0.7)	0/124
注入部位発疹	5/244 (2.0)	2/178 (1.1)	0/143	0/124
注入部位反応	23/244 (9.4)	4/167 (2.4)	2/134 (1.5)	2/114 (1.8)
注入部位痂皮	0/244	1/182 (0.5)	0/148	0/127
注入部位腫脹	6/244 (2.5)	0/177	0/146	0/126
注入部位小水疱	2/244 (0.8)	0/180	0/148	0/127
注入部位熱感	1/244 (0.4)	0/181	0/148	0/127
注射部位内出血	2/244 (0.8)	1/181 (0.6)	0/147	0/126
注射部位変色	0/244	1/182 (0.5)	0/148	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位硬結	0/110	0/1	0/0	10/244 (4.1)
注入部位炎症	2/113 (1.8)	0/1	0/0	9/244 (3.7)
注入部位損傷	0/113	0/1	0/0	3/244 (1.2)
注入部位刺激感	0/111	0/1	0/0	5/244 (2.0)
注入部位腫瘤	0/111	0/1	0/0	8/244 (3.3)
注入部位壊死	0/114	0/1	0/0	1/244 (0.4)
注入部位結節	1/63 (1.6)	0/1	0/0	68/244 (27.9)
注入部位浮腫	1/91 (1.1)	0/1	0/0	47/244 (19.3)
注入部位疼痛	0/93	0/1	0/0	38/244 (15.6)
注入部位蒼白	0/112	0/1	0/0	4/244 (1.6)
注入部位丘疹	3/107 (2.8)	0/1	0/0	18/244 (7.4)
注入部位異常感覚	0/112	0/1	0/0	2/244 (0.8)
注入部位そう痒感	0/110	0/1	0/0	7/244 (2.9)
注入部位発疹	0/110	0/1	0/0	7/244 (2.9)
注入部位反応	0/98	0/1	0/0	31/244 (12.7)
注入部位痂皮	0/113	0/1	0/0	1/244 (0.4)
注入部位腫脹	0/112	0/1	0/0	6/244 (2.5)
注入部位小水疱	0/114	0/1	0/0	2/244 (0.8)
注入部位熱感	0/113	0/1	0/0	1/244 (0.4)
注射部位内出血	0/113	0/1	0/0	3/244 (1.2)
注射部位変色	0/113	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	13/244 (5.3)	0/171	1/139 (0.7)	0/117
注射部位漏出	2/244 (0.8)	0/180	0/147	0/126
注射部位血腫	1/244 (0.4)	0/182	0/149	0/128
注射部位出血	0/244	1/182 (0.5)	0/148	0/127
注射部位炎症	4/244 (1.6)	1/179 (0.6)	1/145 (0.7)	0/123
注射部位結節	5/244 (2.0)	2/177 (1.1)	2/143 (1.4)	0/120
注射部位浮腫	4/244 (1.6)	0/178	0/146	0/125
注射部位疼痛	7/244 (2.9)	1/176 (0.6)	0/144	0/124
注射部位丘疹	1/244 (0.4)	0/182	0/149	0/128
注射部位反応	1/244 (0.4)	0/181	1/148 (0.7)	0/126
注射部位腫脹	2/244 (0.8)	1/181 (0.6)	1/147 (0.7)	0/125
注射部位蕁麻疹	1/244 (0.4)	0/182	0/149	0/128
滴下投与部位熱傷	1/244 (0.4)	0/181	0/148	0/128
滴下投与部位痛	0/244	1/182 (0.5)	0/149	0/128
限局性浮腫	1/244 (0.4)	0/181	0/148	0/127
適用部位からの吸収不良	1/244 (0.4)	0/181	0/148	0/127
倦怠感	2/244 (0.8)	0/182	1/149 (0.7)	0/127
医療機器使用部位刺激感	3/244 (1.2)	0/180	0/147	0/126
医療機器使用部位そう痒感	1/244 (0.4)	0/181	0/148	0/127
医療機器使用部位発疹	2/244 (0.8)	0/180	0/147	0/126

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	0/105	0/1	0/0	14/244 (5.7)
注射部位漏出	0/113	0/1	0/0	2/244 (0.8)
注射部位血腫	0/114	0/1	0/0	1/244 (0.4)
注射部位出血	0/113	0/1	0/0	1/244 (0.4)
注射部位炎症	0/110	0/1	0/0	6/244 (2.5)
注射部位結節	0/107	0/1	0/0	9/244 (3.7)
注射部位浮腫	1/111 (0.9)	0/1	0/0	5/244 (2.0)
注射部位疼痛	0/110	0/1	0/0	8/244 (3.3)
注射部位丘疹	0/114	0/1	0/0	1/244 (0.4)
注射部位反応	0/112	0/1	0/0	2/244 (0.8)
注射部位腫脹	0/111	0/1	0/0	4/244 (1.6)
注射部位蕁麻疹	0/114	0/1	0/0	1/244 (0.4)
滴下投与部位熱傷	0/114	0/1	0/0	1/244 (0.4)
滴下投与部位痛	0/114	0/1	0/0	1/244 (0.4)
限局性浮腫	0/113	0/1	0/0	1/244 (0.4)
適用部位からの吸収不良	0/113	0/1	0/0	1/244 (0.4)
倦怠感	0/113	0/1	0/0	3/244 (1.2)
医療機器使用部位刺激感	0/112	0/1	0/0	3/244 (1.2)
医療機器使用部位そう痒感	0/113	0/1	0/0	1/244 (0.4)
医療機器使用部位発疹	0/112	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
小結節	1/244 (0.4)	0/182	0/149	0/128
非心臓性胸痛	2/244 (0.8)	0/181	0/148	0/127
末梢性浮腫	8/244 (3.3)	0/174	1/143 (0.7)	0/123
疼痛	0/244	1/182 (0.5)	0/148	1/128 (0.8)
末梢腫脹	3/244 (1.2)	0/180	0/147	1/126 (0.8)
穿刺部位内出血	1/244 (0.4)	0/182	0/149	0/128
穿刺部位紅斑	2/244 (0.8)	1/181 (0.6)	0/147	0/126
穿刺部位出血	1/244 (0.4)	0/181	0/148	0/128
穿刺部位硬結	2/244 (0.8)	0/181	0/148	0/127
穿刺部位浮腫	1/244 (0.4)	0/182	0/149	0/128
穿刺部位腫脹	1/244 (0.4)	0/182	0/149	0/128
発熱	3/244 (1.2)	1/181 (0.6)	0/147	0/126
口渇	1/244 (0.4)	0/181	0/148	0/127
血管穿刺部位硬結	1/244 (0.4)	0/182	0/149	0/128
肝胆道系障害	2/244 (0.8)	0/181	0/148	0/127
肝嚢胞	0/244	0/182	0/149	0/128
脂肪肝	1/244 (0.4)	0/181	0/148	0/127
門脈血栓症	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
小結節	0/114	0/1	0/0	1/244 (0.4)
非心臓性胸痛	0/113	0/1	0/0	2/244 (0.8)
末梢性浮腫	0/109	0/1	0/0	9/244 (3.7)
疼痛	0/113	0/1	0/0	2/244 (0.8)
末梢腫脹	0/111	0/1	0/0	4/244 (1.6)
穿刺部位内出血	0/114	0/1	0/0	1/244 (0.4)
穿刺部位紅斑	0/112	0/1	0/0	3/244 (1.2)
穿刺部位出血	0/114	0/1	0/0	1/244 (0.4)
穿刺部位硬結	0/113	0/1	0/0	2/244 (0.8)
穿刺部位浮腫	0/114	0/1	0/0	1/244 (0.4)
穿刺部位腫脹	0/114	0/1	0/0	1/244 (0.4)
発熱	0/112	0/1	0/0	4/244 (1.6)
口渇	0/113	0/1	0/0	1/244 (0.4)
血管穿刺部位硬結	0/114	0/1	0/0	1/244 (0.4)
肝胆道系障害	1/113 (0.9)	0/0	0/0	3/244 (1.2)
肝嚢胞	1/114 (0.9)	0/0	0/0	1/244 (0.4)
脂肪肝	0/113	0/1	0/0	1/244 (0.4)
門脈血栓症	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症	81/244 (33.2)	16/116 (13.8)	10/85 (11.8)	7/65 (10.8)
無症候性COVID-19	0/244	0/182	1/149 (0.7)	0/127
細菌性疾患キャリアー	0/244	0/182	1/149 (0.7)	0/127
ボレリア感染	1/244 (0.4)	0/181	0/149	0/128
ウイルス性気管支炎	0/244	0/182	0/149	1/128 (0.8)
COVID-19	0/244	0/182	0/149	1/128 (0.8)
COVID-19肺炎	0/244	0/182	1/149 (0.7)	0/128
カテーテル留置部位感染	0/244	0/182	0/149	1/128 (0.8)
蜂巣炎	1/244 (0.4)	0/181	1/148 (0.7)	0/126
結膜炎	1/244 (0.4)	1/181 (0.6)	0/148	0/127
膀胱炎	1/244 (0.4)	0/182	0/149	0/128
爪の皮膚糸状菌症	0/244	1/182 (0.5)	0/148	0/127
真菌感染	1/244 (0.4)	0/182	0/149	0/128
胃腸炎	1/244 (0.4)	0/181	0/148	0/127
歯肉炎	1/244 (0.4)	0/181	0/148	0/127
麦粒腫	0/244	1/182 (0.5)	0/148	0/127
感染性皮膚潰瘍	1/244 (0.4)	0/181	0/148	0/127
インフルエンザ	0/244	0/182	0/149	1/128 (0.8)
注入部位膿瘍	18/244 (7.4)	4/170 (2.4)	3/139 (2.2)	1/121 (0.8)
注入部位蜂巣炎	40/244 (16.4)	5/150 (3.3)	6/121 (5.0)	5/96 (5.2)
注入部位感染	7/244 (2.9)	6/177 (3.4)	1/140 (0.7)	3/118 (2.5)
注入部位膿疱	1/244 (0.4)	0/181	0/149	0/128
注射部位蜂巣炎	2/244 (0.8)	1/180 (0.6)	0/146	0/125
上咽頭炎	5/244 (2.0)	3/177 (1.7)	0/142	2/123 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症	0/52	0/1	0/0	114/244 (46.7)
無症候性COVID-19	0/113	0/1	0/0	1/244 (0.4)
細菌性疾患キャリアー	0/113	0/1	0/0	1/244 (0.4)
ボレリア感染	0/114	0/1	0/0	1/244 (0.4)
ウイルス性気管支炎	0/113	0/1	0/0	1/244 (0.4)
COVID-19	0/114	0/1	0/0	1/244 (0.4)
COVID-19肺炎	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位感染	0/113	0/1	0/0	1/244 (0.4)
蜂巣炎	0/112	0/1	0/0	2/244 (0.8)
結膜炎	0/114	0/1	0/0	2/244 (0.8)
膀胱炎	0/114	0/1	0/0	1/244 (0.4)
爪の皮膚糸状菌症	0/113	0/1	0/0	1/244 (0.4)
真菌感染	0/114	0/1	0/0	1/244 (0.4)
胃腸炎	0/113	0/1	0/0	1/244 (0.4)
歯肉炎	0/113	0/1	0/0	1/244 (0.4)
麦粒腫	0/114	0/1	0/0	1/244 (0.4)
感染性皮膚潰瘍	0/114	0/1	0/0	1/244 (0.4)
インフルエンザ	0/113	0/1	0/0	1/244 (0.4)
注入部位膿瘍	0/107	0/1	0/0	26/244 (10.7)
注入部位蜂巣炎	0/80	0/1	0/0	56/244 (23.0)
注入部位感染	0/102	0/1	0/0	17/244 (7.0)
注入部位膿疱	0/114	0/1	0/0	1/244 (0.4)
注射部位蜂巣炎	0/111	0/1	0/0	3/244 (1.2)
上咽頭炎	0/107	0/1	0/0	10/244 (4.1)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
爪真菌症	1/244 (0.4)	0/181	0/148	0/128
耳下腺膿瘍	0/244	0/182	1/149 (0.7)	0/127
肺炎	2/244 (0.8)	0/180	2/148 (1.4)	0/126
術後膿瘍	0/244	0/182	1/149 (0.7)	0/127
シュードモナス感染	1/244 (0.4)	0/181	0/148	0/128
膿疱性皮疹	1/244 (0.4)	0/182	0/149	0/128
気道感染	0/244	0/182	0/149	1/128 (0.8)
敗血症	2/244 (0.8)	0/180	1/148 (0.7)	1/127 (0.8)
敗血症性ショック	1/244 (0.4)	0/181	0/148	0/127
副鼻腔炎	1/244 (0.4)	0/181	0/148	0/128
ブドウ球菌感染	0/244	1/182 (0.5)	0/148	1/128 (0.8)
歯感染	1/244 (0.4)	0/181	0/148	1/128 (0.8)
上気道感染	1/244 (0.4)	0/181	0/148	0/127
尿路感染	11/244 (4.5)	4/172 (2.3)	3/138 (2.2)	1/116 (0.9)
水痘帯状疱疹ウイルス感染	0/244	1/182 (0.5)	0/148	0/127
傷害、中毒および処置合併症	29/244 (11.9)	9/159 (5.7)	5/120 (4.2)	4/103 (3.9)
足関節部骨折	1/244 (0.4)	0/181	0/148	0/127
節足動物咬傷	1/244 (0.4)	0/181	0/148	0/128
骨挫傷	0/244	1/182 (0.5)	0/148	1/128 (0.8)
脳挫傷	1/244 (0.4)	0/181	0/148	0/128
挫傷	3/244 (1.2)	4/179 (2.2)	1/143 (0.7)	0/123

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
爪真菌症	0/114	0/1	0/0	1/244 (0.4)
耳下腺膿瘍	0/113	0/1	0/0	1/244 (0.4)
肺炎	0/113	0/1	0/0	4/244 (1.6)
術後膿瘍	0/113	0/1	0/0	1/244 (0.4)
シュードモナス感染	0/114	0/1	0/0	1/244 (0.4)
膿疱性皮疹	0/114	0/1	0/0	1/244 (0.4)
気道感染	0/114	0/1	0/0	1/244 (0.4)
敗血症	0/112	0/1	0/0	4/244 (1.6)
敗血症性ショック	0/113	0/1	0/0	1/244 (0.4)
副鼻腔炎	0/114	0/1	0/0	1/244 (0.4)
ブドウ球菌感染	0/113	0/1	0/0	2/244 (0.8)
歯感染	0/113	0/1	0/0	2/244 (0.8)
上気道感染	0/113	0/1	0/0	1/244 (0.4)
尿路感染	0/102	0/1	0/0	19/244 (7.8)
水痘帯状疱疹ウイルス感染	0/113	0/1	0/0	1/244 (0.4)
傷害、中毒および処置合併症	0/89	0/1	0/0	47/244 (19.3)
足関節部骨折	0/114	0/1	0/0	1/244 (0.4)
節足動物咬傷	0/114	0/1	0/0	1/244 (0.4)
骨挫傷	0/113	0/1	0/0	2/244 (0.8)
脳挫傷	0/114	0/1	0/0	1/244 (0.4)
挫傷	0/109	0/1	0/0	8/244 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	1/244 (0.4)	0/181	0/148	0/127
医療機器による投与の欠落	1/244 (0.4)	0/182	0/149	0/128
期限切れの製品使用	1/244 (0.4)	0/181	0/149	0/128
眼挫傷	1/244 (0.4)	0/181	0/148	0/128
顔面損傷	0/244	1/182 (0.5)	0/148	0/127
顔面骨骨折	2/244 (0.8)	0/180	0/147	0/126
転倒	22/244 (9.0)	9/163 (5.5)	4/123 (3.3)	4/107 (3.7)
頭部損傷	1/244 (0.4)	2/181 (1.1)	1/147 (0.7)	0/125
注入に伴う反応	1/244 (0.4)	0/182	0/149	0/128
関節脱臼	0/244	1/182 (0.5)	0/148	0/128
靭帯捻挫	0/244	2/182 (1.1)	0/147	0/126
腰椎骨折	1/244 (0.4)	0/182	0/149	0/128
過量投与	0/244	0/182	1/149 (0.7)	0/127
処置後挫傷	1/244 (0.4)	0/181	0/148	0/127
処置によるめまい	1/244 (0.4)	0/182	0/149	0/128
肋骨骨折	1/244 (0.4)	1/181 (0.6)	0/147	1/126 (0.8)
皮膚擦過傷	1/244 (0.4)	1/181 (0.6)	1/147 (0.7)	0/127
皮膚損傷	1/244 (0.4)	0/181	0/148	0/128
皮膚裂傷	2/244 (0.8)	3/180 (1.7)	1/144 (0.7)	1/123 (0.8)
ストレス骨折	0/244	0/182	1/149 (0.7)	0/127
硬膜下血腫	0/244	0/182	0/149	1/128 (0.8)
サンバーン	1/244 (0.4)	0/181	0/148	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	0/113	0/1	0/0	1/244 (0.4)
医療機器による投与の欠落	0/114	0/1	0/0	1/244 (0.4)
期限切れの製品使用	0/114	0/1	0/0	1/244 (0.4)
眼挫傷	0/114	0/1	0/0	1/244 (0.4)
顔面損傷	0/113	0/1	0/0	1/244 (0.4)
顔面骨骨折	0/112	0/1	0/0	2/244 (0.8)
転倒	0/92	0/1	0/0	39/244 (16.0)
頭部損傷	0/111	0/1	0/0	4/244 (1.6)
注入に伴う反応	0/114	0/1	0/0	1/244 (0.4)
関節脱臼	0/114	0/1	0/0	1/244 (0.4)
靭帯捻挫	0/112	0/1	0/0	2/244 (0.8)
腰椎骨折	0/114	0/1	0/0	1/244 (0.4)
過量投与	0/113	0/1	0/0	1/244 (0.4)
処置後挫傷	0/113	0/1	0/0	1/244 (0.4)
処置によるめまい	0/114	0/1	0/0	1/244 (0.4)
肋骨骨折	0/111	0/1	0/0	3/244 (1.2)
皮膚擦過傷	0/113	0/1	0/0	3/244 (1.2)
皮膚損傷	0/114	0/1	0/0	1/244 (0.4)
皮膚裂傷	0/108	0/1	0/0	7/244 (2.9)
ストレス骨折	0/114	0/1	0/0	1/244 (0.4)
硬膜下血腫	0/114	0/1	0/0	1/244 (0.4)
サンバーン	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/244	1/182 (0.5)	0/148	1/128 (0.8)
過少量投与	0/244	0/182	1/149 (0.7)	0/127
創傷	0/244	0/182	0/149	1/128 (0.8)
臨床検査	30/244 (12.3)	5/158 (3.2)	6/125 (4.8)	2/103 (1.9)
血中クレアチンホスホキナーゼ増加	2/244 (0.8)	0/181	0/148	0/127
血中クレアチニン減少	1/244 (0.4)	0/181	0/148	0/127
血中葉酸減少	1/244 (0.4)	0/181	0/148	1/127 (0.8)
血中ホモシステイン増加	1/244 (0.4)	0/181	1/148 (0.7)	0/126
血中リン減少	0/244	1/182 (0.5)	0/148	0/127
血圧上昇	2/244 (0.8)	0/181	0/149	0/128
起立血圧低下	1/244 (0.4)	0/181	0/148	0/127
血中ナトリウム減少	1/244 (0.4)	0/181	0/148	0/127
C-反応性蛋白増加	1/244 (0.4)	0/181	0/148	0/127
握力低下	1/244 (0.4)	0/181	0/148	0/127
ヘモグロビン減少	1/244 (0.4)	0/181	0/149	1/128 (0.8)
リンパ球数減少	1/244 (0.4)	0/182	0/149	0/128
単球数増加	1/244 (0.4)	0/182	0/149	0/128
好中球数増加	2/244 (0.8)	0/181	0/148	0/127
プロトロンビン時間延長	0/244	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/113	0/1	0/0	2/244 (0.8)
過少量投与	0/113	0/1	0/0	1/244 (0.4)
創傷	0/113	0/1	0/0	1/244 (0.4)
臨床検査	2/88 (2.3)	0/1	0/0	45/244 (18.4)
血中クレアチンホスホキナーゼ増加	0/113	0/1	0/0	2/244 (0.8)
血中クレアチニン減少	0/113	0/1	0/0	1/244 (0.4)
血中葉酸減少	1/112 (0.9)	0/1	0/0	3/244 (1.2)
血中ホモシステイン増加	1/112 (0.9)	0/1	0/0	3/244 (1.2)
血中リン減少	0/113	0/1	0/0	1/244 (0.4)
血圧上昇	0/114	0/1	0/0	2/244 (0.8)
起立血圧低下	0/113	0/1	0/0	1/244 (0.4)
血中ナトリウム減少	0/113	0/1	0/0	1/244 (0.4)
C-反応性蛋白増加	0/113	0/1	0/0	1/244 (0.4)
握力低下	0/113	0/1	0/0	1/244 (0.4)
ヘモグロビン減少	0/113	0/1	0/0	2/244 (0.8)
リンパ球数減少	0/114	0/1	0/0	1/244 (0.4)
単球数増加	0/114	0/1	0/0	1/244 (0.4)
好中球数増加	0/113	0/1	0/0	2/244 (0.8)
プロトロンビン時間延長	1/114 (0.9)	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
赤血球数減少	1/244 (0.4)	0/181	0/148	0/127
ビタミンB12減少	1/244 (0.4)	0/182	1/149 (0.7)	0/127
ビタミンB6減少	9/244 (3.7)	0/174	2/141 (1.4)	0/119
ビタミンD減少	1/244 (0.4)	0/181	0/148	0/128
体重減少	12/244 (4.9)	3/171 (1.8)	5/139 (3.6)	2/117 (1.7)
体重増加	1/244 (0.4)	1/181 (0.6)	0/147	0/126
白血球数増加	2/244 (0.8)	0/181	0/148	0/127
代謝および栄養障害	16/244 (6.6)	4/169 (2.4)	5/135 (3.7)	3/113 (2.7)
悪液質	0/244	0/182	1/149 (0.7)	0/127
食欲減退	3/244 (1.2)	1/179 (0.6)	1/146 (0.7)	0/125
脱水	2/244 (0.8)	2/182 (1.1)	0/147	0/126
糖尿病	0/244	0/182	1/149 (0.7)	0/127
水分過負荷	1/244 (0.4)	0/181	0/149	0/128
体液貯留	1/244 (0.4)	0/181	0/148	1/127 (0.8)
葉酸欠乏	1/244 (0.4)	0/181	1/148 (0.7)	0/127
耐糖能障害	1/244 (0.4)	0/181	0/148	0/127
高コレステロール血症	0/244	1/182 (0.5)	0/148	0/127
高血糖	1/244 (0.4)	0/181	0/148	0/127
高ホモシステイン血症	0/244	0/182	1/149 (0.7)	0/128
低カリウム血症	2/244 (0.8)	0/182	0/149	1/128 (0.8)
低ナトリウム血症	0/244	1/182 (0.5)	0/148	1/127 (0.8)
栄養障害	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
赤血球数減少	0/113	0/1	0/0	1/244 (0.4)
ビタミンB12減少	0/113	0/1	0/0	2/244 (0.8)
ビタミンB6減少	0/105	0/1	0/0	11/244 (4.5)
ビタミンD減少	0/114	0/1	0/0	1/244 (0.4)
体重減少	0/102	0/1	0/0	22/244 (9.0)
体重増加	0/112	0/1	0/0	2/244 (0.8)
白血球数増加	0/113	0/1	0/0	2/244 (0.8)
代謝および栄養障害	0/98	0/1	0/0	28/244 (11.5)
悪液質	0/113	0/1	0/0	1/244 (0.4)
食欲減退	0/111	0/1	0/0	5/244 (2.0)
脱水	0/112	0/1	0/0	4/244 (1.6)
糖尿病	0/114	0/1	0/0	1/244 (0.4)
水分過負荷	0/114	0/1	0/0	1/244 (0.4)
体液貯留	0/112	0/1	0/0	2/244 (0.8)
葉酸欠乏	0/113	0/1	0/0	2/244 (0.8)
耐糖能障害	0/113	0/1	0/0	1/244 (0.4)
高コレステロール血症	0/113	0/1	0/0	1/244 (0.4)
高血糖	0/113	0/1	0/0	1/244 (0.4)
高ホモシステイン血症	0/114	0/1	0/0	1/244 (0.4)
低カリウム血症	0/114	0/1	0/0	3/244 (1.2)
低ナトリウム血症	0/113	0/1	0/0	2/244 (0.8)
栄養障害	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB群欠乏	1/244 (0.4)	0/181	1/148 (0.7)	0/126
ビタミンB12欠乏	0/244	0/182	1/149 (0.7)	0/128
ビタミンB6欠乏	5/244 (2.0)	0/177	2/145 (1.4)	1/124 (0.8)
筋骨格系および結合組織障害	27/244 (11.1)	7/160 (4.4)	8/125 (6.4)	2/102 (2.0)
関節痛	4/244 (1.6)	1/179 (0.6)	1/146 (0.7)	0/124
反応性関節炎	1/244 (0.4)	0/181	1/148 (0.7)	0/126
背部痛	6/244 (2.5)	2/176 (1.1)	3/141 (2.1)	1/119 (0.8)
骨痛	0/244	0/182	1/149 (0.7)	0/127
滑液包炎	1/244 (0.4)	0/181	1/148 (0.7)	0/126
外骨腫	0/244	1/182 (0.5)	0/148	0/128
椎間関節症候群	0/244	1/182 (0.5)	0/148	0/128
椎間板変性症	0/244	1/182 (0.5)	0/148	0/127
椎間板突出	0/244	1/182 (0.5)	0/148	0/128
関節滲出液	0/244	1/182 (0.5)	0/148	0/128
関節腫脹	1/244 (0.4)	0/181	0/148	0/127
四肢不快感	0/244	0/182	1/149 (0.7)	0/128
筋萎縮	0/244	1/182 (0.5)	0/148	0/128
筋痙縮	2/244 (0.8)	3/180 (1.7)	0/146	0/125
筋力低下	3/244 (1.2)	1/180 (0.6)	1/147 (0.7)	0/126
筋骨格硬直	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB群欠乏	0/112	0/1	0/0	2/244 (0.8)
ビタミンB12欠乏	1/114 (0.9)	0/1	0/0	2/244 (0.8)
ビタミンB6欠乏	0/109	0/1	0/0	8/244 (3.3)
筋骨格系および結合組織障害	0/88	0/1	0/0	44/244 (18.0)
関節痛	0/110	0/1	0/0	6/244 (2.5)
反応性関節炎	0/113	0/1	0/0	2/244 (0.8)
背部痛	0/104	0/1	0/0	12/244 (4.9)
骨痛	0/113	0/1	0/0	1/244 (0.4)
滑液包炎	0/113	0/1	0/0	2/244 (0.8)
外骨腫	0/114	0/1	0/0	1/244 (0.4)
椎間関節症候群	0/114	0/1	0/0	1/244 (0.4)
椎間板変性症	0/113	0/1	0/0	1/244 (0.4)
椎間板突出	0/114	0/1	0/0	1/244 (0.4)
関節滲出液	1/114 (0.9)	0/1	0/0	2/244 (0.8)
関節腫脹	0/113	0/1	0/0	1/244 (0.4)
四肢不快感	0/114	0/1	0/0	1/244 (0.4)
筋萎縮	0/114	0/1	0/0	1/244 (0.4)
筋痙縮	0/111	0/1	0/0	5/244 (2.0)
筋力低下	0/113	0/1	0/0	5/244 (2.0)
筋骨格硬直	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
筋肉痛	3/244 (1.2)	0/180	0/147	0/126
頚部痛	0/244	0/182	2/149 (1.3)	0/126
骨炎	1/244 (0.4)	0/182	0/149	0/128
変形性関節症	1/244 (0.4)	2/181 (1.1)	1/146 (0.7)	0/125
骨減少症	0/244	1/182 (0.5)	0/148	0/127
四肢痛	5/244 (2.0)	0/177	0/145	1/126 (0.8)
関節周囲炎	0/244	0/182	1/149 (0.7)	0/127
姿勢異常	1/244 (0.4)	0/181	0/148	0/128
横紋筋融解症	1/244 (0.4)	0/182	0/149	1/128 (0.8)
肩回旋筋腱板症候群	0/244	1/182 (0.5)	0/148	0/128
仙腸関節機能障害	1/244 (0.4)	0/181	0/148	0/127
変形性脊椎症	0/244	1/182 (0.5)	0/148	0/127
腱障害	0/244	1/182 (0.5)	0/148	0/128
腱炎	1/244 (0.4)	0/181	0/148	0/127
斜頚	1/244 (0.4)	0/181	0/148	0/127
弾発指	0/244	0/182	1/149 (0.7)	0/127
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)	1/244 (0.4)	2/181 (1.1)	1/146 (0.7)	0/125
基底細胞癌	0/244	2/182 (1.1)	0/147	0/127
脂漏性角化症	0/244	0/182	1/149 (0.7)	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
筋肉痛	0/112	0/1	0/0	3/244 (1.2)
頚部痛	0/112	0/1	0/0	2/244 (0.8)
骨炎	0/114	0/1	0/0	1/244 (0.4)
変形性関節症	1/111 (0.9)	0/1	0/0	5/244 (2.0)
骨減少症	0/113	0/1	0/0	1/244 (0.4)
四肢痛	0/111	0/1	0/0	6/244 (2.5)
関節周囲炎	0/113	0/1	0/0	1/244 (0.4)
姿勢異常	0/114	0/1	0/0	1/244 (0.4)
横紋筋融解症	0/113	0/1	0/0	2/244 (0.8)
肩回旋筋腱板症候群	0/114	0/1	0/0	1/244 (0.4)
仙腸関節機能障害	0/113	0/1	0/0	1/244 (0.4)
変形性脊椎症	0/113	0/1	0/0	1/244 (0.4)
腱障害	0/114	0/1	0/0	1/244 (0.4)
腱炎	0/113	0/1	0/0	1/244 (0.4)
斜頚	0/113	0/1	0/0	1/244 (0.4)
弾発指	0/113	0/1	0/0	1/244 (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)	0/112	0/1	0/0	4/244 (1.6)
基底細胞癌	0/113	0/1	0/0	2/244 (0.8)
脂漏性角化症	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
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） (Cont.)				
皮膚有棘細胞癌	1/244 (0.4)	0/181	0/148	0/127
神経系障害	79/244 (32.4)	14/129 (10.9)	8/96 (8.3)	7/78 (9.0)
アカシジア	0/244	0/182	0/149	1/128 (0.8)
健忘	0/244	0/182	0/149	0/128
失語症	0/244	0/182	1/149 (0.7)	0/127
運動失調	1/244 (0.4)	0/181	0/148	0/127
平衡障害	1/244 (0.4)	0/181	1/148 (0.7)	1/127 (0.8)
運動緩慢	1/244 (0.4)	0/182	1/149 (0.7)	0/127
手根管症候群	0/244	0/182	1/149 (0.7)	0/127
大脳萎縮	0/244	0/182	0/149	1/128 (0.8)
脳出血	0/244	1/182 (0.5)	0/148	0/127
脳圧排効果	0/244	0/182	0/149	1/128 (0.8)
脳血管発作	0/244	1/182 (0.5)	0/149	0/128
認知障害	2/244 (0.8)	1/180 (0.6)	1/148 (0.7)	1/126 (0.8)
振動覚低下	0/244	1/182 (0.5)	0/148	0/127
注意力障害	1/244 (0.4)	0/181	0/149	0/128
浮動性めまい	23/244 (9.4)	2/163 (1.2)	0/131	0/114
体位性めまい	3/244 (1.2)	2/180 (1.1)	0/145	0/125
構語障害	1/244 (0.4)	1/182 (0.5)	1/148 (0.7)	0/126
味覚不全	2/244 (0.8)	0/181	0/148	1/127 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
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） (Cont.)				
皮膚有棘細胞癌	0/113	0/1	0/0	1/244 (0.4)
神経系障害	2/62 (3.2)	0/0	0/0	110/244 (45.1)
アカシジア	0/113	0/1	0/0	1/244 (0.4)
健忘	1/114 (0.9)	0/1	0/0	1/244 (0.4)
失語症	0/113	0/1	0/0	1/244 (0.4)
運動失調	0/114	0/1	0/0	1/244 (0.4)
平衡障害	1/112 (0.9)	0/1	0/0	4/244 (1.6)
運動緩慢	0/113	0/1	0/0	2/244 (0.8)
手根管症候群	0/113	0/1	0/0	1/244 (0.4)
大脳萎縮	0/113	0/1	0/0	1/244 (0.4)
脳出血	0/113	0/1	0/0	1/244 (0.4)
脳圧排効果	0/114	0/1	0/0	1/244 (0.4)
脳血管発作	0/114	0/1	0/0	1/244 (0.4)
認知障害	1/111 (0.9)	0/1	0/0	6/244 (2.5)
振動覚低下	0/113	0/1	0/0	1/244 (0.4)
注意力障害	0/114	0/1	0/0	1/244 (0.4)
浮動性めまい	0/101	0/1	0/0	25/244 (10.2)
体位性めまい	0/111	0/1	0/0	5/244 (2.0)
構語障害	0/113	0/1	0/0	3/244 (1.2)
味覚不全	0/112	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
ジスキネジア	11/244 (4.5)	4/177 (2.3)	1/141 (0.7)	2/119 (1.7)
起立障害	1/244 (0.4)	0/181	0/149	0/128
ジストニア	4/244 (1.6)	2/179 (1.1)	0/144	1/124 (0.8)
脳症	1/244 (0.4)	0/182	0/149	0/128
てんかん	1/244 (0.4)	0/182	0/149	0/128
本態性振戦	1/244 (0.4)	0/181	0/148	0/128
伸展性足底反応	1/244 (0.4)	0/181	0/148	0/127
すくみ現象	4/244 (1.6)	0/180	0/148	0/127
全身性強直性間代性発作	0/244	0/182	0/149	1/128 (0.8)
頭部不快感	1/244 (0.4)	0/182	0/149	0/128
頭痛	9/244 (3.7)	3/174 (1.7)	1/141 (0.7)	1/121 (0.8)
片側感覚消失	1/244 (0.4)	0/181	0/148	0/128
不全片麻痺	1/244 (0.4)	0/181	0/148	0/128
感覚鈍麻	0/244	0/182	3/149 (2.0)	0/125
反射減弱	0/244	1/182 (0.5)	1/148 (0.7)	0/126
不規則睡眠覚醒リズム障害	0/244	0/182	1/149 (0.7)	0/127
嗜眠	0/244	1/182 (0.5)	1/148 (0.7)	0/128
意識消失	0/244	2/182 (1.1)	0/148	0/127
腰仙部神経根障害	1/244 (0.4)	0/181	0/148	0/127
記憶障害	1/244 (0.4)	0/181	1/149 (0.7)	0/127
代謝性脳症	1/244 (0.4)	0/182	1/149 (0.7)	0/127
神経痛	0/244	1/182 (0.5)	0/148	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
ジスキネジア	0/104	0/1	0/0	18/244 (7.4)
起立障害	0/114	0/1	0/0	1/244 (0.4)
ジストニア	0/109	0/1	0/0	7/244 (2.9)
脳症	0/114	0/1	0/0	1/244 (0.4)
てんかん	0/114	0/1	0/0	1/244 (0.4)
本態性振戦	0/114	0/1	0/0	1/244 (0.4)
伸展性足底反応	0/113	0/1	0/0	1/244 (0.4)
すくみ現象	0/113	0/1	0/0	4/244 (1.6)
全身性強直性間代性発作	0/114	0/1	0/0	1/244 (0.4)
頭部不快感	0/114	0/1	0/0	1/244 (0.4)
頭痛	0/106	0/1	0/0	14/244 (5.7)
片側感覚消失	0/114	0/1	0/0	1/244 (0.4)
不全片麻痺	0/114	0/1	0/0	1/244 (0.4)
感覚鈍麻	0/111	0/1	0/0	3/244 (1.2)
反射減弱	1/113 (0.9)	0/1	0/0	3/244 (1.2)
不規則睡眠覚醒リズム障害	0/113	0/1	0/0	1/244 (0.4)
嗜眠	0/114	0/1	0/0	2/244 (0.8)
意識消失	0/113	0/1	0/0	2/244 (0.8)
腰仙部神経根障害	0/114	0/1	0/0	1/244 (0.4)
記憶障害	0/113	0/1	0/0	2/244 (0.8)
代謝性脳症	0/113	0/1	0/0	2/244 (0.8)
神経痛	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
末梢性ニューロパチー	1/244 (0.4)	0/181	0/148	1/128 (0.8)
オンオフ現象	8/244 (3.3)	0/178	0/146	0/125
錯感覚	4/244 (1.6)	1/181 (0.6)	0/147	2/126 (1.6)
パーキンソン病	11/244 (4.5)	4/176 (2.3)	2/140 (1.4)	0/119
パーキンソニズム	2/244 (0.8)	1/182 (0.5)	0/148	0/127
側反弓	1/244 (0.4)	0/181	1/148 (0.7)	1/127 (0.8)
多発ニューロパチー	1/244 (0.4)	0/181	0/148	1/128 (0.8)
失神寸前の状態	0/244	1/182 (0.5)	0/148	0/128
心因性発作	1/244 (0.4)	0/181	0/148	0/127
精神運動亢進	2/244 (0.8)	0/181	0/149	0/128
反射異常	0/244	0/182	0/149	1/128 (0.8)
安静時振戦	1/244 (0.4)	0/181	0/148	0/128
坐骨神経痛	2/244 (0.8)	0/180	1/147 (0.7)	0/127
痙攣発作	0/244	1/182 (0.5)	0/148	0/127
感覚障害	1/244 (0.4)	0/181	0/148	0/127
感覚消失	0/244	1/182 (0.5)	0/148	0/128
睡眠時麻痺	0/244	1/182 (0.5)	0/148	0/127
傾眠	8/244 (3.3)	2/175 (1.1)	1/141 (0.7)	1/121 (0.8)
失神	0/244	1/182 (0.5)	0/148	1/127 (0.8)
振戦	2/244 (0.8)	1/180 (0.6)	0/146	0/126

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
末梢性ニューロパチー	0/113	0/1	0/0	2/244 (0.8)
オンオフ現象	0/111	0/1	0/0	8/244 (3.3)
錯感覚	0/110	0/0	0/0	7/244 (2.9)
パーキンソン病	0/105	0/1	0/0	17/244 (7.0)
パーキンソニズム	0/113	0/1	0/0	3/244 (1.2)
側反弓	0/112	0/1	0/0	3/244 (1.2)
多発ニューロパチー	0/113	0/1	0/0	2/244 (0.8)
失神寸前の状態	0/114	0/1	0/0	1/244 (0.4)
心因性発作	0/113	0/1	0/0	1/244 (0.4)
精神運動亢進	0/114	0/1	0/0	2/244 (0.8)
反射異常	0/113	0/1	0/0	1/244 (0.4)
安静時振戦	0/114	0/1	0/0	1/244 (0.4)
坐骨神経痛	0/113	0/1	0/0	3/244 (1.2)
痙攣発作	0/113	0/1	0/0	1/244 (0.4)
感覚障害	0/113	0/1	0/0	1/244 (0.4)
感覚消失	0/114	0/1	0/0	1/244 (0.4)
睡眠時麻痺	0/113	0/1	0/0	1/244 (0.4)
傾眠	0/107	0/1	0/0	12/244 (4.9)
失神	1/112 (0.9)	0/1	0/0	3/244 (1.2)
振戦	0/112	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
製品の問題	3/244 (1.2)	0/180	0/148	0/127
医療機器送達システムの問題	1/244 (0.4)	0/181	0/149	0/128
医療機器位置異常	1/244 (0.4)	0/181	0/148	0/127
医療機器機能不良	1/244 (0.4)	0/182	0/149	0/128
精神障害	90/244 (36.9)	7/113 (6.2)	4/88 (4.5)	3/75 (4.0)
異常な夢	1/244 (0.4)	0/181	0/148	0/127
感情不安定	1/244 (0.4)	1/182 (0.5)	0/148	0/127
激越	1/244 (0.4)	0/182	0/149	0/128
不安	22/244 (9.0)	2/164 (1.2)	3/134 (2.2)	1/113 (0.9)
不安障害	0/244	0/182	0/149	1/128 (0.8)
無感情	0/244	1/182 (0.5)	0/148	0/128
歯ぎしり	2/244 (0.8)	0/180	0/148	0/127
強迫行為	1/244 (0.4)	0/181	0/148	0/127
強迫性性行動	0/244	0/182	1/149 (0.7)	0/127
錯乱状態	5/244 (2.0)	1/178 (0.6)	1/144 (0.7)	1/122 (0.8)
譫妄	4/244 (1.6)	1/179 (0.6)	0/146	0/126
妄想	7/244 (2.9)	1/176 (0.6)	2/143 (1.4)	0/123
寄生虫妄想	0/244	1/182 (0.5)	0/148	0/128
妄想性障害、詳細不明	1/244 (0.4)	0/181	0/148	0/128
抑うつ気分	2/244 (0.8)	1/180 (0.6)	0/146	0/126
うつ病	1/244 (0.4)	1/181 (0.6)	1/148 (0.7)	1/126 (0.8)
抑うつ症状	2/244 (0.8)	0/181	0/148	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
製品の問題	0/113	0/1	0/0	3/244 (1.2)
医療機器送達システムの問題	0/114	0/1	0/0	1/244 (0.4)
医療機器位置異常	0/113	0/1	0/0	1/244 (0.4)
医療機器機能不良	0/114	0/1	0/0	1/244 (0.4)
精神障害	0/64	0/0	0/0	104/244 (42.6)
異常な夢	0/113	0/1	0/0	1/244 (0.4)
感情不安定	0/113	0/1	0/0	2/244 (0.8)
激越	0/114	0/1	0/0	1/244 (0.4)
不安	0/98	0/1	0/0	28/244 (11.5)
不安障害	0/113	0/1	0/0	1/244 (0.4)
無感情	0/114	0/1	0/0	1/244 (0.4)
歯ぎしり	0/113	0/1	0/0	2/244 (0.8)
強迫行為	0/113	0/1	0/0	1/244 (0.4)
強迫性性行動	0/113	0/1	0/0	1/244 (0.4)
錯乱状態	0/109	0/1	0/0	8/244 (3.3)
譫妄	0/113	0/1	0/0	5/244 (2.0)
妄想	0/110	0/1	0/0	10/244 (4.1)
寄生虫妄想	0/114	0/1	0/0	1/244 (0.4)
妄想性障害、詳細不明	0/114	0/1	0/0	1/244 (0.4)
抑うつ気分	0/112	0/1	0/0	3/244 (1.2)
うつ病	0/111	0/1	0/0	4/244 (1.6)
抑うつ症状	0/113	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
ドーパミン調節障害症候群	0/244	0/182	0/149	1/128 (0.8)
ディスフェミア	0/244	0/182	1/149 (0.7)	0/127
睡眠異常	1/244 (0.4)	0/181	0/148	0/127
情動障害	1/244 (0.4)	1/181 (0.6)	0/147	0/127
注射恐怖	0/244	1/182 (0.5)	0/149	0/128
幻覚	33/244 (13.5)	5/163 (3.1)	2/129 (1.6)	1/110 (0.9)
幻聴	2/244 (0.8)	3/180 (1.7)	0/144	1/126 (0.8)
幻嗅	1/244 (0.4)	0/181	0/149	0/128
幻視	10/244 (4.1)	3/173 (1.7)	2/139 (1.4)	0/120
混合性幻覚	1/244 (0.4)	0/181	0/148	0/127
性欲過剰	1/244 (0.4)	0/181	0/148	0/127
錯覚	1/244 (0.4)	0/181	0/148	0/128
衝動制御障害	2/244 (0.8)	1/180 (0.6)	0/147	1/128 (0.8)
衝動行為	0/244	0/182	0/149	1/128 (0.8)
不眠症	15/244 (6.1)	2/168 (1.2)	0/135	1/116 (0.9)
易刺激性	2/244 (0.8)	0/180	0/149	0/128
嫉妬妄想	1/244 (0.4)	0/181	0/148	0/127
躁病	1/244 (0.4)	0/181	0/148	0/128
気分変化	1/244 (0.4)	0/181	0/148	0/127
気分動揺	0/244	1/182 (0.5)	0/149	0/128
悪夢	1/244 (0.4)	1/182 (0.5)	0/148	0/128
強迫観念	1/244 (0.4)	0/181	0/149	0/128
パニック発作	3/244 (1.2)	0/180	0/147	0/126

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
ドーパミン調節障害症候群	0/113	0/1	0/0	1/244 (0.4)
ディスフェミア	0/113	0/1	0/0	1/244 (0.4)
睡眠異常	0/113	0/1	0/0	1/244 (0.4)
情動障害	0/113	0/1	0/0	2/244 (0.8)
注射恐怖	0/114	0/1	0/0	1/244 (0.4)
幻覚	0/100	0/1	0/0	41/244 (16.8)
幻聴	0/111	0/1	0/0	6/244 (2.5)
幻嗅	0/114	0/1	0/0	1/244 (0.4)
幻視	0/106	0/1	0/0	15/244 (6.1)
混合性幻覚	0/113	0/1	0/0	1/244 (0.4)
性欲過剰	0/113	0/1	0/0	1/244 (0.4)
錯覚	0/114	0/1	0/0	1/244 (0.4)
衝動制御障害	0/113	0/1	0/0	4/244 (1.6)
衝動行為	0/113	0/1	0/0	1/244 (0.4)
不眠症	0/102	0/0	0/0	18/244 (7.4)
易刺激性	0/114	0/1	0/0	2/244 (0.8)
嫉妬妄想	0/113	0/1	0/0	1/244 (0.4)
躁病	0/114	0/1	0/0	1/244 (0.4)
気分変化	0/113	0/1	0/0	1/244 (0.4)
気分動揺	0/114	0/1	0/0	1/244 (0.4)
悪夢	0/114	0/1	0/0	2/244 (0.8)
強迫観念	0/114	0/1	0/0	1/244 (0.4)
パニック発作	0/112	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
パニック反応	0/244	0/182	1/149 (0.7)	0/127
妄想症	0/244	1/182 (0.5)	1/148 (0.7)	0/126
睡眠の質低下	0/244	1/182 (0.5)	0/148	0/128
処置に対する不安	0/244	1/182 (0.5)	0/149	0/128
精神病性障害	3/244 (1.2)	1/179 (0.6)	2/146 (1.4)	0/124
精神病症状	0/244	0/182	0/149	1/128 (0.8)
レム睡眠行動障害	2/244 (0.8)	0/181	0/148	0/127
レム睡眠異常	1/244 (0.4)	0/181	0/148	0/127
睡眠障害	2/244 (0.8)	1/180 (0.6)	0/146	0/126
ねごと	1/244 (0.4)	1/181 (0.6)	0/148	0/128
常同症	0/244	0/182	0/149	1/128 (0.8)
ストレス	1/244 (0.4)	0/181	0/148	0/127
自殺念慮	2/244 (0.8)	1/180 (0.6)	0/148	0/128
自殺企図	0/244	0/182	0/149	1/128 (0.8)
腎および尿路障害	10/244 (4.1)	3/173 (1.7)	3/139 (2.2)	2/118 (1.7)
膀胱痙縮	0/244	0/182	1/149 (0.7)	0/127
膀胱結石	0/244	1/182 (0.5)	0/149	0/128
排尿困難	2/244 (0.8)	0/180	0/147	1/126 (0.8)
緊張性膀胱	0/244	0/182	0/149	1/128 (0.8)
夜間頻尿	0/244	1/182 (0.5)	0/148	0/128
多尿	1/244 (0.4)	0/181	0/148	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
パニック反応	0/113	0/1	0/0	1/244 (0.4)
妄想症	0/112	0/1	0/0	2/244 (0.8)
睡眠の質低下	0/114	0/1	0/0	1/244 (0.4)
処置に対する不安	0/114	0/1	0/0	1/244 (0.4)
精神病性障害	0/110	0/1	0/0	6/244 (2.5)
精神病症状	0/113	0/1	0/0	1/244 (0.4)
レム睡眠行動障害	0/113	0/1	0/0	2/244 (0.8)
レム睡眠異常	0/113	0/1	0/0	1/244 (0.4)
睡眠障害	0/113	0/1	0/0	3/244 (1.2)
ねごと	0/114	0/1	0/0	2/244 (0.8)
常同症	0/113	0/1	0/0	1/244 (0.4)
ストレス	0/114	0/1	0/0	1/244 (0.4)
自殺念慮	0/114	0/1	0/0	3/244 (1.2)
自殺企図	0/113	0/1	0/0	1/244 (0.4)
腎および尿路障害	0/103	0/1	0/0	18/244 (7.4)
膀胱痙縮	0/113	0/1	0/0	1/244 (0.4)
膀胱結石	0/114	0/1	0/0	1/244 (0.4)
排尿困難	0/112	0/1	0/0	3/244 (1.2)
緊張性膀胱	0/113	0/1	0/0	1/244 (0.4)
夜間頻尿	0/114	0/1	0/0	1/244 (0.4)
多尿	0/113	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
腎機能障害	0/244	0/182	1/149 (0.7)	0/128
尿管結石症	1/244 (0.4)	0/182	0/149	0/128
切迫性尿失禁	3/244 (1.2)	0/179	0/147	0/126
尿失禁	2/244 (0.8)	1/180 (0.6)	1/146 (0.7)	1/125 (0.8)
尿閉	0/244	0/182	1/149 (0.7)	2/127 (1.6)
尿路障害	1/244 (0.4)	0/181	0/148	0/127
尿異常	1/244 (0.4)	0/181	0/148	0/127
尿臭異常	0/244	0/182	1/149 (0.7)	0/127
生殖系および乳房障害	3/244 (1.2)	2/180 (1.1)	1/145 (0.7)	0/123
良性前立腺肥大症	0/244	0/182	1/149 (0.7)	0/127
勃起不全	1/244 (0.4)	1/182 (0.5)	0/148	0/127
ペイロニー病	1/244 (0.4)	0/181	0/148	0/127
前立腺腫大	0/244	1/182 (0.5)	0/148	0/127
膣脱	1/244 (0.4)	0/181	0/148	0/127
呼吸器、胸郭および縦隔障害	15/244 (6.1)	5/170 (2.9)	2/136 (1.5)	2/115 (1.7)
急性呼吸不全	1/244 (0.4)	0/181	0/149	0/128
気管支拡張症	0/244	0/182	1/149 (0.7)	0/127
咳嗽	3/244 (1.2)	0/180	0/148	0/127
発声障害	1/244 (0.4)	0/181	1/148 (0.7)	0/126

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
腎機能障害	0/114	0/1	0/0	1/244 (0.4)
尿管結石症	0/114	0/1	0/0	1/244 (0.4)
切迫性尿失禁	0/112	0/1	0/0	3/244 (1.2)
尿失禁	0/110	0/1	0/0	5/244 (2.0)
尿閉	0/111	0/1	0/0	3/244 (1.2)
尿路障害	0/113	0/1	0/0	1/244 (0.4)
尿異常	0/113	0/1	0/0	1/244 (0.4)
尿臭異常	0/113	0/1	0/0	1/244 (0.4)
生殖系および乳房障害	0/110	0/1	0/0	6/244 (2.5)
良性前立腺肥大症	0/114	0/1	0/0	1/244 (0.4)
勃起不全	0/113	0/1	0/0	2/244 (0.8)
ペイロニー病	0/113	0/1	0/0	1/244 (0.4)
前立腺腫大	0/113	0/1	0/0	1/244 (0.4)
膣脱	0/113	0/1	0/0	1/244 (0.4)
呼吸器、胸郭および縦隔障害	1/101 (1.0)	0/1	0/0	25/244 (10.2)
急性呼吸不全	0/114	0/1	0/0	1/244 (0.4)
気管支拡張症	0/113	0/1	0/0	1/244 (0.4)
咳嗽	0/113	0/1	0/0	3/244 (1.2)
発声障害	0/112	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	5/244 (2.0)	2/177 (1.1)	0/144	0/125
労作性呼吸困難	0/244	1/182 (0.5)	0/148	0/127
鼻出血	0/244	0/182	1/149 (0.7)	0/127
過換気	2/244 (0.8)	0/181	0/148	0/127
口腔咽頭痛	1/244 (0.4)	1/181 (0.6)	0/147	0/126
誤嚥性肺炎	0/244	0/182	0/149	1/128 (0.8)
湿性咳嗽	0/244	0/182	1/149 (0.7)	0/127
肺塞栓症	1/244 (0.4)	0/182	0/149	1/128 (0.8)
ラ音	0/244	1/182 (0.5)	0/148	0/127
鼻痛	1/244 (0.4)	0/181	0/148	0/127
鼻漏	2/244 (0.8)	0/180	0/147	0/126
咽喉刺激感	1/244 (0.4)	0/181	0/149	0/128
皮膚および皮下組織障害	22/244 (9.0)	2/163 (1.2)	2/132 (1.5)	2/110 (1.8)
脱毛症	1/244 (0.4)	1/181 (0.6)	0/147	0/126
褥瘡性潰瘍	1/244 (0.4)	0/181	0/148	0/127
皮膚嚢腫	1/244 (0.4)	0/181	0/149	1/128 (0.8)
皮膚炎	1/244 (0.4)	0/181	0/148	0/127
接触皮膚炎	1/244 (0.4)	0/181	0/148	1/127 (0.8)
おむつ皮膚炎	1/244 (0.4)	0/181	0/148	0/127
薬疹	1/244 (0.4)	0/181	0/148	0/127

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/111 (0.9)	0/1	0/0	8/244 (3.3)
労作性呼吸困難	0/113	0/1	0/0	1/244 (0.4)
鼻出血	0/113	0/1	0/0	1/244 (0.4)
過換気	0/113	0/1	0/0	2/244 (0.8)
口腔咽頭痛	0/112	0/1	0/0	2/244 (0.8)
誤嚥性肺炎	0/114	0/1	0/0	1/244 (0.4)
湿性咳嗽	0/113	0/1	0/0	1/244 (0.4)
肺塞栓症	0/113	0/1	0/0	2/244 (0.8)
ラ音	0/114	0/1	0/0	1/244 (0.4)
鼻痛	0/113	0/1	0/0	1/244 (0.4)
鼻漏	0/112	0/1	0/0	2/244 (0.8)
咽喉刺激感	0/114	0/1	0/0	1/244 (0.4)
皮膚および皮下組織障害	0/96	0/0	0/0	28/244 (11.5)
脱毛症	0/112	0/0	0/0	2/244 (0.8)
褥瘡性潰瘍	0/113	0/1	0/0	1/244 (0.4)
皮膚嚢腫	0/113	0/1	0/0	2/244 (0.8)
皮膚炎	0/113	0/1	0/0	1/244 (0.4)
接触皮膚炎	0/112	0/1	0/0	2/244 (0.8)
おむつ皮膚炎	0/113	0/1	0/0	1/244 (0.4)
薬疹	0/113	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	1/244 (0.4)	1/182 (0.5)	0/148	0/127
斑状出血	1/244 (0.4)	0/181	0/148	0/127
紅斑	4/244 (1.6)	0/178	0/147	0/126
爪の障害	0/244	0/182	1/149 (0.7)	0/127
脂肪織炎	0/244	0/182	1/149 (0.7)	0/127
丘疹	2/244 (0.8)	0/180	0/147	0/127
光線過敏性反応	1/244 (0.4)	0/181	0/149	0/128
そう痒症	1/244 (0.4)	0/181	1/148 (0.7)	1/126 (0.8)
乾癬	0/244	1/182 (0.5)	0/148	0/128
発疹	2/244 (0.8)	0/180	1/147 (0.7)	0/125
紅斑性皮疹	1/244 (0.4)	0/181	0/148	0/127
そう痒性皮疹	2/244 (0.8)	0/181	1/148 (0.7)	0/126
皮膚刺激	1/244 (0.4)	0/182	0/149	0/128
皮膚病変	1/244 (0.4)	0/181	0/148	0/128
皮膚潰瘍	2/244 (0.8)	0/180	0/147	0/126
蕁麻疹	0/244	1/182 (0.5)	1/148 (0.7)	0/126
社会環境	1/244 (0.4)	0/181	0/149	0/128
運動不能	1/244 (0.4)	0/181	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	0/113	0/1	0/0	2/244 (0.8)
斑状出血	0/113	0/1	0/0	1/244 (0.4)
紅斑	0/112	0/1	0/0	4/244 (1.6)
爪の障害	0/113	0/1	0/0	1/244 (0.4)
脂肪織炎	0/113	0/1	0/0	1/244 (0.4)
丘疹	0/113	0/1	0/0	2/244 (0.8)
光線過敏性反応	0/114	0/1	0/0	1/244 (0.4)
そう痒症	0/111	0/1	0/0	3/244 (1.2)
乾癬	0/114	0/1	0/0	1/244 (0.4)
発疹	0/112	0/1	0/0	3/244 (1.2)
紅斑性皮疹	0/113	0/1	0/0	1/244 (0.4)
そう痒性皮疹	0/112	0/1	0/0	3/244 (1.2)
皮膚刺激	0/114	0/1	0/0	1/244 (0.4)
皮膚病変	0/114	0/1	0/0	1/244 (0.4)
皮膚潰瘍	0/113	0/1	0/0	2/244 (0.8)
蕁麻疹	0/113	0/1	0/0	2/244 (0.8)
社会環境	0/114	0/1	0/0	1/244 (0.4)
運動不能	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
外科および内科処置	0/244	1/182 (0.5)	0/148	0/127
抜歯	0/244	1/182 (0.5)	0/148	0/127
血管障害	13/244 (5.3)	3/173 (1.7)	5/137 (3.6)	3/113 (2.7)
深部静脈血栓症	1/244 (0.4)	0/182	0/149	0/128
血腫	0/244	0/182	0/149	1/128 (0.8)
出血	0/244	1/182 (0.5)	0/148	0/127
ほてり	1/244 (0.4)	0/182	0/149	0/128
高血圧	4/244 (1.6)	0/179	1/146 (0.7)	1/124 (0.8)
高血圧クリーゼ	1/244 (0.4)	0/182	0/149	0/128
低血圧	3/244 (1.2)	0/179	1/146 (0.7)	1/124 (0.8)
不安定血圧	1/244 (0.4)	0/182	0/149	0/128
起立性高血圧	0/244	0/182	0/149	0/128
起立性低血圧	5/244 (2.0)	2/177 (1.1)	3/142 (2.1)	2/120 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
外科および内科処置	0/113	0/1	0/0	1/244 (0.4)
抜歯	0/113	0/1	0/0	1/244 (0.4)
血管障害	2/97 (2.1)	0/1	0/0	26/244 (10.7)
深部静脈血栓症	0/114	0/1	0/0	1/244 (0.4)
血腫	0/113	0/1	0/0	1/244 (0.4)
出血	0/113	0/1	0/0	1/244 (0.4)
ほてり	0/114	0/1	0/0	1/244 (0.4)
高血圧	0/110	0/1	0/0	6/244 (2.5)
高血圧クリーゼ	0/114	0/1	0/0	1/244 (0.4)
低血圧	1/109 (0.9)	0/1	0/0	6/244 (2.5)
不安定血圧	0/114	0/1	0/0	1/244 (0.4)
起立性高血圧	1/114 (0.9)	0/1	0/0	1/244 (0.4)
起立性低血圧	0/104	0/1	0/0	12/244 (4.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
Any adverse event	120/132 (90.9)	2/8 (25.0)	0/4	0/4
血液およびリンパ系障害	1/132 (0.8)	0/96	0/78	0/69
リンパ節症	1/132 (0.8)	0/96	0/78	0/69
心臓障害	1/132 (0.8)	1/96 (1.0)	0/78	2/69 (2.9)
急性心筋梗塞	0/132	0/97	0/79	1/70 (1.4)
狭心症	0/132	1/97 (1.0)	0/78	0/69
心停止	0/132	0/97	0/79	1/70 (1.4)
冠動脈疾患	0/132	0/97	0/79	1/70 (1.4)
冠動脈狭窄	0/132	0/97	0/79	1/70 (1.4)
心筋梗塞	1/132 (0.8)	0/96	0/79	0/70
耳および迷路障害	2/132 (1.5)	1/95 (1.1)	1/77 (1.3)	0/68
感音性難聴	0/132	0/97	1/79 (1.3)	0/69
回転性めまい	2/132 (1.5)	1/95 (1.1)	0/77	0/69
眼障害	2/132 (1.5)	2/96 (2.1)	1/76 (1.3)	2/66 (3.0)
白内障	0/132	0/97	1/79 (1.3)	1/69 (1.4)
複視	2/132 (1.5)	0/96	0/78	0/69
ドライアイ	1/132 (0.8)	0/97	0/79	0/70
緑内障	0/132	0/97	0/79	1/70 (1.4)
網膜裂孔	0/132	2/97 (2.1)	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
Any adverse event	0/2	0/0	0/0	122/132 (92.4)
血液およびリンパ系障害	0/62	0/1	0/0	1/132 (0.8)
リンパ節症	0/62	0/1	0/0	1/132 (0.8)
心臓障害	0/60	0/1	0/0	4/132 (3.0)
急性心筋梗塞	0/62	0/1	0/0	1/132 (0.8)
狭心症	0/62	0/1	0/0	1/132 (0.8)
心停止	0/62	0/1	0/0	1/132 (0.8)
冠動脈疾患	0/62	0/1	0/0	1/132 (0.8)
冠動脈狭窄	0/62	0/1	0/0	1/132 (0.8)
心筋梗塞	0/63	0/1	0/0	1/132 (0.8)
耳および迷路障害	0/61	0/1	0/0	4/132 (3.0)
感音性難聴	0/62	0/1	0/0	1/132 (0.8)
回転性めまい	0/62	0/1	0/0	3/132 (2.3)
眼障害	0/57	0/1	0/0	7/132 (5.3)
白内障	0/61	0/1	0/0	2/132 (1.5)
複視	0/62	0/1	0/0	2/132 (1.5)
ドライアイ	0/63	0/1	0/0	1/132 (0.8)
緑内障	0/62	0/1	0/0	1/132 (0.8)
網膜裂孔	0/61	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	1/132 (0.8)	0/97	0/79	0/70
胃腸障害	18/132 (13.6)	7/82 (8.5)	2/60 (3.3)	0/54
腹部膨満	0/132	1/97 (1.0)	0/78	0/70
腹痛	1/132 (0.8)	1/97 (1.0)	0/78	0/70
上腹部痛	0/132	1/97 (1.0)	0/78	0/69
アフタ性潰瘍	1/132 (0.8)	0/96	0/78	0/69
呼気臭	2/132 (1.5)	0/95	0/77	0/68
虚血性大腸炎	0/132	1/97 (1.0)	0/78	0/70
便秘	5/132 (3.8)	2/94 (2.1)	1/75 (1.3)	0/66
齲歯	0/132	0/97	1/79 (1.3)	0/70
下痢	3/132 (2.3)	2/95 (2.1)	1/75 (1.3)	0/67
口内乾燥	3/132 (2.3)	0/94	0/77	0/68
消化不良	1/132 (0.8)	0/96	0/78	0/69
胃食道逆流性疾患	0/132	0/97	1/79 (1.3)	0/69
舌炎	0/132	1/97 (1.0)	0/78	0/70
舌痛	0/132	1/97 (1.0)	0/78	0/70
吐血	0/132	0/97	0/79	1/70 (1.4)
痔核	1/132 (0.8)	0/97	0/79	0/70
裂孔ヘルニア	0/132	0/97	0/79	1/70 (1.4)
胃排出不全	0/132	0/97	0/79	1/70 (1.4)
腸出血	0/132	1/97 (1.0)	0/78	0/70
過敏性腸症候群	1/132 (0.8)	0/96	0/78	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	0/63	0/1	0/0	1/132 (0.8)
胃腸障害	0/48	0/1	0/0	27/132 (20.5)
腹部膨満	0/63	0/1	0/0	1/132 (0.8)
腹痛	0/63	0/1	0/0	2/132 (1.5)
上腹部痛	0/63	0/1	0/0	1/132 (0.8)
アフタ性潰瘍	0/62	0/1	0/0	1/132 (0.8)
呼気臭	0/61	0/1	0/0	2/132 (1.5)
虚血性大腸炎	0/63	0/1	0/0	1/132 (0.8)
便秘	0/59	0/1	0/0	8/132 (6.1)
齲歯	0/63	0/1	0/0	1/132 (0.8)
下痢	0/61	0/1	0/0	6/132 (4.5)
口内乾燥	0/61	0/1	0/0	3/132 (2.3)
消化不良	0/62	0/1	0/0	1/132 (0.8)
胃食道逆流性疾患	0/62	0/1	0/0	1/132 (0.8)
舌炎	0/63	0/1	0/0	1/132 (0.8)
舌痛	0/63	0/1	0/0	1/132 (0.8)
吐血	0/62	0/1	0/0	1/132 (0.8)
痔核	0/63	0/1	0/0	1/132 (0.8)
裂孔ヘルニア	0/62	0/1	0/0	1/132 (0.8)
胃排出不全	0/62	0/1	0/0	1/132 (0.8)
腸出血	0/63	0/1	0/0	1/132 (0.8)
過敏性腸症候群	0/62	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
胃腸障害 (Cont.)				
口唇乾燥	0/132	1/97 (1.0)	0/78	0/69
メレナ	1/132 (0.8)	1/96 (1.0)	0/77	0/69
口腔腫脹	0/132	1/97 (1.0)	0/78	0/70
悪心	5/132 (3.8)	3/92 (3.3)	0/72	0/65
口腔内不快感	0/132	1/97 (1.0)	0/78	0/70
口腔内痛	0/132	0/97	1/79 (1.3)	0/70
口の錯感覚	0/132	0/97	1/79 (1.3)	0/70
直腸出血	0/132	1/97 (1.0)	0/78	0/70
嘔吐	2/132 (1.5)	1/95 (1.1)	0/76	0/67
一般・全身障害および投与部位の状態	102/132 (77.3)	0/22	4/18 (22.2)	0/12
投与部位紅斑	1/132 (0.8)	0/97	0/79	0/70
無力症	1/132 (0.8)	1/97 (1.0)	1/78 (1.3)	0/68
カテーテル留置部位紅斑	1/132 (0.8)	0/96	0/78	0/69
カテーテル留置部位漏出	0/132	0/97	1/79 (1.3)	0/69
胸痛	0/132	0/97	0/79	1/70 (1.4)
泣き	0/132	1/97 (1.0)	0/78	0/70
不快感	1/132 (0.8)	0/97	0/79	0/70
薬剤離脱症候群	1/132 (0.8)	0/97	0/79	0/70
疲労	4/132 (3.0)	0/95	1/77 (1.3)	1/68 (1.5)
異常感	1/132 (0.8)	0/96	0/79	0/70
熱感	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
胃腸障害 (Cont.)				
口唇乾燥	0/62	0/1	0/0	1/132 (0.8)
メレナ	0/62	0/1	0/0	2/132 (1.5)
口腔腫脹	0/63	0/1	0/0	1/132 (0.8)
悪心	0/58	0/1	0/0	8/132 (6.1)
口腔内不快感	0/63	0/1	0/0	1/132 (0.8)
口腔内痛	0/63	0/1	0/0	1/132 (0.8)
口の錯感覚	0/63	0/1	0/0	1/132 (0.8)
直腸出血	0/63	0/1	0/0	1/132 (0.8)
嘔吐	0/60	0/1	0/0	3/132 (2.3)
一般・全身障害および投与部位の状態	0/8	0/1	0/0	106/132 (80.3)
投与部位紅斑	0/63	0/1	0/0	1/132 (0.8)
無力症	0/61	0/1	0/0	3/132 (2.3)
カテーテル留置部位紅斑	0/62	0/1	0/0	1/132 (0.8)
カテーテル留置部位漏出	0/62	0/1	0/0	1/132 (0.8)
胸痛	0/62	0/1	0/0	1/132 (0.8)
泣き	0/63	0/1	0/0	1/132 (0.8)
不快感	0/63	0/1	0/0	1/132 (0.8)
薬剤離脱症候群	0/63	0/1	0/0	1/132 (0.8)
疲労	0/60	0/1	0/0	6/132 (4.5)
異常感	0/63	0/1	0/0	1/132 (0.8)
熱感	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
歩行不能	1/132 (0.8)	0/96	0/79	0/70
低体温	1/132 (0.8)	0/96	0/78	0/69
インフルエンザ様疾患	1/132 (0.8)	0/96	0/78	0/69
注入部位内出血	7/132 (5.3)	2/91 (2.2)	1/74 (1.4)	0/65
注入部位皮膚炎	1/132 (0.8)	0/96	0/78	1/69 (1.4)
注入部位分泌物	1/132 (0.8)	0/96	0/78	0/69
注入部位変色	2/132 (1.5)	0/95	0/77	0/68
注入部位不快感	2/132 (1.5)	1/95 (1.1)	0/76	0/68
注入部位びらん	1/132 (0.8)	0/96	0/78	0/69
注入部位紅斑	60/132 (45.5)	0/49	3/43 (7.0)	1/38 (2.6)
注入部位皮膚剥脱	2/132 (1.5)	0/95	1/78 (1.3)	0/68
注入部位血管外漏出	6/132 (4.5)	1/92 (1.1)	1/75 (1.3)	0/66
注入部位血腫	5/132 (3.8)	0/93	1/76 (1.3)	2/66 (3.0)
注入部位出血	3/132 (2.3)	1/94 (1.1)	0/75	0/67
注入部位硬結	6/132 (4.5)	0/93	0/78	1/69 (1.4)
注入部位炎症	2/132 (1.5)	0/96	1/79 (1.3)	0/69
注入部位損傷	1/132 (0.8)	0/97	0/79	0/70
注入部位刺激感	0/132	0/97	1/79 (1.3)	0/69
注入部位腫瘤	5/132 (3.8)	0/95	0/78	0/70
注入部位結節	28/132 (21.2)	1/71 (1.4)	3/54 (5.6)	1/42 (2.4)
注入部位浮腫	16/132 (12.1)	1/86 (1.2)	2/69 (2.9)	0/60

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
歩行不能	0/63	0/1	0/0	1/132 (0.8)
低体温	0/62	0/1	0/0	1/132 (0.8)
インフルエンザ様疾患	0/62	0/1	0/0	1/132 (0.8)
注入部位内出血	0/58	0/1	0/0	10/132 (7.6)
注入部位皮膚炎	0/61	0/1	0/0	2/132 (1.5)
注入部位分泌物	0/62	0/1	0/0	1/132 (0.8)
注入部位変色	0/61	0/1	0/0	2/132 (1.5)
注入部位不快感	0/61	0/1	0/0	3/132 (2.3)
注入部位びらん	0/62	0/1	0/0	1/132 (0.8)
注入部位紅斑	1/32 (3.1)	0/1	0/0	65/132 (49.2)
注入部位皮膚剥脱	0/61	0/1	0/0	3/132 (2.3)
注入部位血管外漏出	0/59	0/1	0/0	8/132 (6.1)
注入部位血腫	0/57	0/1	0/0	8/132 (6.1)
注入部位出血	0/60	0/1	0/0	4/132 (3.0)
注入部位硬結	0/61	0/1	0/0	7/132 (5.3)
注入部位炎症	0/63	0/1	0/0	3/132 (2.3)
注入部位損傷	0/63	0/1	0/0	1/132 (0.8)
注入部位刺激感	0/62	0/1	0/0	1/132 (0.8)
注入部位腫瘤	0/63	0/1	0/0	5/132 (3.8)
注入部位結節	1/34 (2.9)	0/1	0/0	34/132 (25.8)
注入部位浮腫	0/54	0/1	0/0	19/132 (14.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位疼痛	14/132 (10.6)	2/87 (2.3)	1/69 (1.4)	1/60 (1.7)
注入部位蒼白	2/132 (1.5)	1/96 (1.0)	0/78	0/69
注入部位丘疹	2/132 (1.5)	2/96 (2.1)	1/76 (1.3)	0/67
注入部位そう痒感	3/132 (2.3)	1/95 (1.1)	1/76 (1.3)	0/68
注入部位発疹	2/132 (1.5)	1/96 (1.0)	0/77	0/69
注入部位反応	9/132 (6.8)	3/91 (3.3)	1/72 (1.4)	0/63
注入部位腫脹	4/132 (3.0)	0/94	0/77	0/69
注射部位内出血	2/132 (1.5)	0/96	0/78	0/69
注射部位変色	0/132	1/97 (1.0)	0/78	0/69
注射部位紅斑	6/132 (4.5)	0/92	0/74	0/65
注射部位漏出	1/132 (0.8)	0/96	0/78	0/69
注射部位炎症	2/132 (1.5)	0/96	0/78	0/69
注射部位結節	1/132 (0.8)	2/96 (2.1)	0/76	0/67
注射部位浮腫	2/132 (1.5)	0/95	0/78	0/69
注射部位疼痛	2/132 (1.5)	0/95	0/77	0/69
注射部位反応	0/132	0/97	1/79 (1.3)	0/69
注射部位腫脹	1/132 (0.8)	0/97	1/79 (1.3)	0/69
倦怠感	1/132 (0.8)	0/97	0/79	0/70
医療機器使用部位刺激感	1/132 (0.8)	0/96	0/78	0/69
医療機器使用部位そう痒感	1/132 (0.8)	0/96	0/78	0/69
小結節	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位疼痛	0/52	0/1	0/0	18/132 (13.6)
注入部位蒼白	0/62	0/1	0/0	3/132 (2.3)
注入部位丘疹	2/61 (3.3)	0/1	0/0	7/132 (5.3)
注入部位そう痒感	0/61	0/1	0/0	5/132 (3.8)
注入部位発疹	0/62	0/1	0/0	3/132 (2.3)
注入部位反応	0/56	0/1	0/0	13/132 (9.8)
注入部位腫脹	0/62	0/1	0/0	4/132 (3.0)
注射部位内出血	0/62	0/1	0/0	2/132 (1.5)
注射部位変色	0/62	0/1	0/0	1/132 (0.8)
注射部位紅斑	0/58	0/1	0/0	6/132 (4.5)
注射部位漏出	0/62	0/1	0/0	1/132 (0.8)
注射部位炎症	0/63	0/1	0/0	2/132 (1.5)
注射部位結節	0/60	0/1	0/0	3/132 (2.3)
注射部位浮腫	0/62	0/1	0/0	2/132 (1.5)
注射部位疼痛	0/62	0/1	0/0	2/132 (1.5)
注射部位反応	0/62	0/1	0/0	1/132 (0.8)
注射部位腫脹	0/62	0/1	0/0	2/132 (1.5)
倦怠感	0/63	0/1	0/0	1/132 (0.8)
医療機器使用部位刺激感	0/62	0/1	0/0	1/132 (0.8)
医療機器使用部位そう痒感	0/62	0/1	0/0	1/132 (0.8)
小結節	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
末梢性浮腫	4/132 (3.0)	0/93	1/76 (1.3)	0/68
疼痛	0/132	1/97 (1.0)	0/78	1/70 (1.4)
穿刺部位内出血	1/132 (0.8)	0/97	0/79	0/70
穿刺部位出血	1/132 (0.8)	0/96	0/78	0/70
穿刺部位硬結	2/132 (1.5)	0/96	0/78	0/69
発熱	2/132 (1.5)	0/96	0/78	0/69
口渇	1/132 (0.8)	0/96	0/78	0/69
血管穿刺部位硬結	1/132 (0.8)	0/97	0/79	0/70
肝胆道系障害	1/132 (0.8)	0/97	0/79	0/70
肝嚢胞	0/132	0/97	0/79	0/70
門脈血栓症	1/132 (0.8)	0/97	0/79	0/70
感染症および寄生虫症	38/132 (28.8)	11/66 (16.7)	5/49 (10.2)	4/39 (10.3)
ボレリア感染	1/132 (0.8)	0/96	0/79	0/70
COVID-19	0/132	0/97	0/79	1/70 (1.4)
COVID-19肺炎	0/132	0/97	1/79 (1.3)	0/70
カテーテル留置部位感染	0/132	0/97	0/79	1/70 (1.4)
蜂巣炎	1/132 (0.8)	0/96	0/78	0/69
結膜炎	1/132 (0.8)	1/96 (1.0)	0/78	0/69
真菌感染	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
末梢性浮腫	0/61	0/1	0/0	5/132 (3.8)
疼痛	0/62	0/1	0/0	2/132 (1.5)
穿刺部位内出血	0/63	0/1	0/0	1/132 (0.8)
穿刺部位出血	0/63	0/1	0/0	1/132 (0.8)
穿刺部位硬結	0/62	0/1	0/0	2/132 (1.5)
発熱	0/62	0/1	0/0	2/132 (1.5)
口渇	0/62	0/1	0/0	1/132 (0.8)
血管穿刺部位硬結	0/63	0/1	0/0	1/132 (0.8)
肝胆道系障害	1/63 (1.6)	0/0	0/0	2/132 (1.5)
肝嚢胞	1/63 (1.6)	0/0	0/0	1/132 (0.8)
門脈血栓症	0/63	0/1	0/0	1/132 (0.8)
感染症および寄生虫症	0/31	0/1	0/0	58/132 (43.9)
ボレリア感染	0/63	0/1	0/0	1/132 (0.8)
COVID-19	0/63	0/1	0/0	1/132 (0.8)
COVID-19肺炎	0/63	0/1	0/0	1/132 (0.8)
カテーテル留置部位感染	0/62	0/1	0/0	1/132 (0.8)
蜂巣炎	0/62	0/1	0/0	1/132 (0.8)
結膜炎	0/63	0/1	0/0	2/132 (1.5)
真菌感染	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	1/132 (0.8)	0/96	0/78	0/69
麦粒腫	0/132	1/97 (1.0)	0/78	0/69
注入部位膿瘍	9/132 (6.8)	1/91 (1.1)	2/76 (2.6)	1/67 (1.5)
注入部位蜂巣炎	19/132 (14.4)	5/82 (6.1)	3/63 (4.8)	2/51 (3.9)
注入部位感染	1/132 (0.8)	3/96 (3.1)	0/76	2/67 (3.0)
上咽頭炎	1/132 (0.8)	2/96 (2.1)	0/77	2/69 (2.9)
肺炎	1/132 (0.8)	0/96	2/78 (2.6)	0/68
術後膿瘍	0/132	0/97	1/79 (1.3)	0/69
膿疱性皮疹	1/132 (0.8)	0/97	0/79	0/70
敗血症	2/132 (1.5)	0/95	0/78	1/69 (1.4)
敗血症性ショック	1/132 (0.8)	0/96	0/78	0/69
副鼻腔炎	1/132 (0.8)	0/96	0/78	0/70
ブドウ球菌感染	0/132	0/97	0/79	1/70 (1.4)
歯感染	1/132 (0.8)	0/96	0/78	0/70
上気道感染	1/132 (0.8)	0/96	0/78	0/69
尿路感染	5/132 (3.8)	1/92 (1.1)	1/76 (1.3)	1/66 (1.5)
水痘帯状疱疹ウイルス感染	0/132	1/97 (1.0)	0/78	0/69
傷害、中毒および処置合併症	13/132 (9.8)	5/87 (5.7)	2/66 (3.0)	1/58 (1.7)
骨挫傷	0/132	0/97	0/79	1/70 (1.4)
脳挫傷	1/132 (0.8)	0/96	0/78	0/70
挫傷	1/132 (0.8)	1/96 (1.0)	0/77	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	0/62	0/1	0/0	1/132 (0.8)
麦粒腫	0/63	0/1	0/0	1/132 (0.8)
注入部位膿瘍	0/60	0/1	0/0	13/132 (9.8)
注入部位蜂巣炎	0/43	0/1	0/0	29/132 (22.0)
注入部位感染	0/58	0/1	0/0	6/132 (4.5)
上咽頭炎	0/60	0/1	0/0	5/132 (3.8)
肺炎	0/62	0/1	0/0	3/132 (2.3)
術後膿瘍	0/62	0/1	0/0	1/132 (0.8)
膿疱性皮疹	0/63	0/1	0/0	1/132 (0.8)
敗血症	0/61	0/1	0/0	3/132 (2.3)
敗血症性ショック	0/62	0/1	0/0	1/132 (0.8)
副鼻腔炎	0/63	0/1	0/0	1/132 (0.8)
ブドウ球菌感染	0/62	0/1	0/0	1/132 (0.8)
歯感染	0/63	0/1	0/0	1/132 (0.8)
上気道感染	0/62	0/1	0/0	1/132 (0.8)
尿路感染	0/58	0/1	0/0	8/132 (6.1)
水痘帯状疱疹ウイルス感染	0/62	0/1	0/0	1/132 (0.8)
傷害、中毒および処置合併症	0/51	0/1	0/0	21/132 (15.9)
骨挫傷	0/62	0/1	0/0	1/132 (0.8)
脳挫傷	0/63	0/1	0/0	1/132 (0.8)
挫傷	0/61	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	1/132 (0.8)	0/96	0/78	0/69
医療機器による投与の欠落	1/132 (0.8)	0/97	0/79	0/70
期限切れの製品使用	1/132 (0.8)	0/96	0/79	0/70
転倒	9/132 (6.8)	5/90 (5.6)	1/68 (1.5)	1/61 (1.6)
頭部損傷	1/132 (0.8)	1/96 (1.0)	0/78	0/69
注入に伴う反応	1/132 (0.8)	0/97	0/79	0/70
靭帯捻挫	0/132	1/97 (1.0)	0/78	0/69
処置後挫傷	1/132 (0.8)	0/96	0/78	0/69
肋骨骨折	0/132	1/97 (1.0)	0/78	0/69
皮膚擦過傷	1/132 (0.8)	0/96	0/78	0/69
皮膚損傷	1/132 (0.8)	0/96	0/78	0/70
皮膚裂傷	0/132	1/97 (1.0)	0/78	0/69
ストレス骨折	0/132	0/97	1/79 (1.3)	0/69
腱断裂	0/132	0/97	0/79	1/70 (1.4)
創傷	0/132	0/97	0/79	1/70 (1.4)
臨床検査	15/132 (11.4)	2/86 (2.3)	3/68 (4.4)	2/57 (3.5)
血中クレアチンホスホキナーゼ増加	1/132 (0.8)	0/97	0/79	0/70
血中葉酸減少	1/132 (0.8)	0/96	0/78	0/69
血中ホモシステイン増加	0/132	0/97	0/79	0/70
血圧上昇	1/132 (0.8)	0/96	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	0/62	0/1	0/0	1/132 (0.8)
医療機器による投与の欠落	0/63	0/1	0/0	1/132 (0.8)
期限切れの製品使用	0/63	0/1	0/0	1/132 (0.8)
転倒	0/53	0/1	0/0	16/132 (12.1)
頭部損傷	0/62	0/1	0/0	2/132 (1.5)
注入に伴う反応	0/63	0/1	0/0	1/132 (0.8)
靭帯捻挫	0/62	0/1	0/0	1/132 (0.8)
処置後挫傷	0/62	0/1	0/0	1/132 (0.8)
肋骨骨折	0/62	0/1	0/0	1/132 (0.8)
皮膚擦過傷	0/62	0/1	0/0	1/132 (0.8)
皮膚損傷	0/63	0/1	0/0	1/132 (0.8)
皮膚裂傷	0/62	0/1	0/0	1/132 (0.8)
ストレス骨折	0/63	0/1	0/0	1/132 (0.8)
腱断裂	0/62	0/1	0/0	1/132 (0.8)
創傷	0/62	0/1	0/0	1/132 (0.8)
臨床検査	1/48 (2.1)	0/1	0/0	23/132 (17.4)
血中クレアチンホスホキナーゼ増加	0/63	0/1	0/0	1/132 (0.8)
血中葉酸減少	0/62	0/1	0/0	1/132 (0.8)
血中ホモシステイン増加	1/63 (1.6)	0/1	0/0	1/132 (0.8)
血圧上昇	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/132 (0.8)	0/96	0/78	0/69
血中ナトリウム減少	1/132 (0.8)	0/96	0/78	0/69
握力低下	1/132 (0.8)	0/96	0/78	0/69
ヘモグロビン減少	1/132 (0.8)	0/96	0/79	0/70
ビタミンB12減少	1/132 (0.8)	0/97	0/79	0/70
ビタミンB6減少	4/132 (3.0)	0/94	1/76 (1.3)	0/66
体重減少	4/132 (3.0)	1/94 (1.1)	3/76 (3.9)	2/65 (3.1)
体重増加	1/132 (0.8)	1/96 (1.0)	0/77	0/68
代謝および栄養障害	4/132 (3.0)	3/93 (3.2)	2/72 (2.8)	2/61 (3.3)
悪液質	0/132	0/97	1/79 (1.3)	0/69
食欲減退	1/132 (0.8)	1/96 (1.0)	1/77 (1.3)	0/67
脱水	0/132	1/97 (1.0)	0/78	0/69
体液貯留	1/132 (0.8)	0/96	0/78	0/69
葉酸欠乏	0/132	0/97	1/79 (1.3)	0/69
低ナトリウム血症	0/132	1/97 (1.0)	0/78	1/69 (1.4)
ビタミンB群欠乏	1/132 (0.8)	0/96	0/78	0/69
ビタミンB6欠乏	1/132 (0.8)	0/96	1/78 (1.3)	1/68 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	0/62	0/1	0/0	1/132 (0.8)
血中ナトリウム減少	0/62	0/1	0/0	1/132 (0.8)
握力低下	0/62	0/1	0/0	1/132 (0.8)
ヘモグロビン減少	0/63	0/1	0/0	1/132 (0.8)
ビタミンB12減少	0/63	0/1	0/0	1/132 (0.8)
ビタミンB6減少	0/59	0/1	0/0	5/132 (3.8)
体重減少	0/56	0/1	0/0	10/132 (7.6)
体重増加	0/61	0/1	0/0	2/132 (1.5)
代謝および栄養障害	0/53	0/1	0/0	11/132 (8.3)
悪液質	0/62	0/1	0/0	1/132 (0.8)
食欲減退	0/60	0/1	0/0	3/132 (2.3)
脱水	0/62	0/1	0/0	1/132 (0.8)
体液貯留	0/62	0/1	0/0	1/132 (0.8)
葉酸欠乏	0/62	0/1	0/0	1/132 (0.8)
低ナトリウム血症	0/62	0/1	0/0	2/132 (1.5)
ビタミンB群欠乏	0/62	0/1	0/0	1/132 (0.8)
ビタミンB6欠乏	0/60	0/1	0/0	3/132 (2.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
筋骨格系および結合組織障害	14/132 (10.6)	4/86 (4.7)	4/66 (6.1)	2/56 (3.6)
関節痛	2/132 (1.5)	0/96	1/78 (1.3)	0/68
反応性関節炎	0/132	0/97	1/79 (1.3)	0/69
背部痛	4/132 (3.0)	1/93 (1.1)	2/74 (2.7)	1/64 (1.6)
滑液包炎	1/132 (0.8)	0/96	1/78 (1.3)	0/68
椎間板変性症	0/132	1/97 (1.0)	0/78	0/69
筋痙縮	0/132	2/97 (2.1)	0/77	0/68
筋力低下	3/132 (2.3)	1/95 (1.1)	0/77	0/69
筋肉痛	2/132 (1.5)	0/95	0/77	0/68
頚部痛	0/132	0/97	2/79 (2.5)	0/68
変形性関節症	1/132 (0.8)	0/96	0/78	0/69
骨減少症	0/132	1/97 (1.0)	0/78	0/69
四肢痛	2/132 (1.5)	0/95	0/78	1/70 (1.4)
横紋筋融解症	1/132 (0.8)	0/97	0/79	1/70 (1.4)
仙腸関節機能障害	1/132 (0.8)	0/96	0/78	0/69
変形性脊椎症	0/132	1/97 (1.0)	0/78	0/69
腱炎	1/132 (0.8)	0/96	0/78	0/69
弾発指	0/132	0/97	1/79 (1.3)	0/69
神経系障害	47/132 (35.6)	7/67 (10.4)	4/50 (8.0)	3/40 (7.5)
アカシジア	0/132	0/97	0/79	1/70 (1.4)
健忘	0/132	0/97	0/79	0/70
運動失調	1/132 (0.8)	0/96	0/78	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
筋骨格系および結合組織障害	0/48	0/1	0/0	24/132 (18.2)
関節痛	0/61	0/1	0/0	3/132 (2.3)
反応性関節炎	0/63	0/1	0/0	1/132 (0.8)
背部痛	0/56	0/1	0/0	8/132 (6.1)
滑液包炎	0/62	0/1	0/0	2/132 (1.5)
椎間板変性症	0/62	0/1	0/0	1/132 (0.8)
筋痙縮	0/61	0/1	0/0	2/132 (1.5)
筋力低下	0/62	0/1	0/0	4/132 (3.0)
筋肉痛	0/61	0/1	0/0	2/132 (1.5)
頚部痛	0/61	0/1	0/0	2/132 (1.5)
変形性関節症	0/62	0/1	0/0	1/132 (0.8)
骨減少症	0/62	0/1	0/0	1/132 (0.8)
四肢痛	0/62	0/1	0/0	3/132 (2.3)
横紋筋融解症	0/62	0/1	0/0	2/132 (1.5)
仙腸関節機能障害	0/62	0/1	0/0	1/132 (0.8)
変形性脊椎症	0/62	0/1	0/0	1/132 (0.8)
腱炎	0/62	0/1	0/0	1/132 (0.8)
弾発指	0/62	0/1	0/0	1/132 (0.8)
神経系障害	1/32 (3.1)	0/0	0/0	62/132 (47.0)
アカシジア	0/62	0/1	0/0	1/132 (0.8)
健忘	1/63 (1.6)	0/1	0/0	1/132 (0.8)
運動失調	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
運動緩慢	1/132 (0.8)	0/97	0/79	0/70
認知障害	2/132 (1.5)	0/95	0/78	1/69 (1.4)
振動覚低下	0/132	1/97 (1.0)	0/78	0/69
浮動性めまい	13/132 (9.8)	2/88 (2.3)	0/71	0/64
体位性めまい	3/132 (2.3)	2/95 (2.1)	0/75	0/67
味覚不全	2/132 (1.5)	0/96	0/78	0/69
ジスキネジア	8/132 (6.1)	3/94 (3.2)	0/74	1/65 (1.5)
起立障害	1/132 (0.8)	0/96	0/79	0/70
ジストニア	2/132 (1.5)	0/95	0/77	0/69
伸展性足底反応	1/132 (0.8)	0/96	0/78	0/69
すくみ現象	4/132 (3.0)	0/95	0/78	0/69
頭部不快感	1/132 (0.8)	0/97	0/79	0/70
頭痛	5/132 (3.8)	1/93 (1.1)	1/76 (1.3)	0/68
感覚鈍麻	0/132	0/97	1/79 (1.3)	0/69
反射減弱	0/132	0/97	1/79 (1.3)	0/69
不規則睡眠覚醒リズム障害	0/132	0/97	1/79 (1.3)	0/69
嗜眠	0/132	1/97 (1.0)	0/78	0/70
意識消失	0/132	1/97 (1.0)	0/79	0/70
代謝性脳症	0/132	0/97	1/79 (1.3)	0/69
末梢性ニューロパチー	0/132	0/97	0/79	1/70 (1.4)
オンオフ現象	4/132 (3.0)	0/96	0/78	0/69
錯感覚	2/132 (1.5)	1/97 (1.0)	0/78	1/69 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
運動緩慢	0/63	0/1	0/0	1/132 (0.8)
認知障害	1/61 (1.6)	0/1	0/0	4/132 (3.0)
振動覚低下	0/62	0/1	0/0	1/132 (0.8)
浮動性めまい	0/57	0/1	0/0	15/132 (11.4)
体位性めまい	0/60	0/1	0/0	5/132 (3.8)
味覚不全	0/62	0/1	0/0	2/132 (1.5)
ジスキネジア	0/58	0/1	0/0	12/132 (9.1)
起立障害	0/63	0/1	0/0	1/132 (0.8)
ジストニア	0/62	0/1	0/0	2/132 (1.5)
伸展性足底反応	0/62	0/1	0/0	1/132 (0.8)
すくみ現象	0/62	0/1	0/0	4/132 (3.0)
頭部不快感	0/63	0/1	0/0	1/132 (0.8)
頭痛	0/61	0/1	0/0	7/132 (5.3)
感覚鈍麻	0/62	0/1	0/0	1/132 (0.8)
反射減弱	1/62 (1.6)	0/1	0/0	2/132 (1.5)
不規則睡眠覚醒リズム障害	0/62	0/1	0/0	1/132 (0.8)
嗜眠	0/63	0/1	0/0	1/132 (0.8)
意識消失	0/63	0/1	0/0	1/132 (0.8)
代謝性脳症	0/62	0/1	0/0	1/132 (0.8)
末梢性ニューロパチー	0/62	0/1	0/0	1/132 (0.8)
オンオフ現象	0/62	0/1	0/0	4/132 (3.0)
錯感覚	0/61	0/0	0/0	4/132 (3.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
パーキンソン病	8/132 (6.1)	3/92 (3.3)	1/72 (1.4)	0/64
側反弓	0/132	0/97	0/79	1/70 (1.4)
精神運動亢進	1/132 (0.8)	0/97	0/79	0/70
睡眠時麻痺	0/132	1/97 (1.0)	0/78	0/69
傾眠	6/132 (4.5)	2/91 (2.2)	0/72	1/65 (1.5)
振戦	0/132	1/97 (1.0)	0/78	0/70
製品の問題	2/132 (1.5)	0/95	0/78	0/69
医療機器送達システムの問題	1/132 (0.8)	0/96	0/79	0/70
医療機器位置異常	1/132 (0.8)	0/96	0/78	0/69
精神障害	45/132 (34.1)	2/62 (3.2)	2/48 (4.2)	1/43 (2.3)
感情不安定	1/132 (0.8)	0/97	0/79	0/70
不安	7/132 (5.3)	2/91 (2.2)	0/74	1/66 (1.5)
無感情	0/132	1/97 (1.0)	0/78	0/70
歯ぎしり	2/132 (1.5)	0/95	0/78	0/69
強迫性性行動	0/132	0/97	1/79 (1.3)	0/69
錯乱状態	4/132 (3.0)	0/93	0/75	0/66
譫妄	1/132 (0.8)	0/96	0/78	0/69
妄想	6/132 (4.5)	0/92	2/75 (2.7)	0/65
寄生虫妄想	0/132	1/97 (1.0)	0/78	0/70
抑うつ気分	1/132 (0.8)	1/96 (1.0)	0/77	0/69
うつ病	1/132 (0.8)	0/96	1/79 (1.3)	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
パーキンソン病	0/57	0/1	0/0	12/132 (9.1)
側反弓	0/62	0/1	0/0	1/132 (0.8)
精神運動亢進	0/63	0/1	0/0	1/132 (0.8)
睡眠時麻痺	0/62	0/1	0/0	1/132 (0.8)
傾眠	0/57	0/1	0/0	9/132 (6.8)
振戦	0/63	0/1	0/0	1/132 (0.8)
製品の問題	0/62	0/1	0/0	2/132 (1.5)
医療機器送達システムの問題	0/63	0/1	0/0	1/132 (0.8)
医療機器位置異常	0/62	0/1	0/0	1/132 (0.8)
精神障害	0/38	0/0	0/0	50/132 (37.9)
感情不安定	0/63	0/1	0/0	1/132 (0.8)
不安	0/58	0/1	0/0	10/132 (7.6)
無感情	0/63	0/1	0/0	1/132 (0.8)
歯ぎしり	0/62	0/1	0/0	2/132 (1.5)
強迫性性行動	0/62	0/1	0/0	1/132 (0.8)
錯乱状態	0/60	0/1	0/0	4/132 (3.0)
譫妄	0/62	0/1	0/0	1/132 (0.8)
妄想	0/59	0/1	0/0	8/132 (6.1)
寄生虫妄想	0/63	0/1	0/0	1/132 (0.8)
抑うつ気分	0/62	0/1	0/0	2/132 (1.5)
うつ病	0/62	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ症状	2/132 (1.5)	0/96	0/78	0/69
ドーパミン調節障害症候群	0/132	0/97	0/79	1/70 (1.4)
睡眠異常	1/132 (0.8)	0/96	0/78	0/69
情動障害	0/132	1/97 (1.0)	0/78	0/70
幻覚	17/132 (12.9)	1/86 (1.2)	1/70 (1.4)	1/61 (1.6)
幻聴	1/132 (0.8)	1/96 (1.0)	0/77	1/68 (1.5)
幻視	6/132 (4.5)	2/92 (2.2)	2/73 (2.7)	0/65
混合性幻覚	1/132 (0.8)	0/96	0/78	0/69
性欲過剰	1/132 (0.8)	0/96	0/78	0/69
錯覚	1/132 (0.8)	0/96	0/78	0/70
不眠症	9/132 (6.8)	0/89	0/72	0/64
易刺激性	1/132 (0.8)	0/96	0/79	0/70
嫉妬妄想	1/132 (0.8)	0/96	0/78	0/69
気分変化	1/132 (0.8)	0/96	0/78	0/69
悪夢	0/132	1/97 (1.0)	0/78	0/70
強迫観念	1/132 (0.8)	0/96	0/79	0/70
妄想症	0/132	1/97 (1.0)	1/78 (1.3)	0/68
睡眠の質低下	0/132	1/97 (1.0)	0/78	0/70
精神病性障害	3/132 (2.3)	0/94	1/77 (1.3)	0/67
精神病症状	0/132	0/97	0/79	1/70 (1.4)
レム睡眠行動障害	1/132 (0.8)	0/97	0/79	0/70
レム睡眠異常	1/132 (0.8)	0/96	0/78	0/69

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ症状	0/62	0/1	0/0	2/132 (1.5)
ドーパミン調節障害症候群	0/62	0/1	0/0	1/132 (0.8)
睡眠異常	0/62	0/1	0/0	1/132 (0.8)
情動障害	0/63	0/1	0/0	1/132 (0.8)
幻覚	0/55	0/1	0/0	20/132 (15.2)
幻聴	0/60	0/1	0/0	3/132 (2.3)
幻視	0/58	0/1	0/0	10/132 (7.6)
混合性幻覚	0/62	0/1	0/0	1/132 (0.8)
性欲過剰	0/62	0/1	0/0	1/132 (0.8)
錯覚	0/63	0/1	0/0	1/132 (0.8)
不眠症	0/57	0/0	0/0	9/132 (6.8)
易刺激性	0/63	0/1	0/0	1/132 (0.8)
嫉妬妄想	0/62	0/1	0/0	1/132 (0.8)
気分変化	0/62	0/1	0/0	1/132 (0.8)
悪夢	0/63	0/1	0/0	1/132 (0.8)
強迫観念	0/63	0/1	0/0	1/132 (0.8)
妄想症	0/61	0/1	0/0	2/132 (1.5)
睡眠の質低下	0/63	0/1	0/0	1/132 (0.8)
精神病性障害	0/60	0/1	0/0	4/132 (3.0)
精神病症状	0/62	0/1	0/0	1/132 (0.8)
レム睡眠行動障害	0/63	0/1	0/0	1/132 (0.8)
レム睡眠異常	0/62	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
睡眠障害	1/132 (0.8)	1/96 (1.0)	0/77	0/69
ねごと	0/132	1/97 (1.0)	0/78	0/70
自殺念慮	0/132	1/97 (1.0)	0/79	0/70
自殺企図	0/132	0/97	0/79	1/70 (1.4)
腎および尿路障害	7/132 (5.3)	2/90 (2.2)	1/72 (1.4)	1/63 (1.6)
膀胱痙縮	0/132	0/97	1/79 (1.3)	0/69
膀胱結石	0/132	1/97 (1.0)	0/79	0/70
排尿困難	1/132 (0.8)	0/96	0/78	0/69
緊張性膀胱	0/132	0/97	0/79	1/70 (1.4)
切迫性尿失禁	3/132 (2.3)	0/94	0/77	0/68
尿失禁	2/132 (1.5)	1/95 (1.1)	0/76	0/68
尿路障害	1/132 (0.8)	0/96	0/78	0/69
生殖系および乳房障害	0/132	1/97 (1.0)	1/78 (1.3)	0/68
良性前立腺肥大症	0/132	0/97	1/79 (1.3)	0/69
勃起不全	0/132	1/97 (1.0)	0/78	0/69
呼吸器、胸郭および縦隔障害	2/132 (1.5)	2/96 (2.1)	1/76 (1.3)	0/67
気管支拡張症	0/132	0/97	1/79 (1.3)	0/69
咳嗽	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
睡眠障害	0/63	0/1	0/0	2/132 (1.5)
ねごと	0/63	0/1	0/0	1/132 (0.8)
自殺念慮	0/63	0/1	0/0	1/132 (0.8)
自殺企図	0/62	0/1	0/0	1/132 (0.8)
腎および尿路障害	0/56	0/1	0/0	11/132 (8.3)
膀胱痙縮	0/62	0/1	0/0	1/132 (0.8)
膀胱結石	0/63	0/1	0/0	1/132 (0.8)
排尿困難	0/63	0/1	0/0	1/132 (0.8)
緊張性膀胱	0/62	0/1	0/0	1/132 (0.8)
切迫性尿失禁	0/61	0/1	0/0	3/132 (2.3)
尿失禁	0/61	0/1	0/0	3/132 (2.3)
尿路障害	0/62	0/1	0/0	1/132 (0.8)
生殖系および乳房障害	0/62	0/1	0/0	2/132 (1.5)
良性前立腺肥大症	0/63	0/1	0/0	1/132 (0.8)
勃起不全	0/62	0/1	0/0	1/132 (0.8)
呼吸器、胸郭および縦隔障害	1/60 (1.7)	0/1	0/0	6/132 (4.5)
気管支拡張症	0/62	0/1	0/0	1/132 (0.8)
咳嗽	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/132 (0.8)	0/96	0/78	0/70
労作性呼吸困難	0/132	1/97 (1.0)	0/78	0/69
口腔咽頭痛	0/132	1/97 (1.0)	0/78	0/69
皮膚および皮下組織障害	10/132 (7.6)	2/88 (2.3)	1/69 (1.4)	1/59 (1.7)
脱毛症	1/132 (0.8)	1/96 (1.0)	0/77	0/68
皮膚嚢腫	1/132 (0.8)	0/96	0/79	0/70
接触皮膚炎	1/132 (0.8)	0/96	0/78	1/69 (1.4)
おむつ皮膚炎	1/132 (0.8)	0/96	0/78	0/69
薬疹	1/132 (0.8)	0/96	0/78	0/69
皮膚乾燥	0/132	1/97 (1.0)	0/78	0/69
斑状出血	1/132 (0.8)	0/96	0/78	0/69
紅斑	1/132 (0.8)	0/96	0/78	0/69
爪の障害	0/132	0/97	1/79 (1.3)	0/69
そう痒症	0/132	0/97	1/79 (1.3)	1/69 (1.4)
発疹	1/132 (0.8)	0/96	1/78 (1.3)	0/68
そう痒性皮疹	1/132 (0.8)	0/97	1/79 (1.3)	0/69
皮膚潰瘍	1/132 (0.8)	0/96	0/78	0/69
蕁麻疹	0/132	1/97 (1.0)	1/78 (1.3)	0/68

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/63 (1.6)	0/1	0/0	2/132 (1.5)
労作性呼吸困難	0/62	0/1	0/0	1/132 (0.8)
口腔咽頭痛	0/62	0/1	0/0	1/132 (0.8)
皮膚および皮下組織障害	0/52	0/0	0/0	14/132 (10.6)
脱毛症	0/61	0/0	0/0	2/132 (1.5)
皮膚嚢腫	0/63	0/1	0/0	1/132 (0.8)
接触皮膚炎	0/61	0/1	0/0	2/132 (1.5)
おむつ皮膚炎	0/62	0/1	0/0	1/132 (0.8)
薬疹	0/62	0/1	0/0	1/132 (0.8)
皮膚乾燥	0/62	0/1	0/0	1/132 (0.8)
斑状出血	0/62	0/1	0/0	1/132 (0.8)
紅斑	0/62	0/1	0/0	1/132 (0.8)
爪の障害	0/62	0/1	0/0	1/132 (0.8)
そう痒症	0/61	0/1	0/0	2/132 (1.5)
発疹	0/62	0/1	0/0	2/132 (1.5)
そう痒性皮疹	0/62	0/1	0/0	2/132 (1.5)
皮膚潰瘍	0/62	0/1	0/0	1/132 (0.8)
蕁麻疹	0/62	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
社会環境	1/132 (0.8)	0/96	0/79	0/70
運動不能	1/132 (0.8)	0/96	0/79	0/70
血管障害	5/132 (3.8)	1/93 (1.1)	3/74 (4.1)	2/63 (3.2)
高血圧	2/132 (1.5)	0/95	1/77 (1.3)	0/67
高血圧クリーゼ	1/132 (0.8)	0/97	0/79	0/70
低血圧	1/132 (0.8)	0/96	0/78	1/69 (1.4)
起立性低血圧	1/132 (0.8)	1/96 (1.0)	2/77 (2.6)	2/67 (3.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
社会環境	0/63	0/1	0/0	1/132 (0.8)
運動不能	0/63	0/1	0/0	1/132 (0.8)
血管障害	0/55	0/1	0/0	11/132 (8.3)
高血圧	0/61	0/1	0/0	3/132 (2.3)
高血圧クリーゼ	0/63	0/1	0/0	1/132 (0.8)
低血圧	0/61	0/1	0/0	2/132 (1.5)
起立性低血圧	0/58	0/1	0/0	6/132 (4.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
Any adverse event	105/112 (93.8)	1/5 (20.0)	1/4 (25.0)	1/3 (33.3)
血液およびリンパ系障害	1/112 (0.9)	1/85 (1.2)	0/69	1/57 (1.8)
大球性貧血	0/112	0/85	0/70	1/58 (1.7)
凝血異常	1/112 (0.9)	0/85	0/70	0/58
縦隔リンパ節腫脹	0/112	1/85 (1.2)	0/69	0/57
心臓障害	4/112 (3.6)	1/83 (1.2)	2/68 (2.9)	0/54
心房細動	0/112	0/85	1/70 (1.4)	0/57
徐脈	1/112 (0.9)	0/84	0/69	0/57
心肺停止	0/112	1/85 (1.2)	0/70	0/58
冠動脈疾患	0/112	0/85	1/70 (1.4)	0/57
期外収縮	1/112 (0.9)	0/84	0/69	0/57
左室肥大	1/112 (0.9)	0/85	0/70	0/58
動悸	1/112 (0.9)	0/85	1/70 (1.4)	0/57
耳および迷路障害	4/112 (3.6)	0/82	0/67	0/55
乗物酔い	1/112 (0.9)	0/84	0/69	0/57
回転性めまい	2/112 (1.8)	0/84	0/69	0/57
頭位性回転性めまい	1/112 (0.9)	0/84	0/69	0/57
眼障害	3/112 (2.7)	4/83 (4.8)	1/65 (1.5)	0/54
白内障	1/112 (0.9)	0/84	1/69 (1.4)	0/56
複視	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
Any adverse event	0/2	0/0	0/0	108/112 (96.4)
血液およびリンパ系障害	0/49	0/0	0/0	3/112 (2.7)
大球性貧血	0/50	0/0	0/0	1/112 (0.9)
凝血異常	0/51	0/0	0/0	1/112 (0.9)
縦隔リンパ節腫脹	0/50	0/0	0/0	1/112 (0.9)
心臓障害	0/47	0/0	0/0	7/112 (6.3)
心房細動	0/50	0/0	0/0	1/112 (0.9)
徐脈	0/50	0/0	0/0	1/112 (0.9)
心肺停止	0/51	0/0	0/0	1/112 (0.9)
冠動脈疾患	0/50	0/0	0/0	1/112 (0.9)
期外収縮	0/50	0/0	0/0	1/112 (0.9)
左室肥大	0/51	0/0	0/0	1/112 (0.9)
動悸	0/50	0/0	0/0	2/112 (1.8)
耳および迷路障害	0/50	0/0	0/0	4/112 (3.6)
乗物酔い	0/50	0/0	0/0	1/112 (0.9)
回転性めまい	0/51	0/0	0/0	2/112 (1.8)
頭位性回転性めまい	0/51	0/0	0/0	1/112 (0.9)
眼障害	0/47	0/0	0/0	8/112 (7.1)
白内障	0/49	0/0	0/0	2/112 (1.8)
複視	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/112 (0.9)	1/84 (1.2)	1/68 (1.5)	0/56
緑内障	0/112	1/85 (1.2)	0/69	0/57
眼窩周囲痛	0/112	1/85 (1.2)	0/69	0/57
眼窩周囲腫脹	1/112 (0.9)	1/84 (1.2)	0/69	0/57
視野欠損	0/112	1/85 (1.2)	0/69	0/58
胃腸障害	23/112 (20.5)	1/68 (1.5)	3/56 (5.4)	2/44 (4.5)
腹部膨満	3/112 (2.7)	0/82	0/67	0/56
腹痛	0/112	0/85	0/70	1/58 (1.7)
上腹部痛	1/112 (0.9)	0/85	0/70	0/58
呼気臭	1/112 (0.9)	0/84	0/70	0/58
便秘	6/112 (5.4)	4/81 (4.9)	1/63 (1.6)	1/52 (1.9)
下痢	2/112 (1.8)	0/83	1/68 (1.5)	0/56
口内乾燥	5/112 (4.5)	0/80	0/67	0/56
嚥下障害	1/112 (0.9)	0/84	0/70	0/58
糞塊	1/112 (0.9)	0/85	0/70	0/58
排便回数増加	0/112	1/85 (1.2)	0/70	0/58
胃食道逆流性疾患	1/112 (0.9)	0/84	0/69	0/57
過敏性腸症候群	1/112 (0.9)	0/84	0/69	0/57
大腸ポリープ	0/112	0/85	0/70	1/58 (1.7)
悪心	8/112 (7.1)	0/82	2/67 (3.0)	1/53 (1.9)
口の錯感覚	1/112 (0.9)	0/84	0/69	0/57
直腸出血	0/112	0/85	1/70 (1.4)	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	0/49	0/0	0/0	3/112 (2.7)
緑内障	0/50	0/0	0/0	1/112 (0.9)
眼窩周囲痛	0/50	0/0	0/0	1/112 (0.9)
眼窩周囲腫脹	0/50	0/0	0/0	2/112 (1.8)
視野欠損	0/51	0/0	0/0	1/112 (0.9)
胃腸障害	0/36	0/0	0/0	29/112 (25.9)
腹部膨満	0/49	0/0	0/0	3/112 (2.7)
腹痛	0/50	0/0	0/0	1/112 (0.9)
上腹部痛	0/51	0/0	0/0	1/112 (0.9)
呼気臭	0/51	0/0	0/0	1/112 (0.9)
便秘	0/45	0/0	0/0	12/112 (10.7)
下痢	0/49	0/0	0/0	3/112 (2.7)
口内乾燥	0/49	0/0	0/0	5/112 (4.5)
嚥下障害	0/51	0/0	0/0	1/112 (0.9)
糞塊	0/51	0/0	0/0	1/112 (0.9)
排便回数増加	0/51	0/0	0/0	1/112 (0.9)
胃食道逆流性疾患	0/50	0/0	0/0	1/112 (0.9)
過敏性腸症候群	0/50	0/0	0/0	1/112 (0.9)
大腸ポリープ	0/50	0/0	0/0	1/112 (0.9)
悪心	0/45	0/0	0/0	11/112 (9.8)
口の錯感覚	0/50	0/0	0/0	1/112 (0.9)
直腸出血	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	1/112 (0.9)	0/84	0/69	0/57
嘔吐	2/112 (1.8)	0/85	1/70 (1.4)	0/57
一般・全身障害および投与部位の状態	92/112 (82.1)	3/13 (23.1)	1/7 (14.3)	0/5
投与部位内出血	0/112	0/85	0/70	1/58 (1.7)
投与部位漏出	2/112 (1.8)	0/83	0/68	0/57
カテーテル留置部位紅斑	1/112 (0.9)	0/84	0/69	0/58
カテーテル留置部位出血	1/112 (0.9)	0/84	0/69	0/57
カテーテル留置部位炎症	1/112 (0.9)	0/84	0/69	0/58
カテーテル留置部位刺激感	1/112 (0.9)	0/84	0/69	0/57
カテーテル留置部位浮腫	1/112 (0.9)	0/84	0/69	0/58
カテーテル留置部位疼痛	2/112 (1.8)	0/83	0/68	0/57
胸部不快感	0/112	1/85 (1.2)	0/69	0/57
胸痛	1/112 (0.9)	0/84	0/69	0/57
薬効欠如	0/112	1/85 (1.2)	0/69	0/57
薬剤離脱症候群	1/112 (0.9)	0/84	0/69	0/57
疲労	3/112 (2.7)	0/83	0/69	0/57
異常感	1/112 (0.9)	0/84	0/70	0/58
冷感	0/112	0/85	1/70 (1.4)	0/57
歩行障害	1/112 (0.9)	1/85 (1.2)	0/69	0/58
低体温	0/112	0/85	0/70	1/58 (1.7)
インフルエンザ様疾患	2/112 (1.8)	0/83	0/68	0/56

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	0/50	0/0	0/0	1/112 (0.9)
嘔吐	0/51	0/0	0/0	3/112 (2.7)
一般・全身障害および投与部位の状態	0/4	0/0	0/0	96/112 (85.7)
投与部位内出血	0/50	0/0	0/0	1/112 (0.9)
投与部位漏出	0/50	0/0	0/0	2/112 (1.8)
カテーテル留置部位紅斑	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位出血	0/50	0/0	0/0	1/112 (0.9)
カテーテル留置部位炎症	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位刺激感	0/50	0/0	0/0	1/112 (0.9)
カテーテル留置部位浮腫	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位疼痛	0/50	0/0	0/0	2/112 (1.8)
胸部不快感	0/50	0/0	0/0	1/112 (0.9)
胸痛	0/50	0/0	0/0	1/112 (0.9)
薬効欠如	0/50	0/0	0/0	1/112 (0.9)
薬剤離脱症候群	0/50	0/0	0/0	1/112 (0.9)
疲労	0/50	0/0	0/0	3/112 (2.7)
異常感	0/51	0/0	0/0	1/112 (0.9)
冷感	0/50	0/0	0/0	1/112 (0.9)
歩行障害	0/51	0/0	0/0	2/112 (1.8)
低体温	0/50	0/0	0/0	1/112 (0.9)
インフルエンザ様疾患	0/49	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	7/112 (6.3)	0/78	1/63 (1.6)	0/50
注入部位皮膚炎	0/112	1/85 (1.2)	0/69	1/58 (1.7)
注入部位分泌物	1/112 (0.9)	0/84	0/69	0/57
注入部位不快感	1/112 (0.9)	0/84	0/69	0/57
注入部位びらん	1/112 (0.9)	0/84	0/70	0/58
注入部位紅斑	53/112 (47.3)	4/42 (9.5)	2/32 (6.3)	1/24 (4.2)
注入部位皮膚剥脱	1/112 (0.9)	0/85	0/70	2/58 (3.4)
注入部位血管外漏出	11/112 (9.8)	0/78	0/64	1/53 (1.9)
注入部位血腫	7/112 (6.3)	1/79 (1.3)	0/64	0/55
注入部位出血	3/112 (2.7)	1/83 (1.2)	0/67	1/56 (1.8)
注入部位硬結	2/112 (1.8)	0/84	1/69 (1.4)	0/56
注入部位炎症	3/112 (2.7)	0/82	0/68	1/58 (1.7)
注入部位損傷	1/112 (0.9)	0/84	1/70 (1.4)	0/57
注入部位刺激感	3/112 (2.7)	1/82 (1.2)	0/66	0/56
注入部位腫瘤	3/112 (2.7)	0/82	0/67	0/55
注入部位壊死	1/112 (0.9)	0/84	0/70	0/58
注入部位結節	25/112 (22.3)	8/60 (13.3)	0/41	1/35 (2.9)
注入部位浮腫	20/112 (17.9)	4/73 (5.5)	0/55	3/46 (6.5)
注入部位疼痛	18/112 (16.1)	2/69 (2.9)	0/54	0/47
注入部位蒼白	1/112 (0.9)	0/84	0/69	0/57
注入部位丘疹	6/112 (5.4)	2/81 (2.5)	1/65 (1.5)	1/53 (1.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	0/43	0/0	0/0	8/112 (7.1)
注入部位皮膚炎	0/50	0/0	0/0	2/112 (1.8)
注入部位分泌物	0/50	0/0	0/0	1/112 (0.9)
注入部位不快感	0/50	0/0	0/0	1/112 (0.9)
注入部位びらん	0/51	0/0	0/0	1/112 (0.9)
注入部位紅斑	0/19	0/0	0/0	60/112 (53.6)
注入部位皮膚剥脱	0/49	0/0	0/0	3/112 (2.7)
注入部位血管外漏出	0/46	0/0	0/0	12/112 (10.7)
注入部位血腫	0/48	0/0	0/0	8/112 (7.1)
注入部位出血	0/49	0/0	0/0	5/112 (4.5)
注入部位硬結	0/49	0/0	0/0	3/112 (2.7)
注入部位炎症	2/50 (4.0)	0/0	0/0	6/112 (5.4)
注入部位損傷	0/50	0/0	0/0	2/112 (1.8)
注入部位刺激感	0/49	0/0	0/0	4/112 (3.6)
注入部位腫瘤	0/48	0/0	0/0	3/112 (2.7)
注入部位壊死	0/51	0/0	0/0	1/112 (0.9)
注入部位結節	0/29	0/0	0/0	34/112 (30.4)
注入部位浮腫	1/37 (2.7)	0/0	0/0	28/112 (25.0)
注入部位疼痛	0/41	0/0	0/0	20/112 (17.9)
注入部位蒼白	0/50	0/0	0/0	1/112 (0.9)
注入部位丘疹	1/46 (2.2)	0/0	0/0	11/112 (9.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位異常感覚	2/112 (1.8)	0/83	0/68	0/56
注入部位そう痒感	1/112 (0.9)	1/84 (1.2)	0/68	0/56
注入部位発疹	3/112 (2.7)	1/82 (1.2)	0/66	0/55
注入部位反応	14/112 (12.5)	1/76 (1.3)	1/62 (1.6)	2/51 (3.9)
注入部位痂皮	0/112	1/85 (1.2)	0/69	0/57
注入部位腫脹	2/112 (1.8)	0/83	0/69	0/57
注入部位小水疱	2/112 (1.8)	0/83	0/69	0/57
注入部位熱感	1/112 (0.9)	0/84	0/69	0/57
注射部位内出血	0/112	1/85 (1.2)	0/69	0/57
注射部位紅斑	7/112 (6.3)	0/79	1/65 (1.5)	0/52
注射部位漏出	1/112 (0.9)	0/84	0/69	0/57
注射部位血腫	1/112 (0.9)	0/85	0/70	0/58
注射部位出血	0/112	1/85 (1.2)	0/69	0/57
注射部位炎症	2/112 (1.8)	1/83 (1.2)	1/67 (1.5)	0/54
注射部位結節	4/112 (3.6)	0/81	2/67 (3.0)	0/53
注射部位浮腫	2/112 (1.8)	0/83	0/68	0/56
注射部位疼痛	5/112 (4.5)	1/81 (1.2)	0/67	0/55
注射部位丘疹	1/112 (0.9)	0/85	0/70	0/58
注射部位反応	1/112 (0.9)	0/84	0/69	0/57
注射部位腫脹	1/112 (0.9)	1/84 (1.2)	0/68	0/56
注射部位蕁麻疹	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位異常感覚	0/49	0/0	0/0	2/112 (1.8)
注入部位そう痒感	0/49	0/0	0/0	2/112 (1.8)
注入部位発疹	0/48	0/0	0/0	4/112 (3.6)
注入部位反応	0/42	0/0	0/0	18/112 (16.1)
注入部位痂皮	0/50	0/0	0/0	1/112 (0.9)
注入部位腫脹	0/50	0/0	0/0	2/112 (1.8)
注入部位小水疱	0/51	0/0	0/0	2/112 (1.8)
注入部位熱感	0/50	0/0	0/0	1/112 (0.9)
注射部位内出血	0/51	0/0	0/0	1/112 (0.9)
注射部位紅斑	0/47	0/0	0/0	8/112 (7.1)
注射部位漏出	0/51	0/0	0/0	1/112 (0.9)
注射部位血腫	0/51	0/0	0/0	1/112 (0.9)
注射部位出血	0/50	0/0	0/0	1/112 (0.9)
注射部位炎症	0/47	0/0	0/0	4/112 (3.6)
注射部位結節	0/47	0/0	0/0	6/112 (5.4)
注射部位浮腫	1/49 (2.0)	0/0	0/0	3/112 (2.7)
注射部位疼痛	0/48	0/0	0/0	6/112 (5.4)
注射部位丘疹	0/51	0/0	0/0	1/112 (0.9)
注射部位反応	0/50	0/0	0/0	1/112 (0.9)
注射部位腫脹	0/49	0/0	0/0	2/112 (1.8)
注射部位蕁麻疹	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
滴下投与部位熱傷	1/112 (0.9)	0/84	0/69	0/58
滴下投与部位痛	0/112	1/85 (1.2)	0/70	0/58
限局性浮腫	1/112 (0.9)	0/84	0/69	0/57
適用部位からの吸収不良	1/112 (0.9)	0/84	0/69	0/57
倦怠感	1/112 (0.9)	0/85	1/70 (1.4)	0/57
医療機器使用部位刺激感	2/112 (1.8)	0/84	0/69	0/57
医療機器使用部位発疹	2/112 (1.8)	0/83	0/68	0/56
非心臓性胸痛	2/112 (1.8)	0/84	0/69	0/57
末梢性浮腫	4/112 (3.6)	0/81	0/67	0/55
末梢腫脹	3/112 (2.7)	0/83	0/68	1/56 (1.8)
穿刺部位紅斑	2/112 (1.8)	1/84 (1.2)	0/68	0/56
穿刺部位浮腫	1/112 (0.9)	0/85	0/70	0/58
穿刺部位腫脹	1/112 (0.9)	0/85	0/70	0/58
発熱	1/112 (0.9)	1/85 (1.2)	0/69	0/57
肝胆道系障害	1/112 (0.9)	0/84	0/69	0/57
脂肪肝	1/112 (0.9)	0/84	0/69	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
滴下投与部位熱傷	0/51	0/0	0/0	1/112 (0.9)
滴下投与部位痛	0/51	0/0	0/0	1/112 (0.9)
限局性浮腫	0/50	0/0	0/0	1/112 (0.9)
適用部位からの吸収不良	0/50	0/0	0/0	1/112 (0.9)
倦怠感	0/50	0/0	0/0	2/112 (1.8)
医療機器使用部位刺激感	0/50	0/0	0/0	2/112 (1.8)
医療機器使用部位発疹	0/49	0/0	0/0	2/112 (1.8)
非心臓性胸痛	0/50	0/0	0/0	2/112 (1.8)
末梢性浮腫	0/48	0/0	0/0	4/112 (3.6)
末梢腫脹	0/48	0/0	0/0	4/112 (3.6)
穿刺部位紅斑	0/49	0/0	0/0	3/112 (2.7)
穿刺部位浮腫	0/51	0/0	0/0	1/112 (0.9)
穿刺部位腫脹	0/51	0/0	0/0	1/112 (0.9)
発熱	0/50	0/0	0/0	2/112 (1.8)
肝胆道系障害	0/50	0/0	0/0	1/112 (0.9)
脂肪肝	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
感染症および寄生虫症	43/112 (38.4)	5/50 (10.0)	5/36 (13.9)	3/26 (11.5)
無症候性COVID-19	0/112	0/85	1/70 (1.4)	0/57
細菌性疾患キャリアー	0/112	0/85	1/70 (1.4)	0/57
ウイルス性気管支炎	0/112	0/85	0/70	1/58 (1.7)
蜂巣炎	0/112	0/85	1/70 (1.4)	0/57
膀胱炎	1/112 (0.9)	0/85	0/70	0/58
爪の皮膚糸状菌症	0/112	1/85 (1.2)	0/69	0/57
胃腸炎	1/112 (0.9)	0/84	0/69	0/57
感染性皮膚潰瘍	1/112 (0.9)	0/84	0/69	0/57
インフルエンザ	0/112	0/85	0/70	1/58 (1.7)
注入部位膿瘍	9/112 (8.0)	3/79 (3.8)	1/63 (1.6)	0/54
注入部位蜂巣炎	21/112 (18.8)	0/68	3/58 (5.2)	3/45 (6.7)
注入部位感染	6/112 (5.4)	3/81 (3.7)	1/64 (1.6)	1/51 (2.0)
注入部位膿疱	1/112 (0.9)	0/84	0/70	0/58
注射部位蜂巣炎	2/112 (1.8)	1/83 (1.2)	0/67	0/55
上咽頭炎	4/112 (3.6)	1/81 (1.2)	0/65	0/54
爪真菌症	1/112 (0.9)	0/84	0/69	0/58
耳下腺膿瘍	0/112	0/85	1/70 (1.4)	0/57
肺炎	1/112 (0.9)	0/84	0/70	0/58
シュードモナス感染	1/112 (0.9)	0/84	0/69	0/58
気道感染	0/112	0/85	0/70	1/58 (1.7)
敗血症	0/112	0/85	1/70 (1.4)	0/58
ブドウ球菌感染	0/112	1/85 (1.2)	0/69	0/58
歯感染	0/112	0/85	0/70	1/58 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
感染症および寄生虫症	0/21	0/0	0/0	56/112 (50.0)
無症候性COVID-19	0/50	0/0	0/0	1/112 (0.9)
細菌性疾患キャリアー	0/50	0/0	0/0	1/112 (0.9)
ウイルス性気管支炎	0/50	0/0	0/0	1/112 (0.9)
蜂巣炎	0/50	0/0	0/0	1/112 (0.9)
膀胱炎	0/51	0/0	0/0	1/112 (0.9)
爪の皮膚糸状菌症	0/50	0/0	0/0	1/112 (0.9)
胃腸炎	0/50	0/0	0/0	1/112 (0.9)
感染性皮膚潰瘍	0/51	0/0	0/0	1/112 (0.9)
インフルエンザ	0/50	0/0	0/0	1/112 (0.9)
注入部位膿瘍	0/47	0/0	0/0	13/112 (11.6)
注入部位蜂巣炎	0/37	0/0	0/0	27/112 (24.1)
注入部位感染	0/44	0/0	0/0	11/112 (9.8)
注入部位膿疱	0/51	0/0	0/0	1/112 (0.9)
注射部位蜂巣炎	0/48	0/0	0/0	3/112 (2.7)
上咽頭炎	0/47	0/0	0/0	5/112 (4.5)
爪真菌症	0/51	0/0	0/0	1/112 (0.9)
耳下腺膿瘍	0/50	0/0	0/0	1/112 (0.9)
肺炎	0/51	0/0	0/0	1/112 (0.9)
シュードモナス感染	0/51	0/0	0/0	1/112 (0.9)
気道感染	0/51	0/0	0/0	1/112 (0.9)
敗血症	0/51	0/0	0/0	1/112 (0.9)
ブドウ球菌感染	0/51	0/0	0/0	1/112 (0.9)
歯感染	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	6/112 (5.4)	3/80 (3.8)	2/62 (3.2)	0/50
傷害、中毒および処置合併症	16/112 (14.3)	4/72 (5.6)	3/54 (5.6)	3/45 (6.7)
足関節部骨折	1/112 (0.9)	0/84	0/69	0/57
節足動物咬傷	1/112 (0.9)	0/84	0/69	0/58
骨挫傷	0/112	1/85 (1.2)	0/69	0/58
挫傷	2/112 (1.8)	3/83 (3.6)	1/66 (1.5)	0/55
眼挫傷	1/112 (0.9)	0/84	0/69	0/58
顔面損傷	0/112	1/85 (1.2)	0/69	0/57
顔面骨骨折	2/112 (1.8)	0/83	0/68	0/56
転倒	13/112 (11.6)	4/73 (5.5)	3/55 (5.5)	3/46 (6.5)
頭部損傷	0/112	1/85 (1.2)	1/69 (1.4)	0/56
関節脱臼	0/112	1/85 (1.2)	0/69	0/58
靭帯捻挫	0/112	1/85 (1.2)	0/69	0/57
腰椎骨折	1/112 (0.9)	0/85	0/70	0/58
過量投与	0/112	0/85	1/70 (1.4)	0/57
処置によるめまい	1/112 (0.9)	0/85	0/70	0/58
肋骨骨折	1/112 (0.9)	0/84	0/69	1/57 (1.8)
皮膚擦過傷	0/112	1/85 (1.2)	1/69 (1.4)	0/58
皮膚裂傷	2/112 (1.8)	2/83 (2.4)	1/66 (1.5)	1/54 (1.9)
硬膜下血腫	0/112	0/85	0/70	1/58 (1.7)
サンバーン	1/112 (0.9)	0/84	0/69	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	0/44	0/0	0/0	11/112 (9.8)
傷害、中毒および処置合併症	0/38	0/0	0/0	26/112 (23.2)
足関節部骨折	0/51	0/0	0/0	1/112 (0.9)
節足動物咬傷	0/51	0/0	0/0	1/112 (0.9)
骨挫傷	0/51	0/0	0/0	1/112 (0.9)
挫傷	0/48	0/0	0/0	6/112 (5.4)
眼挫傷	0/51	0/0	0/0	1/112 (0.9)
顔面損傷	0/50	0/0	0/0	1/112 (0.9)
顔面骨骨折	0/49	0/0	0/0	2/112 (1.8)
転倒	0/39	0/0	0/0	23/112 (20.5)
頭部損傷	0/49	0/0	0/0	2/112 (1.8)
関節脱臼	0/51	0/0	0/0	1/112 (0.9)
靭帯捻挫	0/50	0/0	0/0	1/112 (0.9)
腰椎骨折	0/51	0/0	0/0	1/112 (0.9)
過量投与	0/50	0/0	0/0	1/112 (0.9)
処置によるめまい	0/51	0/0	0/0	1/112 (0.9)
肋骨骨折	0/49	0/0	0/0	2/112 (1.8)
皮膚擦過傷	0/51	0/0	0/0	2/112 (1.8)
皮膚裂傷	0/46	0/0	0/0	6/112 (5.4)
硬膜下血腫	0/51	0/0	0/0	1/112 (0.9)
サンバーン	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/112	1/85 (1.2)	0/69	0/58
過少量投与	0/112	0/85	1/70 (1.4)	0/57
臨床検査	15/112 (13.4)	3/72 (4.2)	3/57 (5.3)	0/46
血中クレアチンホスホキナーゼ増加	1/112 (0.9)	0/84	0/69	0/57
血中クレアチニン減少	1/112 (0.9)	0/84	0/69	0/57
血中葉酸減少	0/112	0/85	0/70	1/58 (1.7)
血中ホモシステイン増加	1/112 (0.9)	0/84	1/69 (1.4)	0/56
血中リン減少	0/112	1/85 (1.2)	0/69	0/57
血圧上昇	1/112 (0.9)	0/85	0/70	0/58
C-反応性蛋白増加	1/112 (0.9)	0/84	0/69	0/57
ヘモグロビン減少	0/112	0/85	0/70	1/58 (1.7)
リンパ球数減少	1/112 (0.9)	0/85	0/70	0/58
単球数増加	1/112 (0.9)	0/85	0/70	0/58
好中球数増加	2/112 (1.8)	0/84	0/69	0/57
プロトロンビン時間延長	0/112	0/85	0/70	0/58
赤血球数減少	1/112 (0.9)	0/84	0/69	0/57
ビタミンB12減少	0/112	0/85	1/70 (1.4)	0/57
ビタミンB6減少	5/112 (4.5)	0/80	1/65 (1.5)	0/53
ビタミンD減少	1/112 (0.9)	0/84	0/69	0/58
体重減少	8/112 (7.1)	2/77 (2.6)	2/63 (3.2)	0/52

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/51	0/0	0/0	1/112 (0.9)
過少量投与	0/50	0/0	0/0	1/112 (0.9)
臨床検査	1/40 (2.5)	0/0	0/0	22/112 (19.6)
血中クレアチンホスホキナーゼ増加	0/50	0/0	0/0	1/112 (0.9)
血中クレアチニン減少	0/50	0/0	0/0	1/112 (0.9)
血中葉酸減少	1/50 (2.0)	0/0	0/0	2/112 (1.8)
血中ホモシステイン増加	0/49	0/0	0/0	2/112 (1.8)
血中リン減少	0/50	0/0	0/0	1/112 (0.9)
血圧上昇	0/51	0/0	0/0	1/112 (0.9)
C-反応性蛋白増加	0/50	0/0	0/0	1/112 (0.9)
ヘモグロビン減少	0/50	0/0	0/0	1/112 (0.9)
リンパ球数減少	0/51	0/0	0/0	1/112 (0.9)
単球数増加	0/51	0/0	0/0	1/112 (0.9)
好中球数増加	0/50	0/0	0/0	2/112 (1.8)
プロトロンビン時間延長	1/51 (2.0)	0/0	0/0	1/112 (0.9)
赤血球数減少	0/50	0/0	0/0	1/112 (0.9)
ビタミンB12減少	0/50	0/0	0/0	1/112 (0.9)
ビタミンB6減少	0/46	0/0	0/0	6/112 (5.4)
ビタミンD減少	0/51	0/0	0/0	1/112 (0.9)
体重減少	0/46	0/0	0/0	12/112 (10.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
臨床検査 (Cont.)				
白血球数増加	2/112 (1.8)	0/84	0/69	0/57
代謝および栄養障害	12/112 (10.7)	1/76 (1.3)	3/63 (4.8)	1/52 (1.9)
食欲減退	2/112 (1.8)	0/83	0/69	0/58
脱水	2/112 (1.8)	1/85 (1.2)	0/69	0/57
糖尿病	0/112	0/85	1/70 (1.4)	0/57
水分過負荷	1/112 (0.9)	0/84	0/70	0/58
体液貯留	0/112	0/85	0/70	1/58 (1.7)
葉酸欠乏	1/112 (0.9)	0/84	0/69	0/58
耐糖能障害	1/112 (0.9)	0/84	0/69	0/57
高コレステロール血症	0/112	1/85 (1.2)	0/69	0/57
高血糖	1/112 (0.9)	0/84	0/69	0/57
高ホモシステイン血症	0/112	0/85	1/70 (1.4)	0/58
低カリウム血症	2/112 (1.8)	0/85	0/70	1/58 (1.7)
栄養障害	1/112 (0.9)	0/85	0/70	0/58
ビタミンB群欠乏	0/112	0/85	1/70 (1.4)	0/57
ビタミンB12欠乏	0/112	0/85	1/70 (1.4)	0/58
ビタミンB6欠乏	4/112 (3.6)	0/81	1/67 (1.5)	0/56
筋骨格系および結合組織障害	13/112 (11.6)	3/74 (4.1)	4/59 (6.8)	0/46
関節痛	2/112 (1.8)	1/83 (1.2)	0/68	0/56
反応性関節炎	1/112 (0.9)	0/84	0/69	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
臨床検査 (Cont.)				
白血球数増加	0/50	0/0	0/0	2/112 (1.8)
代謝および栄養障害	0/45	0/0	0/0	17/112 (15.2)
食欲減退	0/51	0/0	0/0	2/112 (1.8)
脱水	0/50	0/0	0/0	3/112 (2.7)
糖尿病	0/51	0/0	0/0	1/112 (0.9)
水分過負荷	0/51	0/0	0/0	1/112 (0.9)
体液貯留	0/50	0/0	0/0	1/112 (0.9)
葉酸欠乏	0/51	0/0	0/0	1/112 (0.9)
耐糖能障害	0/50	0/0	0/0	1/112 (0.9)
高コレステロール血症	0/50	0/0	0/0	1/112 (0.9)
高血糖	0/50	0/0	0/0	1/112 (0.9)
高ホモシステイン血症	0/51	0/0	0/0	1/112 (0.9)
低カリウム血症	0/51	0/0	0/0	3/112 (2.7)
栄養障害	0/51	0/0	0/0	1/112 (0.9)
ビタミンB群欠乏	0/50	0/0	0/0	1/112 (0.9)
ビタミンB12欠乏	1/51 (2.0)	0/0	0/0	2/112 (1.8)
ビタミンB6欠乏	0/49	0/0	0/0	5/112 (4.5)
筋骨格系および結合組織障害	0/40	0/0	0/0	20/112 (17.9)
関節痛	0/49	0/0	0/0	3/112 (2.7)
反応性関節炎	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
背部痛	2/112 (1.8)	1/83 (1.2)	1/67 (1.5)	0/55
骨痛	0/112	0/85	1/70 (1.4)	0/57
外骨腫	0/112	1/85 (1.2)	0/69	0/58
椎間関節症候群	0/112	1/85 (1.2)	0/69	0/58
椎間板突出	0/112	1/85 (1.2)	0/69	0/58
関節滲出液	0/112	1/85 (1.2)	0/69	0/58
関節腫脹	1/112 (0.9)	0/84	0/69	0/57
四肢不快感	0/112	0/85	1/70 (1.4)	0/58
筋萎縮	0/112	1/85 (1.2)	0/69	0/58
筋痙縮	2/112 (1.8)	1/83 (1.2)	0/69	0/57
筋力低下	0/112	0/85	1/70 (1.4)	0/57
筋骨格硬直	1/112 (0.9)	0/85	0/70	0/58
筋肉痛	1/112 (0.9)	0/85	0/70	0/58
骨炎	1/112 (0.9)	0/85	0/70	0/58
変形性関節症	0/112	2/85 (2.4)	1/68 (1.5)	0/56
四肢痛	3/112 (2.7)	0/82	0/67	0/56
関節周囲炎	0/112	0/85	1/70 (1.4)	0/57
姿勢異常	1/112 (0.9)	0/84	0/69	0/58
肩回旋筋腱板症候群	0/112	1/85 (1.2)	0/69	0/58
腱障害	0/112	1/85 (1.2)	0/69	0/58
斜頚	1/112 (0.9)	0/84	0/69	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
背部痛	0/48	0/0	0/0	4/112 (3.6)
骨痛	0/50	0/0	0/0	1/112 (0.9)
外骨腫	0/51	0/0	0/0	1/112 (0.9)
椎間関節症候群	0/51	0/0	0/0	1/112 (0.9)
椎間板突出	0/51	0/0	0/0	1/112 (0.9)
関節滲出液	1/51 (2.0)	0/0	0/0	2/112 (1.8)
関節腫脹	0/50	0/0	0/0	1/112 (0.9)
四肢不快感	0/51	0/0	0/0	1/112 (0.9)
筋萎縮	0/51	0/0	0/0	1/112 (0.9)
筋痙縮	0/50	0/0	0/0	3/112 (2.7)
筋力低下	0/51	0/0	0/0	1/112 (0.9)
筋骨格硬直	0/51	0/0	0/0	1/112 (0.9)
筋肉痛	0/51	0/0	0/0	1/112 (0.9)
骨炎	0/51	0/0	0/0	1/112 (0.9)
変形性関節症	1/49 (2.0)	0/0	0/0	4/112 (3.6)
四肢痛	0/49	0/0	0/0	3/112 (2.7)
関節周囲炎	0/50	0/0	0/0	1/112 (0.9)
姿勢異常	0/51	0/0	0/0	1/112 (0.9)
肩回旋筋腱板症候群	0/51	0/0	0/0	1/112 (0.9)
腱障害	0/51	0/0	0/0	1/112 (0.9)
斜頸	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
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）	1/112 (0.9)	2/84 (2.4)	1/67 (1.5)	0/55
基底細胞癌	0/112	2/85 (2.4)	0/68	0/57
脂漏性角化症	0/112	0/85	1/70 (1.4)	0/57
皮膚有棘細胞癌	1/112 (0.9)	0/84	0/69	0/57
神経系障害	32/112 (28.6)	7/62 (11.3)	4/46 (8.7)	4/38 (10.5)
失語症	0/112	0/85	1/70 (1.4)	0/57
平衡障害	1/112 (0.9)	0/84	1/69 (1.4)	1/57 (1.8)
運動緩慢	0/112	0/85	1/70 (1.4)	0/57
手根管症候群	0/112	0/85	1/70 (1.4)	0/57
大脳萎縮	0/112	0/85	0/70	1/58 (1.7)
脳出血	0/112	1/85 (1.2)	0/69	0/57
脳圧排効果	0/112	0/85	0/70	1/58 (1.7)
脳血管発作	0/112	1/85 (1.2)	0/70	0/58
認知障害	0/112	1/85 (1.2)	1/70 (1.4)	0/57
注意力障害	1/112 (0.9)	0/84	0/70	0/58
浮動性めまい	10/112 (8.9)	0/75	0/60	0/50
構語障害	1/112 (0.9)	1/85 (1.2)	1/69 (1.4)	0/56
味覚不全	0/112	0/85	0/70	1/58 (1.7)
ジスキネジア	3/112 (2.7)	1/83 (1.2)	1/67 (1.5)	1/54 (1.9)
ジストニア	2/112 (1.8)	2/84 (2.4)	0/67	1/55 (1.8)
脳症	1/112 (0.9)	0/85	0/70	0/58
てんかん	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
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）	0/49	0/0	0/0	4/112 (3.6)
基底細胞癌	0/50	0/0	0/0	2/112 (1.8)
脂漏性角化症	0/51	0/0	0/0	1/112 (0.9)
皮膚有棘細胞癌	0/50	0/0	0/0	1/112 (0.9)
神経系障害	1/30 (3.3)	0/0	0/0	48/112 (42.9)
失語症	0/50	0/0	0/0	1/112 (0.9)
平衡障害	1/49 (2.0)	0/0	0/0	4/112 (3.6)
運動緩慢	0/50	0/0	0/0	1/112 (0.9)
手根管症候群	0/50	0/0	0/0	1/112 (0.9)
大脳萎縮	0/50	0/0	0/0	1/112 (0.9)
脳出血	0/50	0/0	0/0	1/112 (0.9)
脳圧排効果	0/51	0/0	0/0	1/112 (0.9)
脳血管発作	0/51	0/0	0/0	1/112 (0.9)
認知障害	0/50	0/0	0/0	2/112 (1.8)
注意力障害	0/51	0/0	0/0	1/112 (0.9)
浮動性めまい	0/44	0/0	0/0	10/112 (8.9)
構語障害	0/50	0/0	0/0	3/112 (2.7)
味覚不全	0/50	0/0	0/0	1/112 (0.9)
ジスキネジア	0/46	0/0	0/0	6/112 (5.4)
ジストニア	0/47	0/0	0/0	5/112 (4.5)
脳症	0/51	0/0	0/0	1/112 (0.9)
てんかん	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
本態性振戦	1/112 (0.9)	0/84	0/69	0/58
全身性強直性間代性発作	0/112	0/85	0/70	1/58 (1.7)
頭痛	4/112 (3.6)	2/81 (2.5)	0/65	1/53 (1.9)
片側感覚消失	1/112 (0.9)	0/84	0/69	0/58
不全片麻痺	1/112 (0.9)	0/84	0/69	0/58
感覚鈍麻	0/112	0/85	2/70 (2.9)	0/56
反射減弱	0/112	1/85 (1.2)	0/69	0/57
嗜眠	0/112	0/85	1/70 (1.4)	0/58
意識消失	0/112	1/85 (1.2)	0/69	0/57
腰仙部神経根障害	1/112 (0.9)	0/84	0/69	0/57
記憶障害	1/112 (0.9)	0/84	1/70 (1.4)	0/57
代謝性脳症	1/112 (0.9)	0/85	0/70	0/58
神経痛	0/112	1/85 (1.2)	0/69	0/58
末梢性ニューロパチー	1/112 (0.9)	0/84	0/69	0/58
オンオフ現象	4/112 (3.6)	0/82	0/68	0/56
錯感覚	2/112 (1.8)	0/84	0/69	1/57 (1.8)
パーキンソン病	3/112 (2.7)	1/84 (1.2)	1/68 (1.5)	0/55
パーキンソニズム	2/112 (1.8)	1/85 (1.2)	0/69	0/57
側反弓	1/112 (0.9)	0/84	1/69 (1.4)	0/57
多発ニューロパチー	1/112 (0.9)	0/84	0/69	1/58 (1.7)
失神寸前の状態	0/112	1/85 (1.2)	0/69	0/58
心因性発作	1/112 (0.9)	0/84	0/69	0/57
精神運動亢進	1/112 (0.9)	0/84	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
本態性振戦	0/51	0/0	0/0	1/112 (0.9)
全身性強直性間代性発作	0/51	0/0	0/0	1/112 (0.9)
頭痛	0/45	0/0	0/0	7/112 (6.3)
片側感覚消失	0/51	0/0	0/0	1/112 (0.9)
不全片麻痺	0/51	0/0	0/0	1/112 (0.9)
感覚鈍麻	0/49	0/0	0/0	2/112 (1.8)
反射減弱	0/51	0/0	0/0	1/112 (0.9)
嗜眠	0/51	0/0	0/0	1/112 (0.9)
意識消失	0/50	0/0	0/0	1/112 (0.9)
腰仙部神経根障害	0/51	0/0	0/0	1/112 (0.9)
記憶障害	0/50	0/0	0/0	2/112 (1.8)
代謝性脳症	0/51	0/0	0/0	1/112 (0.9)
神経痛	0/51	0/0	0/0	1/112 (0.9)
末梢性ニューロパチー	0/51	0/0	0/0	1/112 (0.9)
オンオフ現象	0/49	0/0	0/0	4/112 (3.6)
錯感覚	0/49	0/0	0/0	3/112 (2.7)
パーキンソン病	0/48	0/0	0/0	5/112 (4.5)
パーキンソニズム	0/50	0/0	0/0	3/112 (2.7)
側反弓	0/50	0/0	0/0	2/112 (1.8)
多発ニューロパチー	0/50	0/0	0/0	2/112 (1.8)
失神寸前の状態	0/51	0/0	0/0	1/112 (0.9)
心因性発作	0/50	0/0	0/0	1/112 (0.9)
精神運動亢進	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
反射異常	0/112	0/85	0/70	1/58 (1.7)
安静時振戦	1/112 (0.9)	0/84	0/69	0/58
坐骨神経痛	2/112 (1.8)	0/83	1/68 (1.5)	0/57
痙攣発作	0/112	1/85 (1.2)	0/69	0/57
感覚障害	1/112 (0.9)	0/84	0/69	0/57
感覚消失	0/112	1/85 (1.2)	0/69	0/58
傾眠	2/112 (1.8)	0/84	1/69 (1.4)	0/56
失神	0/112	1/85 (1.2)	0/69	1/57 (1.8)
振戦	2/112 (1.8)	0/83	0/68	0/56
製品の問題	1/112 (0.9)	0/85	0/70	0/58
医療機器機能不良	1/112 (0.9)	0/85	0/70	0/58
精神障害	45/112 (40.2)	5/51 (9.8)	2/40 (5.0)	2/32 (6.3)
異常な夢	1/112 (0.9)	0/84	0/69	0/57
感情不安定	0/112	1/85 (1.2)	0/69	0/57
激越	1/112 (0.9)	0/85	0/70	0/58
不安	15/112 (13.4)	0/73	3/60 (5.0)	0/47
不安障害	0/112	0/85	0/70	1/58 (1.7)
強迫行為	1/112 (0.9)	0/84	0/69	0/57
錯乱状態	1/112 (0.9)	1/85 (1.2)	1/69 (1.4)	1/56 (1.8)
譫妄	3/112 (2.7)	1/83 (1.2)	0/68	0/57
妄想	1/112 (0.9)	1/84 (1.2)	0/68	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
反射異常	0/50	0/0	0/0	1/112 (0.9)
安静時振戦	0/51	0/0	0/0	1/112 (0.9)
坐骨神経痛	0/50	0/0	0/0	3/112 (2.7)
痙攣発作	0/50	0/0	0/0	1/112 (0.9)
感覚障害	0/50	0/0	0/0	1/112 (0.9)
感覚消失	0/51	0/0	0/0	1/112 (0.9)
傾眠	0/50	0/0	0/0	3/112 (2.7)
失神	1/49 (2.0)	0/0	0/0	3/112 (2.7)
振戦	0/49	0/0	0/0	2/112 (1.8)
製品の問題	0/51	0/0	0/0	1/112 (0.9)
医療機器機能不良	0/51	0/0	0/0	1/112 (0.9)
精神障害	0/26	0/0	0/0	54/112 (48.2)
異常な夢	0/50	0/0	0/0	1/112 (0.9)
感情不安定	0/50	0/0	0/0	1/112 (0.9)
激越	0/51	0/0	0/0	1/112 (0.9)
不安	0/40	0/0	0/0	18/112 (16.1)
不安障害	0/50	0/0	0/0	1/112 (0.9)
強迫行為	0/50	0/0	0/0	1/112 (0.9)
錯乱状態	0/49	0/0	0/0	4/112 (3.6)
譫妄	0/51	0/0	0/0	4/112 (3.6)
妄想	0/51	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
妄想性障害、詳細不明	1/112 (0.9)	0/84	0/69	0/58
抑うつ気分	1/112 (0.9)	0/84	0/69	0/57
うつ病	0/112	1/85 (1.2)	0/69	1/57 (1.8)
ディスフェミア	0/112	0/85	1/70 (1.4)	0/57
情動障害	1/112 (0.9)	0/84	0/69	0/57
注射恐怖	0/112	1/85 (1.2)	0/70	0/58
幻覚	16/112 (14.3)	4/77 (5.2)	1/59 (1.7)	0/49
幻聴	1/112 (0.9)	2/84 (2.4)	0/67	0/58
幻嗅	1/112 (0.9)	0/84	0/70	0/58
幻視	4/112 (3.6)	1/81 (1.2)	0/66	0/55
衝動制御障害	2/112 (1.8)	1/83 (1.2)	0/68	1/58 (1.7)
衝動行為	0/112	0/85	0/70	1/58 (1.7)
不眠症	6/112 (5.4)	2/79 (2.5)	0/63	1/52 (1.9)
易刺激性	1/112 (0.9)	0/84	0/70	0/58
躁病	1/112 (0.9)	0/84	0/69	0/58
気分動揺	0/112	1/85 (1.2)	0/70	0/58
悪夢	1/112 (0.9)	0/85	0/70	0/58
パニック発作	3/112 (2.7)	0/83	0/68	0/56
パニック反応	0/112	0/85	1/70 (1.4)	0/57
処置に対する不安	0/112	1/85 (1.2)	0/70	0/58
精神病性障害	0/112	1/85 (1.2)	1/69 (1.4)	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
妄想性障害、詳細不明	0/51	0/0	0/0	1/112 (0.9)
抑うつ気分	0/50	0/0	0/0	1/112 (0.9)
うつ病	0/49	0/0	0/0	2/112 (1.8)
ディスフェミア	0/50	0/0	0/0	1/112 (0.9)
情動障害	0/50	0/0	0/0	1/112 (0.9)
注射恐怖	0/51	0/0	0/0	1/112 (0.9)
幻覚	0/45	0/0	0/0	21/112 (18.8)
幻聴	0/51	0/0	0/0	3/112 (2.7)
幻嗅	0/51	0/0	0/0	1/112 (0.9)
幻視	0/48	0/0	0/0	5/112 (4.5)
衝動制御障害	0/50	0/0	0/0	4/112 (3.6)
衝動行為	0/50	0/0	0/0	1/112 (0.9)
不眠症	0/45	0/0	0/0	9/112 (8.0)
易刺激性	0/51	0/0	0/0	1/112 (0.9)
躁病	0/51	0/0	0/0	1/112 (0.9)
気分動揺	0/51	0/0	0/0	1/112 (0.9)
悪夢	0/51	0/0	0/0	1/112 (0.9)
パニック発作	0/49	0/0	0/0	3/112 (2.7)
パニック反応	0/50	0/0	0/0	1/112 (0.9)
処置に対する不安	0/51	0/0	0/0	1/112 (0.9)
精神病性障害	0/50	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
レム睡眠行動障害	1/112 (0.9)	0/84	0/69	0/57
睡眠障害	1/112 (0.9)	0/84	0/69	0/57
ねごと	1/112 (0.9)	0/84	0/70	0/58
常同症	0/112	0/85	0/70	1/58 (1.7)
ストレス	1/112 (0.9)	0/84	0/69	0/57
自殺念慮	2/112 (1.8)	0/83	0/69	0/58
腎および尿路障害	3/112 (2.7)	1/83 (1.2)	2/67 (3.0)	1/55 (1.8)
排尿困難	1/112 (0.9)	0/84	0/69	1/57 (1.8)
夜間頻尿	0/112	1/85 (1.2)	0/69	0/58
多尿	1/112 (0.9)	0/84	0/69	0/57
腎機能障害	0/112	0/85	1/70 (1.4)	0/58
尿管結石症	1/112 (0.9)	0/85	0/70	0/58
尿失禁	0/112	0/85	1/70 (1.4)	1/57 (1.8)
尿閉	0/112	0/85	1/70 (1.4)	2/57 (3.5)
尿異常	1/112 (0.9)	0/84	0/69	0/57
尿臭異常	0/112	0/85	1/70 (1.4)	0/57
生殖系および乳房障害	3/112 (2.7)	1/83 (1.2)	0/67	0/55
勃起不全	1/112 (0.9)	0/85	0/70	0/58
ペイロニー病	1/112 (0.9)	0/84	0/69	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
レム睡眠行動障害	0/50	0/0	0/0	1/112 (0.9)
睡眠障害	0/50	0/0	0/0	1/112 (0.9)
ねごと	0/51	0/0	0/0	1/112 (0.9)
常同症	0/50	0/0	0/0	1/112 (0.9)
ストレス	0/51	0/0	0/0	1/112 (0.9)
自殺念慮	0/51	0/0	0/0	2/112 (1.8)
腎および尿路障害	0/47	0/0	0/0	7/112 (6.3)
排尿困難	0/49	0/0	0/0	2/112 (1.8)
夜間頻尿	0/51	0/0	0/0	1/112 (0.9)
多尿	0/50	0/0	0/0	1/112 (0.9)
腎機能障害	0/51	0/0	0/0	1/112 (0.9)
尿管結石症	0/51	0/0	0/0	1/112 (0.9)
尿失禁	0/49	0/0	0/0	2/112 (1.8)
尿閉	0/48	0/0	0/0	3/112 (2.7)
尿異常	0/50	0/0	0/0	1/112 (0.9)
尿臭異常	0/50	0/0	0/0	1/112 (0.9)
生殖系および乳房障害	0/48	0/0	0/0	4/112 (3.6)
勃起不全	0/51	0/0	0/0	1/112 (0.9)
ペイロニー病	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
生殖系および乳房障害(Cont.)				
前立腺腫大	0/112	1/85 (1.2)	0/69	0/57
膣脱	1/112 (0.9)	0/84	0/69	0/57
呼吸器、胸郭および縦隔障害	13/112 (11.6)	3/74 (4.1)	1/60 (1.7)	2/48 (4.2)
急性呼吸不全	1/112 (0.9)	0/84	0/70	0/58
咳嗽	2/112 (1.8)	0/83	0/69	0/57
発声障害	1/112 (0.9)	0/84	1/69 (1.4)	0/56
呼吸困難	4/112 (3.6)	2/81 (2.5)	0/66	0/55
鼻出血	0/112	0/85	1/70 (1.4)	0/57
過換気	2/112 (1.8)	0/84	0/69	0/57
口腔咽頭痛	1/112 (0.9)	0/84	0/69	0/57
誤嚥性肺炎	0/112	0/85	0/70	1/58 (1.7)
湿性咳嗽	0/112	0/85	1/70 (1.4)	0/57
肺塞栓症	1/112 (0.9)	0/85	0/70	1/58 (1.7)
ラ音	0/112	1/85 (1.2)	0/69	0/57
鼻痛	1/112 (0.9)	0/84	0/69	0/57
鼻漏	2/112 (1.8)	0/83	0/68	0/56
咽喉刺激感	1/112 (0.9)	0/84	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
生殖系および乳房障害(Cont.)				
前立腺腫大	0/50	0/0	0/0	1/112 (0.9)
膣脱	0/50	0/0	0/0	1/112 (0.9)
呼吸器、胸郭および縦隔障害	0/41	0/0	0/0	19/112 (17.0)
急性呼吸不全	0/51	0/0	0/0	1/112 (0.9)
咳嗽	0/50	0/0	0/0	2/112 (1.8)
発声障害	0/49	0/0	0/0	2/112 (1.8)
呼吸困難	0/48	0/0	0/0	6/112 (5.4)
鼻出血	0/50	0/0	0/0	1/112 (0.9)
過換気	0/50	0/0	0/0	2/112 (1.8)
口腔咽頭痛	0/50	0/0	0/0	1/112 (0.9)
誤嚥性肺炎	0/51	0/0	0/0	1/112 (0.9)
湿性咳嗽	0/50	0/0	0/0	1/112 (0.9)
肺塞栓症	0/50	0/0	0/0	2/112 (1.8)
ラ音	0/51	0/0	0/0	1/112 (0.9)
鼻痛	0/50	0/0	0/0	1/112 (0.9)
鼻漏	0/49	0/0	0/0	2/112 (1.8)
咽喉刺激感	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N_eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
皮膚および皮下組織障害	12/112 (10.7)	0/75	1/63 (1.6)	1/51 (2.0)
褥瘡性潰瘍	1/112 (0.9)	0/84	0/69	0/57
皮膚嚢腫	0/112	0/85	0/70	1/58 (1.7)
皮膚炎	1/112 (0.9)	0/84	0/69	0/57
皮膚乾燥	1/112 (0.9)	0/85	0/70	0/58
紅斑	3/112 (2.7)	0/82	0/69	0/57
脂肪織炎	0/112	0/85	1/70 (1.4)	0/57
丘疹	2/112 (1.8)	0/83	0/68	0/57
光線過敏性反応	1/112 (0.9)	0/84	0/70	0/58
そう痒症	1/112 (0.9)	0/84	0/69	0/57
乾癬	0/112	1/85 (1.2)	0/69	0/58
発疹	1/112 (0.9)	0/84	0/69	0/57
紅斑性皮疹	1/112 (0.9)	0/84	0/69	0/57
そう痒性皮疹	1/112 (0.9)	0/84	0/69	0/57
皮膚刺激	1/112 (0.9)	0/85	0/70	0/58
皮膚病変	1/112 (0.9)	0/84	0/69	0/58
皮膚潰瘍	1/112 (0.9)	0/84	0/69	0/57
外科および内科処置	0/112	1/85 (1.2)	0/69	0/57
抜歯	0/112	1/85 (1.2)	0/69	0/57

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
皮膚および皮下組織障害	0/44	0/0	0/0	14/112 (12.5)
褥瘡性潰瘍	0/50	0/0	0/0	1/112 (0.9)
皮膚嚢腫	0/50	0/0	0/0	1/112 (0.9)
皮膚炎	0/50	0/0	0/0	1/112 (0.9)
皮膚乾燥	0/51	0/0	0/0	1/112 (0.9)
紅斑	0/50	0/0	0/0	3/112 (2.7)
脂肪織炎	0/50	0/0	0/0	1/112 (0.9)
丘疹	0/50	0/0	0/0	2/112 (1.8)
光線過敏性反応	0/51	0/0	0/0	1/112 (0.9)
そう痒症	0/50	0/0	0/0	1/112 (0.9)
乾癬	0/51	0/0	0/0	1/112 (0.9)
発疹	0/50	0/0	0/0	1/112 (0.9)
紅斑性皮疹	0/50	0/0	0/0	1/112 (0.9)
そう痒性皮疹	0/50	0/0	0/0	1/112 (0.9)
皮膚刺激	0/51	0/0	0/0	1/112 (0.9)
皮膚病変	0/51	0/0	0/0	1/112 (0.9)
皮膚潰瘍	0/51	0/0	0/0	1/112 (0.9)
外科および内科処置	0/50	0/0	0/0	1/112 (0.9)
抜歯	0/50	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
血管障害	8/112 (7.1)	2/80 (2.5)	2/63 (3.2)	1/50 (2.0)
深部静脈血栓症	1/112 (0.9)	0/85	0/70	0/58
血腫	0/112	0/85	0/70	1/58 (1.7)
出血	0/112	1/85 (1.2)	0/69	0/57
ほてり	1/112 (0.9)	0/85	0/70	0/58
高血圧	2/112 (1.8)	0/84	0/69	1/57 (1.8)
低血圧	2/112 (1.8)	0/83	1/68 (1.5)	0/55
不安定血圧	1/112 (0.9)	0/85	0/70	0/58
起立性高血圧	0/112	0/85	0/70	0/58
起立性低血圧	4/112 (3.6)	1/81 (1.2)	1/65 (1.5)	0/53

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.1

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
血管障害	2/42 (4.8)	0/0	0/0	15/112 (13.4)
深部静脈血栓症	0/51	0/0	0/0	1/112 (0.9)
血腫	0/50	0/0	0/0	1/112 (0.9)
出血	0/50	0/0	0/0	1/112 (0.9)
ほてり	0/51	0/0	0/0	1/112 (0.9)
高血圧	0/49	0/0	0/0	3/112 (2.7)
低血圧	1/48 (2.1)	0/0	0/0	4/112 (3.6)
不安定血圧	0/51	0/0	0/0	1/112 (0.9)
起立性高血圧	1/51 (2.0)	0/0	0/0	1/112 (0.9)
起立性低血圧	0/46	0/0	0/0	6/112 (5.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval and did not experience an event within a previous interval.
n = Number of subjects included in the N eval who a) had the first occurrence of the event in that time interval, or b) discontinued treatment during the time interval and had the first occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

表41　有害事象の90日間ごとの有病割合の推移（安全性解析対象集団）：M15-741試験

[redacted]20[redacted] 04:29 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3 1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N eval (%)	 Days 91 to 180 (N=182) n/N eval (%)	 Days 181 to 270 (N=149) n/N eval (%)	 Days 271 to 360 (N=128) n/N eval (%)
Total (Any Dose)				
Any adverse event	225/244 (92.2)	158/182 (86.8)	127/149 (85.2)	109/128 (85.2)
血液およびリンパ系障害	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	2/128 (1.6)
大球性貧血	0/244	0/182	0/149	1/128 (0.8)
凝血異常	1/244 (0.4)	0/182	0/149	0/128
リンパ節症	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
縦隔リンパ節腫脹	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
心臓障害	5/244 (2.0)	4/182 (2.2)	3/149 (2.0)	5/128 (3.9)
急性心筋梗塞	0/244	0/182	0/149	1/128 (0.8)
狭心症	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
心房細動	0/244	0/182	1/149 (0.7)	1/128 (0.8)
徐脈	1/244 (0.4)	0/182	0/149	0/128
心停止	0/244	0/182	0/149	1/128 (0.8)
心肺停止	0/244	1/182 (0.5)	0/149	0/128
冠動脈疾患	0/244	0/182	1/149 (0.7)	2/128 (1.6)
冠動脈狭窄	0/244	0/182	0/149	1/128 (0.8)
期外収縮	1/244 (0.4)	1/182 (0.5)	0/149	0/128
左室肥大	1/244 (0.4)	0/182	0/149	0/128
心筋梗塞	1/244 (0.4)	1/182 (0.5)	0/149	0/128
動悸	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
Any adverse event	90/114 (78.9)	1/1 (100)	0/0	230/244 (94.3)
血液およびリンパ系障害	2/114 (1.8)	0/1	0/0	4/244 (1.6)
大球性貧血	1/114 (0.9)	0/1	0/0	1/244 (0.4)
凝血異常	0/114	0/1	0/0	1/244 (0.4)
リンパ節症	0/114	0/1	0/0	1/244 (0.4)
縦隔リンパ節腫脹	1/114 (0.9)	0/1	0/0	1/244 (0.4)
心臓障害	4/114 (3.5)	0/1	0/0	11/244 (4.5)
急性心筋梗塞	0/114	0/1	0/0	1/244 (0.4)
狭心症	1/114 (0.9)	0/1	0/0	1/244 (0.4)
心房細動	1/114 (0.9)	0/1	0/0	1/244 (0.4)
徐脈	0/114	0/1	0/0	1/244 (0.4)
心停止	0/114	0/1	0/0	1/244 (0.4)
心肺停止	0/114	0/1	0/0	1/244 (0.4)
冠動脈疾患	2/114 (1.8)	0/1	0/0	2/244 (0.8)
冠動脈狭窄	0/114	0/1	0/0	1/244 (0.4)
期外収縮	0/114	0/1	0/0	1/244 (0.4)
左室肥大	0/114	0/1	0/0	1/244 (0.4)
心筋梗塞	0/114	0/1	0/0	1/244 (0.4)
動悸	1/114 (0.9)	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
耳および迷路障害	6/244 (2.5)	3/182 (1.6)	2/149 (1.3)	2/128 (1.6)
感音性難聴	0/244	0/182	1/149 (0.7)	1/128 (0.8)
乗物酔い	1/244 (0.4)	0/182	0/149	0/128
回転性めまい	4/244 (1.6)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
頭位性回転性めまい	1/244 (0.4)	1/182 (0.5)	0/149	0/128
眼障害	5/244 (2.0)	8/182 (4.4)	9/149 (6.0)	7/128 (5.5)
白内障	1/244 (0.4)	1/182 (0.5)	3/149 (2.0)	3/128 (2.3)
複視	3/244 (1.2)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
ドライアイ	2/244 (0.8)	2/182 (1.1)	3/149 (2.0)	2/128 (1.6)
緑内障	0/244	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
眼窩周囲痛	0/244	1/182 (0.5)	0/149	0/128
眼窩周囲腫脹	1/244 (0.4)	1/182 (0.5)	0/149	0/128
網膜裂孔	0/244	2/182 (1.1)	1/149 (0.7)	0/128
霧視	1/244 (0.4)	0/182	0/149	0/128
視野欠損	0/244	1/182 (0.5)	1/149 (0.7)	0/128
胃腸障害	41/244 (16.8)	27/182 (14.8)	26/149 (17.4)	17/128 (13.3)
腹部膨満	3/244 (1.2)	1/182 (0.5)	2/149 (1.3)	0/128
腹痛	1/244 (0.4)	1/182 (0.5)	0/149	1/128 (0.8)
上腹部痛	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
アフタ性潰瘍	1/244 (0.4)	0/182	0/149	0/128
呼気臭	3/244 (1.2)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
虚血性大腸炎	0/244	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
耳および迷路障害	1/114 (0.9)	0/1	0/0	8/244 (3.3)
感音性難聴	1/114 (0.9)	0/1	0/0	1/244 (0.4)
乗物酔い	0/114	0/1	0/0	1/244 (0.4)
回転性めまい	0/114	0/1	0/0	5/244 (2.0)
頭位性回転性めまい	0/114	0/1	0/0	1/244 (0.4)
眼障害	4/114 (3.5)	0/1	0/0	15/244 (6.1)
白内障	1/114 (0.9)	0/1	0/0	4/244 (1.6)
複視	1/114 (0.9)	0/1	0/0	3/244 (1.2)
ドライアイ	1/114 (0.9)	0/1	0/0	4/244 (1.6)
緑内障	2/114 (1.8)	0/1	0/0	2/244 (0.8)
眼窩周囲痛	0/114	0/1	0/0	1/244 (0.4)
眼窩周囲腫脹	0/114	0/1	0/0	2/244 (0.8)
網膜裂孔	0/114	0/1	0/0	2/244 (0.8)
霧視	0/114	0/1	0/0	1/244 (0.4)
視野欠損	0/114	0/1	0/0	1/244 (0.4)
胃腸障害	12/114 (10.5)	0/1	0/0	56/244 (23.0)
腹部膨満	0/114	0/1	0/0	4/244 (1.6)
腹痛	0/114	0/1	0/0	3/244 (1.2)
上腹部痛	0/114	0/1	0/0	2/244 (0.8)
アフタ性潰瘍	0/114	0/1	0/0	1/244 (0.4)
呼気臭	0/114	0/1	0/0	3/244 (1.2)
虚血性大腸炎	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	11/244 (4.5)	10/182 (5.5)	9/149 (6.0)	6/128 (4.7)
齲歯	0/244	0/182	1/149 (0.7)	0/128
下痢	5/244 (2.0)	2/182 (1.1)	3/149 (2.0)	0/128
口内乾燥	8/244 (3.3)	7/182 (3.8)	4/149 (2.7)	3/128 (2.3)
消化不良	1/244 (0.4)	0/182	0/149	0/128
嚥下障害	1/244 (0.4)	1/182 (0.5)	0/149	0/128
糞塊	1/244 (0.4)	0/182	0/149	0/128
排便回数増加	0/244	1/182 (0.5)	0/149	0/128
胃食道逆流性疾患	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
舌炎	0/244	1/182 (0.5)	1/149 (0.7)	0/128
舌痛	0/244	1/182 (0.5)	1/149 (0.7)	0/128
吐血	0/244	0/182	0/149	1/128 (0.8)
痔核	1/244 (0.4)	0/182	0/149	0/128
裂孔ヘルニア	0/244	0/182	0/149	1/128 (0.8)
胃排出不全	0/244	0/182	0/149	1/128 (0.8)
腸出血	0/244	1/182 (0.5)	0/149	0/128
過敏性腸症候群	2/244 (0.8)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
大腸ポリープ	0/244	0/182	0/149	1/128 (0.8)
口唇乾燥	0/244	1/182 (0.5)	0/149	0/128
メレナ	1/244 (0.4)	2/182 (1.1)	0/149	0/128
口腔腫脹	0/244	1/182 (0.5)	0/149	0/128
悪心	13/244 (5.3)	5/182 (2.7)	6/149 (4.0)	5/128 (3.9)
口腔内不快感	0/244	1/182 (0.5)	1/149 (0.7)	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
便秘	5/114 (4.4)	0/1	0/0	20/244 (8.2)
齲歯	0/114	0/1	0/0	1/244 (0.4)
下痢	0/114	0/1	0/0	9/244 (3.7)
口内乾燥	2/114 (1.8)	0/1	0/0	8/244 (3.3)
消化不良	0/114	0/1	0/0	1/244 (0.4)
嚥下障害	0/114	0/1	0/0	1/244 (0.4)
糞塊	0/114	0/1	0/0	1/244 (0.4)
排便回数増加	0/114	0/1	0/0	1/244 (0.4)
胃食道逆流性疾患	2/114 (1.8)	0/1	0/0	2/244 (0.8)
舌炎	0/114	0/1	0/0	1/244 (0.4)
舌痛	0/114	0/1	0/0	1/244 (0.4)
吐血	0/114	0/1	0/0	1/244 (0.4)
痔核	0/114	0/1	0/0	1/244 (0.4)
裂孔ヘルニア	1/114 (0.9)	0/1	0/0	1/244 (0.4)
胃排出不全	1/114 (0.9)	0/1	0/0	1/244 (0.4)
腸出血	0/114	0/1	0/0	1/244 (0.4)
過敏性腸症候群	1/114 (0.9)	0/1	0/0	2/244 (0.8)
大腸ポリープ	0/114	0/1	0/0	1/244 (0.4)
口唇乾燥	0/114	0/1	0/0	1/244 (0.4)
メレナ	0/114	0/1	0/0	2/244 (0.8)
口腔腫脹	0/114	0/1	0/0	1/244 (0.4)
悪心	3/114 (2.6)	0/1	0/0	19/244 (7.8)
口腔内不快感	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内痛	0/244	0/182	1/149 (0.7)	0/128
口の錯感覚	1/244 (0.4)	0/182	1/149 (0.7)	0/128
直腸出血	0/244	1/182 (0.5)	2/149 (1.3)	0/128
歯痛	1/244 (0.4)	0/182	0/149	0/128
嘔吐	4/244 (1.6)	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
一般・全身障害および投与部位の状態	194/244 (79.5)	127/182 (69.8)	94/149 (63.1)	77/128 (60.2)
投与部位内出血	0/244	0/182	0/149	1/128 (0.8)
投与部位紅斑	1/244 (0.4)	0/182	0/149	0/128
投与部位漏出	2/244 (0.8)	2/182 (1.1)	1/149 (0.7)	0/128
無力症	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
カテーテル留置部位紅斑	2/244 (0.8)	1/182 (0.5)	0/149	0/128
カテーテル留置部位漏出	0/244	0/182	1/149 (0.7)	0/128
カテーテル留置部位出血	1/244 (0.4)	0/182	0/149	0/128
カテーテル留置部位炎症	1/244 (0.4)	1/182 (0.5)	0/149	0/128
カテーテル留置部位刺激感	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
カテーテル留置部位浮腫	1/244 (0.4)	0/182	0/149	0/128
カテーテル留置部位疼痛	2/244 (0.8)	0/182	0/149	0/128
胸部不快感	0/244	1/182 (0.5)	0/149	0/128
胸痛	1/244 (0.4)	1/182 (0.5)	0/149	1/128 (0.8)
泣き	0/244	1/182 (0.5)	0/149	0/128
不快感	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
胃腸障害 (Cont.)				
口腔内痛	0/114	0/1	0/0	1/244 (0.4)
口の錯感覚	0/114	0/1	0/0	2/244 (0.8)
直腸出血	0/114	0/1	0/0	2/244 (0.8)
歯痛	0/114	0/1	0/0	1/244 (0.4)
嘔吐	0/114	0/1	0/0	6/244 (2.5)
一般・全身障害および投与部位の状態	64/114 (56.1)	0/1	0/0	202/244 (82.8)
投与部位内出血	1/114 (0.9)	0/1	0/0	1/244 (0.4)
投与部位紅斑	0/114	0/1	0/0	1/244 (0.4)
投与部位漏出	0/114	0/1	0/0	2/244 (0.8)
無力症	0/114	0/1	0/0	3/244 (1.2)
カテーテル留置部位紅斑	0/114	0/1	0/0	2/244 (0.8)
カテーテル留置部位漏出	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位出血	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位炎症	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位刺激感	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位浮腫	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位疼痛	0/114	0/1	0/0	2/244 (0.8)
胸部不快感	0/114	0/1	0/0	1/244 (0.4)
胸痛	1/114 (0.9)	0/1	0/0	2/244 (0.8)
泣き	0/114	0/1	0/0	1/244 (0.4)
不快感	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
薬効欠如	0/244	1/182 (0.5)	0/149	0/128
薬剤離脱症候群	2/244 (0.8)	0/182	0/149	0/128
疲労	7/244 (2.9)	4/182 (2.2)	3/149 (2.0)	3/128 (2.3)
異常感	2/244 (0.8)	1/182 (0.5)	0/149	0/128
冷感	0/244	0/182	1/149 (0.7)	0/128
熱感	1/244 (0.4)	0/182	0/149	0/128
歩行障害	1/244 (0.4)	1/182 (0.5)	0/149	0/128
歩行不能	1/244 (0.4)	0/182	0/149	0/128
低体温	1/244 (0.4)	0/182	0/149	1/128 (0.8)
インフルエンザ様疾患	3/244 (1.2)	0/182	0/149	0/128
注入部位内出血	14/244 (5.7)	6/182 (3.3)	6/149 (4.0)	3/128 (2.3)
注入部位皮膚炎	1/244 (0.4)	2/182 (1.1)	1/149 (0.7)	3/128 (2.3)
注入部位分泌物	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
注入部位変色	2/244 (0.8)	1/182 (0.5)	0/149	0/128
注入部位不快感	3/244 (1.2)	1/182 (0.5)	1/149 (0.7)	0/128
注入部位びらん	2/244 (0.8)	0/182	0/149	0/128
注入部位紅斑	113/244 (46.3)	57/182 (31.3)	36/149 (24.2)	28/128 (21.9)
注入部位皮膚剥脱	3/244 (1.2)	2/182 (1.1)	1/149 (0.7)	3/128 (2.3)
注入部位血管外漏出	17/244 (7.0)	9/182 (4.9)	4/149 (2.7)	3/128 (2.3)
注入部位血腫	12/244 (4.9)	4/182 (2.2)	2/149 (1.3)	2/128 (1.6)
注入部位出血	6/244 (2.5)	3/182 (1.6)	1/149 (0.7)	2/128 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
薬効欠如	0/114	0/1	0/0	1/244 (0.4)
薬剤離脱症候群	0/114	0/1	0/0	2/244 (0.8)
疲労	3/114 (2.6)	0/1	0/0	9/244 (3.7)
異常感	0/114	0/1	0/0	2/244 (0.8)
冷感	0/114	0/1	0/0	1/244 (0.4)
熱感	0/114	0/1	0/0	1/244 (0.4)
歩行障害	0/114	0/1	0/0	2/244 (0.8)
歩行不能	0/114	0/1	0/0	1/244 (0.4)
低体温	0/114	0/1	0/0	2/244 (0.8)
インフルエンザ様疾患	0/114	0/1	0/0	3/244 (1.2)
注入部位内出血	2/114 (1.8)	0/1	0/0	18/244 (7.4)
注入部位皮膚炎	2/114 (1.8)	0/1	0/0	4/244 (1.6)
注入部位分泌物	1/114 (0.9)	0/1	0/0	2/244 (0.8)
注入部位変色	0/114	0/1	0/0	2/244 (0.8)
注入部位不快感	0/114	0/1	0/0	4/244 (1.6)
注入部位びらん	0/114	0/1	0/0	2/244 (0.8)
注入部位紅斑	20/114 (17.5)	0/1	0/0	125/244 (51.2)
注入部位皮膚剥脱	3/114 (2.6)	0/1	0/0	6/244 (2.5)
注入部位血管外漏出	1/114 (0.9)	0/1	0/0	20/244 (8.2)
注入部位血腫	1/114 (0.9)	0/1	0/0	16/244 (6.6)
注入部位出血	1/114 (0.9)	0/1	0/0	9/244 (3.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位硬結	8/244 (3.3)	5/182 (2.7)	3/149 (2.0)	4/128 (3.1)
注入部位炎症	5/244 (2.0)	4/182 (2.2)	2/149 (1.3)	2/128 (1.6)
注入部位損傷	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
注入部位刺激感	3/244 (1.2)	3/182 (1.6)	2/149 (1.3)	0/128
注入部位腫瘤	8/244 (3.3)	3/182 (1.6)	3/149 (2.0)	2/128 (1.6)
注入部位壊死	1/244 (0.4)	0/182	0/149	0/128
注入部位結節	53/244 (21.7)	52/182 (28.6)	43/149 (28.9)	40/128 (31.3)
注入部位浮腫	36/244 (14.8)	13/182 (7.1)	10/149 (6.7)	8/128 (6.3)
注入部位疼痛	32/244 (13.1)	20/182 (11.0)	15/149 (10.1)	10/128 (7.8)
注入部位蒼白	3/244 (1.2)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
注入部位丘疹	8/244 (3.3)	6/182 (3.3)	3/149 (2.0)	3/128 (2.3)
注入部位異常感覚	2/244 (0.8)	0/182	1/149 (0.7)	0/128
注入部位そう痒感	4/244 (1.6)	2/182 (1.1)	3/149 (2.0)	1/128 (0.8)
注入部位発疹	5/244 (2.0)	3/182 (1.6)	1/149 (0.7)	0/128
注入部位反応	23/244 (9.4)	11/182 (6.0)	7/149 (4.7)	9/128 (7.0)
注入部位痂皮	0/244	1/182 (0.5)	0/149	1/128 (0.8)
注入部位腫脹	6/244 (2.5)	1/182 (0.5)	2/149 (1.3)	0/128
注入部位小水疱	2/244 (0.8)	1/182 (0.5)	0/149	0/128
注入部位熱感	1/244 (0.4)	0/182	0/149	0/128
注射部位内出血	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	0/128
注射部位変色	0/244	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注入部位硬結	4/114 (3.5)	0/1	0/0	10/244 (4.1)
注入部位炎症	3/114 (2.6)	0/1	0/0	9/244 (3.7)
注入部位損傷	0/114	0/1	0/0	3/244 (1.2)
注入部位刺激感	0/114	0/1	0/0	5/244 (2.0)
注入部位腫瘤	2/114 (1.8)	0/1	0/0	8/244 (3.3)
注入部位壊死	0/114	0/1	0/0	1/244 (0.4)
注入部位結節	35/114 (30.7)	0/1	0/0	68/244 (27.9)
注入部位浮腫	6/114 (5.3)	0/1	0/0	47/244 (19.3)
注入部位疼痛	9/114 (7.9)	0/1	0/0	38/244 (15.6)
注入部位蒼白	1/114 (0.9)	0/1	0/0	4/244 (1.6)
注入部位丘疹	4/114 (3.5)	0/1	0/0	18/244 (7.4)
注入部位異常感覚	0/114	0/1	0/0	2/244 (0.8)
注入部位そう痒感	1/114 (0.9)	0/1	0/0	7/244 (2.9)
注入部位発疹	0/114	0/1	0/0	7/244 (2.9)
注入部位反応	8/114 (7.0)	0/1	0/0	31/244 (12.7)
注入部位痂皮	1/114 (0.9)	0/1	0/0	1/244 (0.4)
注入部位腫脹	0/114	0/1	0/0	6/244 (2.5)
注入部位小水疱	0/114	0/1	0/0	2/244 (0.8)
注入部位熱感	0/114	0/1	0/0	1/244 (0.4)
注射部位内出血	0/114	0/1	0/0	3/244 (1.2)
注射部位変色	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	13/244 (5.3)	7/182 (3.8)	6/149 (4.0)	3/128 (2.3)
注射部位漏出	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	2/128 (1.6)
注射部位血腫	1/244 (0.4)	0/182	0/149	0/128
注射部位出血	0/244	1/182 (0.5)	0/149	0/128
注射部位炎症	4/244 (1.6)	4/182 (2.2)	2/149 (1.3)	1/128 (0.8)
注射部位結節	5/244 (2.0)	6/182 (3.3)	6/149 (4.0)	3/128 (2.3)
注射部位浮腫	4/244 (1.6)	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
注射部位疼痛	7/244 (2.9)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
注射部位丘疹	1/244 (0.4)	0/182	0/149	0/128
注射部位反応	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)
注射部位腫脹	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	1/128 (0.8)
注射部位蕁麻疹	1/244 (0.4)	0/182	0/149	0/128
滴下投与部位熱傷	1/244 (0.4)	0/182	0/149	0/128
滴下投与部位痛	0/244	1/182 (0.5)	0/149	0/128
限局性浮腫	1/244 (0.4)	0/182	0/149	0/128
適用部位からの吸収不良	1/244 (0.4)	0/182	0/149	0/128
倦怠感	2/244 (0.8)	0/182	1/149 (0.7)	0/128
医療機器使用部位刺激感	3/244 (1.2)	1/182 (0.5)	0/149	0/128
医療機器使用部位そう痒感	1/244 (0.4)	0/182	0/149	0/128
医療機器使用部位発疹	2/244 (0.8)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
注射部位紅斑	1/114 (0.9)	0/1	0/0	14/244 (5.7)
注射部位漏出	1/114 (0.9)	0/1	0/0	2/244 (0.8)
注射部位血腫	0/114	0/1	0/0	1/244 (0.4)
注射部位出血	0/114	0/1	0/0	1/244 (0.4)
注射部位炎症	1/114 (0.9)	0/1	0/0	6/244 (2.5)
注射部位結節	2/114 (1.8)	0/1	0/0	9/244 (3.7)
注射部位浮腫	2/114 (1.8)	0/1	0/0	5/244 (2.0)
注射部位疼痛	1/114 (0.9)	0/1	0/0	8/244 (3.3)
注射部位丘疹	0/114	0/1	0/0	1/244 (0.4)
注射部位反応	1/114 (0.9)	0/1	0/0	2/244 (0.8)
注射部位腫脹	0/114	0/1	0/0	4/244 (1.6)
注射部位蕁麻疹	0/114	0/1	0/0	1/244 (0.4)
滴下投与部位熱傷	0/114	0/1	0/0	1/244 (0.4)
滴下投与部位痛	0/114	0/1	0/0	1/244 (0.4)
限局性浮腫	0/114	0/1	0/0	1/244 (0.4)
適用部位からの吸収不良	0/114	0/1	0/0	1/244 (0.4)
倦怠感	0/114	0/1	0/0	3/244 (1.2)
医療機器使用部位刺激感	0/114	0/1	0/0	3/244 (1.2)
医療機器使用部位そう痒感	0/114	0/1	0/0	1/244 (0.4)
医療機器使用部位発疹	0/114	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
小結節	1/244 (0.4)	0/182	0/149	0/128
非心臓性胸痛	2/244 (0.8)	0/182	0/149	0/128
末梢性浮腫	8/244 (3.3)	4/182 (2.2)	4/149 (2.7)	1/128 (0.8)
疼痛	0/244	1/182 (0.5)	0/149	1/128 (0.8)
末梢腫脹	3/244 (1.2)	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
穿刺部位内出血	1/244 (0.4)	0/182	0/149	0/128
穿刺部位紅斑	2/244 (0.8)	2/182 (1.1)	0/149	0/128
穿刺部位出血	1/244 (0.4)	0/182	0/149	0/128
穿刺部位硬結	2/244 (0.8)	1/182 (0.5)	0/149	0/128
穿刺部位浮腫	1/244 (0.4)	0/182	0/149	0/128
穿刺部位腫脹	1/244 (0.4)	0/182	0/149	0/128
発熱	3/244 (1.2)	1/182 (0.5)	1/149 (0.7)	0/128
口渇	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
血管穿刺部位硬結	1/244 (0.4)	0/182	0/149	0/128
肝胆道系障害	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
肝嚢胞	0/244	0/182	0/149	0/128
脂肪肝	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
門脈血栓症	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
一般・全身障害および投与部位の状態(Cont.)				
小結節	0/114	0/1	0/0	1/244 (0.4)
非心臓性胸痛	0/114	0/1	0/0	2/244 (0.8)
末梢性浮腫	1/114 (0.9)	0/1	0/0	9/244 (3.7)
疼痛	0/114	0/1	0/0	2/244 (0.8)
末梢腫脹	2/114 (1.8)	0/1	0/0	4/244 (1.6)
穿刺部位内出血	0/114	0/1	0/0	1/244 (0.4)
穿刺部位紅斑	0/114	0/1	0/0	3/244 (1.2)
穿刺部位出血	0/114	0/1	0/0	1/244 (0.4)
穿刺部位硬結	0/114	0/1	0/0	2/244 (0.8)
穿刺部位浮腫	0/114	0/1	0/0	1/244 (0.4)
穿刺部位腫脹	0/114	0/1	0/0	1/244 (0.4)
発熱	0/114	0/1	0/0	4/244 (1.6)
口渇	1/114 (0.9)	0/1	0/0	1/244 (0.4)
血管穿刺部位硬結	0/114	0/1	0/0	1/244 (0.4)
肝胆道系障害	2/114 (1.8)	1/1 (100)	0/0	3/244 (1.2)
肝嚢胞	1/114 (0.9)	1/1 (100)	0/0	1/244 (0.4)
脂肪肝	1/114 (0.9)	0/1	0/0	1/244 (0.4)
門脈血栓症	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症	81/244 (33.2)	47/182 (25.8)	35/149 (23.5)	33/128 (25.8)
無症候性COVID-19	0/244	0/182	1/149 (0.7)	1/128 (0.8)
細菌性疾患キャリアー	0/244	0/182	1/149 (0.7)	1/128 (0.8)
ボレリア感染	1/244 (0.4)	0/182	0/149	0/128
ウイルス性気管支炎	0/244	0/182	0/149	1/128 (0.8)
COVID-19	0/244	0/182	0/149	1/128 (0.8)
COVID-19肺炎	0/244	0/182	1/149 (0.7)	0/128
カテーテル留置部位感染	0/244	0/182	0/149	1/128 (0.8)
蜂巣炎	1/244 (0.4)	0/182	1/149 (0.7)	0/128
結膜炎	1/244 (0.4)	2/182 (1.1)	0/149	0/128
膀胱炎	1/244 (0.4)	0/182	0/149	0/128
爪の皮膚糸状菌症	0/244	1/182 (0.5)	1/149 (0.7)	0/128
真菌感染	1/244 (0.4)	0/182	0/149	0/128
胃腸炎	1/244 (0.4)	0/182	0/149	0/128
歯肉炎	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
麦粒腫	0/244	1/182 (0.5)	0/149	0/128
感染性皮膚潰瘍	1/244 (0.4)	1/182 (0.5)	0/149	0/128
インフルエンザ	0/244	0/182	0/149	1/128 (0.8)
注入部位膿瘍	18/244 (7.4)	10/182 (5.5)	6/149 (4.0)	3/128 (2.3)
注入部位蜂巣炎	40/244 (16.4)	17/182 (9.3)	15/149 (10.1)	16/128 (12.5)
注入部位感染	7/244 (2.9)	8/182 (4.4)	1/149 (0.7)	4/128 (3.1)
注入部位膿疱	1/244 (0.4)	1/182 (0.5)	0/149	0/128
注射部位蜂巣炎	2/244 (0.8)	1/182 (0.5)	0/149	1/128 (0.8)
上咽頭炎	5/244 (2.0)	3/182 (1.6)	0/149	2/128 (1.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症	14/114 (12.3)	0/1	0/0	114/244 (46.7)
無症候性COVID-19	0/114	0/1	0/0	1/244 (0.4)
細菌性疾患キャリアー	1/114 (0.9)	0/1	0/0	1/244 (0.4)
ボレリア感染	0/114	0/1	0/0	1/244 (0.4)
ウイルス性気管支炎	0/114	0/1	0/0	1/244 (0.4)
COVID-19	0/114	0/1	0/0	1/244 (0.4)
COVID-19肺炎	0/114	0/1	0/0	1/244 (0.4)
カテーテル留置部位感染	1/114 (0.9)	0/1	0/0	1/244 (0.4)
蜂巣炎	0/114	0/1	0/0	2/244 (0.8)
結膜炎	0/114	0/1	0/0	2/244 (0.8)
膀胱炎	0/114	0/1	0/0	1/244 (0.4)
爪の皮膚糸状菌症	0/114	0/1	0/0	1/244 (0.4)
真菌感染	0/114	0/1	0/0	1/244 (0.4)
胃腸炎	0/114	0/1	0/0	1/244 (0.4)
歯肉炎	0/114	0/1	0/0	1/244 (0.4)
麦粒腫	0/114	0/1	0/0	1/244 (0.4)
感染性皮膚潰瘍	0/114	0/1	0/0	1/244 (0.4)
インフルエンザ	1/114 (0.9)	0/1	0/0	1/244 (0.4)
注入部位膿瘍	1/114 (0.9)	0/1	0/0	26/244 (10.7)
注入部位蜂巣炎	5/114 (4.4)	0/1	0/0	56/244 (23.0)
注入部位感染	2/114 (1.8)	0/1	0/0	17/244 (7.0)
注入部位膿疱	0/114	0/1	0/0	1/244 (0.4)
注射部位蜂巣炎	0/114	0/1	0/0	3/244 (1.2)
上咽頭炎	1/114 (0.9)	0/1	0/0	10/244 (4.1)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
爪真菌症	1/244 (0.4)	0/182	0/149	0/128
耳下腺膿瘍	0/244	0/182	1/149 (0.7)	0/128
肺炎	2/244 (0.8)	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
術後膿瘍	0/244	0/182	1/149 (0.7)	0/128
シュードモナス感染	1/244 (0.4)	1/182 (0.5)	0/149	0/128
膿疱性皮疹	1/244 (0.4)	0/182	0/149	0/128
気道感染	0/244	0/182	0/149	1/128 (0.8)
敗血症	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
敗血症性ショック	1/244 (0.4)	0/182	0/149	0/128
副鼻腔炎	1/244 (0.4)	1/182 (0.5)	0/149	0/128
ブドウ球菌感染	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
歯感染	1/244 (0.4)	1/182 (0.5)	0/149	1/128 (0.8)
上気道感染	1/244 (0.4)	0/182	0/149	0/128
尿路感染	11/244 (4.5)	7/182 (3.8)	5/149 (3.4)	4/128 (3.1)
水痘帯状疱疹ウイルス感染	0/244	1/182 (0.5)	0/149	0/128
傷害、中毒および処置合併症	29/244 (11.9)	18/182 (9.9)	14/149 (9.4)	11/128 (8.6)
足関節部骨折	1/244 (0.4)	1/182 (0.5)	0/149	0/128
節足動物咬傷	1/244 (0.4)	0/182	0/149	0/128
骨挫傷	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
脳挫傷	1/244 (0.4)	0/182	0/149	0/128
挫傷	3/244 (1.2)	4/182 (2.2)	2/149 (1.3)	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
感染症および寄生虫症 (Cont.)				
爪真菌症	0/114	0/1	0/0	1/244 (0.4)
耳下腺膿瘍	0/114	0/1	0/0	1/244 (0.4)
肺炎	0/114	0/1	0/0	4/244 (1.6)
術後膿瘍	0/114	0/1	0/0	1/244 (0.4)
シュードモナス感染	0/114	0/1	0/0	1/244 (0.4)
膿疱性皮疹	0/114	0/1	0/0	1/244 (0.4)
気道感染	0/114	0/1	0/0	1/244 (0.4)
敗血症	0/114	0/1	0/0	4/244 (1.6)
敗血症性ショック	0/114	0/1	0/0	1/244 (0.4)
副鼻腔炎	0/114	0/1	0/0	1/244 (0.4)
ブドウ球菌感染	0/114	0/1	0/0	2/244 (0.8)
歯感染	0/114	0/1	0/0	2/244 (0.8)
上気道感染	0/114	0/1	0/0	1/244 (0.4)
尿路感染	2/114 (1.8)	0/1	0/0	19/244 (7.8)
水痘帯状疱疹ウイルス感染	0/114	0/1	0/0	1/244 (0.4)
傷害、中毒および処置合併症	6/114 (5.3)	0/1	0/0	47/244 (19.3)
足関節部骨折	0/114	0/1	0/0	1/244 (0.4)
節足動物咬傷	0/114	0/1	0/0	1/244 (0.4)
骨挫傷	1/114 (0.9)	0/1	0/0	2/244 (0.8)
脳挫傷	0/114	0/1	0/0	1/244 (0.4)
挫傷	1/114 (0.9)	0/1	0/0	8/244 (3.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	1/244 (0.4)	0/182	0/149	0/128
医療機器による投与の欠落	1/244 (0.4)	0/182	0/149	0/128
期限切れの製品使用	1/244 (0.4)	0/182	0/149	0/128
眼挫傷	1/244 (0.4)	0/182	0/149	0/128
顔面損傷	0/244	1/182 (0.5)	0/149	0/128
顔面骨骨折	2/244 (0.8)	0/182	0/149	0/128
転倒	22/244 (9.0)	14/182 (7.7)	9/149 (6.0)	7/128 (5.5)
頭部損傷	1/244 (0.4)	2/182 (1.1)	1/149 (0.7)	0/128
注入に伴う反応	1/244 (0.4)	0/182	0/149	0/128
関節脱臼	0/244	1/182 (0.5)	1/149 (0.7)	0/128
靭帯捻挫	0/244	2/182 (1.1)	0/149	0/128
腰椎骨折	1/244 (0.4)	0/182	0/149	0/128
過量投与	0/244	0/182	1/149 (0.7)	1/128 (0.8)
処置後挫傷	1/244 (0.4)	0/182	0/149	0/128
処置によるめまい	1/244 (0.4)	0/182	0/149	0/128
肋骨骨折	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
皮膚擦過傷	1/244 (0.4)	2/182 (1.1)	3/149 (2.0)	0/128
皮膚損傷	1/244 (0.4)	0/182	0/149	0/128
皮膚裂傷	2/244 (0.8)	3/182 (1.6)	1/149 (0.7)	2/128 (1.6)
ストレス骨折	0/244	0/182	1/149 (0.7)	1/128 (0.8)
硬膜下血腫	0/244	0/182	0/149	1/128 (0.8)
サンバーン	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	0/114	0/1	0/0	1/244 (0.4)
医療機器による投与の欠落	0/114	0/1	0/0	1/244 (0.4)
期限切れの製品使用	0/114	0/1	0/0	1/244 (0.4)
眼挫傷	0/114	0/1	0/0	1/244 (0.4)
顔面損傷	0/114	0/1	0/0	1/244 (0.4)
顔面骨骨折	0/114	0/1	0/0	2/244 (0.8)
転倒	2/114 (1.8)	0/1	0/0	39/244 (16.0)
頭部損傷	0/114	0/1	0/0	4/244 (1.6)
注入に伴う反応	0/114	0/1	0/0	1/244 (0.4)
関節脱臼	0/114	0/1	0/0	1/244 (0.4)
靭帯捻挫	0/114	0/1	0/0	2/244 (0.8)
腰椎骨折	0/114	0/1	0/0	1/244 (0.4)
過量投与	0/114	0/1	0/0	1/244 (0.4)
処置後挫傷	0/114	0/1	0/0	1/244 (0.4)
処置によるめまい	0/114	0/1	0/0	1/244 (0.4)
肋骨骨折	1/114 (0.9)	0/1	0/0	3/244 (1.2)
皮膚擦過傷	0/114	0/1	0/0	3/244 (1.2)
皮膚損傷	0/114	0/1	0/0	1/244 (0.4)
皮膚裂傷	0/114	0/1	0/0	7/244 (2.9)
ストレス骨折	0/114	0/1	0/0	1/244 (0.4)
硬膜下血腫	0/114	0/1	0/0	1/244 (0.4)
サンバーン	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
過少量投与	0/244	0/182	1/149 (0.7)	0/128
創傷	0/244	0/182	0/149	1/128 (0.8)
臨床検査	30/244 (12.3)	27/182 (14.8)	27/149 (18.1)	23/128 (18.0)
血中クレアチンホスホキナーゼ増加	2/244 (0.8)	0/182	0/149	0/128
血中クレアチニン減少	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
血中葉酸減少	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
血中ホモシステイン増加	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
血中リン減少	0/244	1/182 (0.5)	0/149	0/128
血圧上昇	2/244 (0.8)	0/182	0/149	0/128
起立血圧低下	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
血中ナトリウム減少	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
C-反応性蛋白増加	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
握力低下	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
ヘモグロビン減少	1/244 (0.4)	1/182 (0.5)	0/149	1/128 (0.8)
リンパ球数減少	1/244 (0.4)	0/182	0/149	0/128
単球数増加	1/244 (0.4)	0/182	0/149	0/128
好中球数増加	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
プロトロンビン時間延長	0/244	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症(Cont.)				
腱断裂	1/114 (0.9)	0/1	0/0	2/244 (0.8)
過少量投与	0/114	0/1	0/0	1/244 (0.4)
創傷	1/114 (0.9)	0/1	0/0	1/244 (0.4)
臨床検査	21/114 (18.4)	0/1	0/0	45/244 (18.4)
血中クレアチンホスホキナーゼ増加	0/114	0/1	0/0	2/244 (0.8)
血中クレアチニン減少	1/114 (0.9)	0/1	0/0	1/244 (0.4)
血中葉酸減少	3/114 (2.6)	0/1	0/0	3/244 (1.2)
血中ホモシステイン増加	3/114 (2.6)	0/1	0/0	3/244 (1.2)
血中リン減少	0/114	0/1	0/0	1/244 (0.4)
血圧上昇	0/114	0/1	0/0	2/244 (0.8)
起立血圧低下	1/114 (0.9)	0/1	0/0	1/244 (0.4)
血中ナトリウム減少	1/114 (0.9)	0/1	0/0	1/244 (0.4)
C-反応性蛋白増加	1/114 (0.9)	0/1	0/0	1/244 (0.4)
握力低下	1/114 (0.9)	0/1	0/0	1/244 (0.4)
ヘモグロビン減少	0/114	0/1	0/0	2/244 (0.8)
リンパ球数減少	0/114	0/1	0/0	1/244 (0.4)
単球数増加	0/114	0/1	0/0	1/244 (0.4)
好中球数増加	1/114 (0.9)	0/1	0/0	2/244 (0.8)
プロトロンビン時間延長	1/114 (0.9)	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
赤血球数減少	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
ビタミンB12減少	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)
ビタミンB6減少	9/244 (3.7)	8/182 (4.4)	9/149 (6.0)	9/128 (7.0)
ビタミンD減少	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
体重減少	12/244 (4.9)	14/182 (7.7)	14/149 (9.4)	10/128 (7.8)
体重増加	1/244 (0.4)	2/182 (1.1)	2/149 (1.3)	2/128 (1.6)
白血球数増加	2/244 (0.8)	0/182	0/149	0/128
代謝および栄養障害	16/244 (6.6)	14/182 (7.7)	13/149 (8.7)	10/128 (7.8)
悪液質	0/244	0/182	1/149 (0.7)	0/128
食欲減退	3/244 (1.2)	3/182 (1.6)	2/149 (1.3)	0/128
脱水	2/244 (0.8)	2/182 (1.1)	0/149	0/128
糖尿病	0/244	0/182	1/149 (0.7)	1/128 (0.8)
水分過負荷	1/244 (0.4)	0/182	0/149	0/128
体液貯留	1/244 (0.4)	0/182	0/149	1/128 (0.8)
葉酸欠乏	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
耐糖能障害	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
高コレステロール血症	0/244	1/182 (0.5)	0/149	0/128
高血糖	1/244 (0.4)	0/182	0/149	0/128
高ホモシステイン血症	0/244	0/182	1/149 (0.7)	0/128
低カリウム血症	2/244 (0.8)	0/182	0/149	1/128 (0.8)
低ナトリウム血症	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
栄養障害	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
臨床検査 (Cont.)				
赤血球数減少	1/114 (0.9)	0/1	0/0	1/244 (0.4)
ビタミンB12減少	1/114 (0.9)	0/1	0/0	2/244 (0.8)
ビタミンB6減少	9/114 (7.9)	0/1	0/0	11/244 (4.5)
ビタミンD減少	0/114	0/1	0/0	1/244 (0.4)
体重減少	6/114 (5.3)	0/1	0/0	22/244 (9.0)
体重増加	2/114 (1.8)	0/1	0/0	2/244 (0.8)
白血球数増加	0/114	0/1	0/0	2/244 (0.8)
代謝および栄養障害	7/114 (6.1)	0/1	0/0	28/244 (11.5)
悪液質	0/114	0/1	0/0	1/244 (0.4)
食欲減退	0/114	0/1	0/0	5/244 (2.0)
脱水	0/114	0/1	0/0	4/244 (1.6)
糖尿病	0/114	0/1	0/0	1/244 (0.4)
水分過負荷	0/114	0/1	0/0	1/244 (0.4)
体液貯留	1/114 (0.9)	0/1	0/0	2/244 (0.8)
葉酸欠乏	0/114	0/1	0/0	2/244 (0.8)
耐糖能障害	1/114 (0.9)	0/1	0/0	1/244 (0.4)
高コレステロール血症	0/114	0/1	0/0	1/244 (0.4)
高血糖	0/114	0/1	0/0	1/244 (0.4)
高ホモシステイン血症	0/114	0/1	0/0	1/244 (0.4)
低カリウム血症	0/114	0/1	0/0	3/244 (1.2)
低ナトリウム血症	0/114	0/1	0/0	2/244 (0.8)
栄養障害	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB群欠乏	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
ビタミンB12欠乏	0/244	0/182	1/149 (0.7)	0/128
ビタミンB6欠乏	5/244 (2.0)	5/182 (2.7)	6/149 (4.0)	4/128 (3.1)
筋骨格系および結合組織障害	27/244 (11.1)	18/182 (9.9)	20/149 (13.4)	18/128 (14.1)
関節痛	4/244 (1.6)	3/182 (1.6)	2/149 (1.3)	2/128 (1.6)
反応性関節炎	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)
背部痛	6/244 (2.5)	4/182 (2.2)	6/149 (4.0)	5/128 (3.9)
骨痛	0/244	0/182	1/149 (0.7)	0/128
滑液包炎	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)
外骨腫	0/244	1/182 (0.5)	1/149 (0.7)	0/128
椎間関節症候群	0/244	1/182 (0.5)	1/149 (0.7)	0/128
椎間板変性症	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
椎間板突出	0/244	1/182 (0.5)	1/149 (0.7)	0/128
関節滲出液	0/244	1/182 (0.5)	1/149 (0.7)	0/128
関節腫脹	1/244 (0.4)	1/182 (0.5)	0/149	0/128
四肢不快感	0/244	0/182	1/149 (0.7)	0/128
筋萎縮	0/244	1/182 (0.5)	1/149 (0.7)	0/128
筋痙縮	2/244 (0.8)	4/182 (2.2)	1/149 (0.7)	0/128
筋力低下	3/244 (1.2)	2/182 (1.1)	2/149 (1.3)	2/128 (1.6)
筋骨格硬直	1/244 (0.4)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB群欠乏	2/114 (1.8)	0/1	0/0	2/244 (0.8)
ビタミンB12欠乏	1/114 (0.9)	0/1	0/0	2/244 (0.8)
ビタミンB6欠乏	4/114 (3.5)	0/1	0/0	8/244 (3.3)
筋骨格系および結合組織障害	16/114 (14.0)	0/1	0/0	44/244 (18.0)
関節痛	2/114 (1.8)	0/1	0/0	6/244 (2.5)
反応性関節炎	0/114	0/1	0/0	2/244 (0.8)
背部痛	5/114 (4.4)	0/1	0/0	12/244 (4.9)
骨痛	0/114	0/1	0/0	1/244 (0.4)
滑液包炎	0/114	0/1	0/0	2/244 (0.8)
外骨腫	0/114	0/1	0/0	1/244 (0.4)
椎間関節症候群	0/114	0/1	0/0	1/244 (0.4)
椎間板変性症	1/114 (0.9)	0/1	0/0	1/244 (0.4)
椎間板突出	0/114	0/1	0/0	1/244 (0.4)
関節滲出液	1/114 (0.9)	0/1	0/0	2/244 (0.8)
関節腫脹	0/114	0/1	0/0	1/244 (0.4)
四肢不快感	0/114	0/1	0/0	1/244 (0.4)
筋萎縮	0/114	0/1	0/0	1/244 (0.4)
筋痙縮	0/114	0/1	0/0	5/244 (2.0)
筋力低下	1/114 (0.9)	0/1	0/0	5/244 (2.0)
筋骨格硬直	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
筋肉痛	3/244 (1.2)	0/182	0/149	0/128
頚部痛	0/244	0/182	2/149 (1.3)	2/128 (1.6)
骨炎	1/244 (0.4)	0/182	0/149	0/128
変形性関節症	1/244 (0.4)	3/182 (1.6)	4/149 (2.7)	2/128 (1.6)
骨減少症	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
四肢痛	5/244 (2.0)	3/182 (1.6)	2/149 (1.3)	1/128 (0.8)
関節周囲炎	0/244	0/182	1/149 (0.7)	1/128 (0.8)
姿勢異常	1/244 (0.4)	0/182	0/149	0/128
横紋筋融解症	1/244 (0.4)	0/182	0/149	1/128 (0.8)
肩回旋筋腱板症候群	0/244	1/182 (0.5)	1/149 (0.7)	0/128
仙腸関節機能障害	1/244 (0.4)	0/182	0/149	0/128
変形性脊椎症	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
腱障害	0/244	1/182 (0.5)	1/149 (0.7)	0/128
腱炎	1/244 (0.4)	0/182	0/149	0/128
斜頚	1/244 (0.4)	0/182	0/149	0/128
弾発指	0/244	0/182	1/149 (0.7)	1/128 (0.8)
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）	1/244 (0.4)	2/182 (1.1)	3/149 (2.0)	1/128 (0.8)
基底細胞癌	0/244	2/182 (1.1)	2/149 (1.3)	0/128
脂漏性角化症	0/244	0/182	1/149 (0.7)	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害(Cont.)				
筋肉痛	0/114	0/1	0/0	3/244 (1.2)
頚部痛	2/114 (1.8)	0/1	0/0	2/244 (0.8)
骨炎	0/114	0/1	0/0	1/244 (0.4)
変形性関節症	3/114 (2.6)	0/1	0/0	5/244 (2.0)
骨減少症	1/114 (0.9)	0/1	0/0	1/244 (0.4)
四肢痛	1/114 (0.9)	0/1	0/0	6/244 (2.5)
関節周囲炎	1/114 (0.9)	0/1	0/0	1/244 (0.4)
姿勢異常	0/114	0/1	0/0	1/244 (0.4)
横紋筋融解症	0/114	0/1	0/0	2/244 (0.8)
肩回旋筋腱板症候群	0/114	0/1	0/0	1/244 (0.4)
仙腸関節機能障害	0/114	0/1	0/0	1/244 (0.4)
変形性脊椎症	1/114 (0.9)	0/1	0/0	1/244 (0.4)
腱障害	0/114	0/1	0/0	1/244 (0.4)
腱炎	0/114	0/1	0/0	1/244 (0.4)
斜頚	0/114	0/1	0/0	1/244 (0.4)
弾発指	1/114 (0.9)	0/1	0/0	1/244 (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）	0/114	0/1	0/0	4/244 (1.6)
基底細胞癌	0/114	0/1	0/0	2/244 (0.8)
脂漏性角化症	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
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） (Cont.)				
皮膚有棘細胞癌	1/244 (0.4)	0/182	0/149	0/128
神経系障害	79/244 (32.4)	49/182 (26.9)	41/149 (27.5)	37/128 (28.9)
アカシジア	0/244	0/182	0/149	1/128 (0.8)
健忘	0/244	0/182	0/149	0/128
失語症	0/244	0/182	1/149 (0.7)	0/128
運動失調	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
平衡障害	1/244 (0.4)	0/182	2/149 (1.3)	2/128 (1.6)
運動緩慢	1/244 (0.4)	0/182	1/149 (0.7)	0/128
手根管症候群	0/244	0/182	1/149 (0.7)	1/128 (0.8)
大脳萎縮	0/244	0/182	0/149	1/128 (0.8)
脳出血	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
脳圧排効果	0/244	0/182	0/149	1/128 (0.8)
脳血管発作	0/244	1/182 (0.5)	0/149	0/128
認知障害	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	3/128 (2.3)
振動覚低下	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
注意力障害	1/244 (0.4)	1/182 (0.5)	0/149	0/128
浮動性めまい	23/244 (9.4)	10/182 (5.5)	6/149 (4.0)	5/128 (3.9)
体位性めまい	3/244 (1.2)	3/182 (1.6)	1/149 (0.7)	0/128
構語障害	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
味覚不全	2/244 (0.8)	0/182	0/149	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
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） (Cont.)				
皮膚有棘細胞癌	0/114	0/1	0/0	1/244 (0.4)
神経系障害	34/114 (29.8)	1/1 (100)	0/0	110/244 (45.1)
アカシジア	0/114	0/1	0/0	1/244 (0.4)
健忘	1/114 (0.9)	0/1	0/0	1/244 (0.4)
失語症	0/114	0/1	0/0	1/244 (0.4)
運動失調	0/114	0/1	0/0	1/244 (0.4)
平衡障害	3/114 (2.6)	0/1	0/0	4/244 (1.6)
運動緩慢	0/114	0/1	0/0	2/244 (0.8)
手根管症候群	1/114 (0.9)	0/1	0/0	1/244 (0.4)
大脳萎縮	1/114 (0.9)	0/1	0/0	1/244 (0.4)
脳出血	1/114 (0.9)	0/1	0/0	1/244 (0.4)
脳圧排効果	0/114	0/1	0/0	1/244 (0.4)
脳血管発作	0/114	0/1	0/0	1/244 (0.4)
認知障害	4/114 (3.5)	0/1	0/0	6/244 (2.5)
振動覚低下	0/114	0/1	0/0	1/244 (0.4)
注意力障害	0/114	0/1	0/0	1/244 (0.4)
浮動性めまい	5/114 (4.4)	0/1	0/0	25/244 (10.2)
体位性めまい	0/114	0/1	0/0	5/244 (2.0)
構語障害	0/114	0/1	0/0	3/244 (1.2)
味覚不全	1/114 (0.9)	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
ジスキネジア	11/244 (4.5)	5/182 (2.7)	3/149 (2.0)	4/128 (3.1)
起立障害	1/244 (0.4)	0/182	0/149	0/128
ジストニア	4/244 (1.6)	4/182 (2.2)	4/149 (2.7)	4/128 (3.1)
脳症	1/244 (0.4)	0/182	0/149	0/128
てんかん	1/244 (0.4)	0/182	0/149	0/128
本態性振戦	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
伸展性足底反応	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
すくみ現象	4/244 (1.6)	2/182 (1.1)	0/149	0/128
全身性強直性間代性発作	0/244	0/182	0/149	1/128 (0.8)
頭部不快感	1/244 (0.4)	0/182	0/149	0/128
頭痛	9/244 (3.7)	5/182 (2.7)	5/149 (3.4)	4/128 (3.1)
片側感覚消失	1/244 (0.4)	0/182	0/149	0/128
不全片麻痺	1/244 (0.4)	0/182	0/149	0/128
感覚鈍麻	0/244	0/182	3/149 (2.0)	2/128 (1.6)
反射減弱	0/244	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
不規則睡眠覚醒リズム障害	0/244	0/182	1/149 (0.7)	1/128 (0.8)
嗜眠	0/244	1/182 (0.5)	1/149 (0.7)	0/128
意識消失	0/244	2/182 (1.1)	0/149	0/128
腰仙部神経根障害	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
記憶障害	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
代謝性脳症	1/244 (0.4)	0/182	1/149 (0.7)	1/128 (0.8)
神経痛	0/244	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
ジスキネジア	2/114 (1.8)	0/1	0/0	18/244 (7.4)
起立障害	0/114	0/1	0/0	1/244 (0.4)
ジストニア	4/114 (3.5)	0/1	0/0	7/244 (2.9)
脳症	0/114	0/1	0/0	1/244 (0.4)
てんかん	0/114	0/1	0/0	1/244 (0.4)
本態性振戦	0/114	0/1	0/0	1/244 (0.4)
伸展性足底反応	1/114 (0.9)	0/1	0/0	1/244 (0.4)
すくみ現象	0/114	0/1	0/0	4/244 (1.6)
全身性強直性間代性発作	0/114	0/1	0/0	1/244 (0.4)
頭部不快感	0/114	0/1	0/0	1/244 (0.4)
頭痛	4/114 (3.5)	0/1	0/0	14/244 (5.7)
片側感覚消失	0/114	0/1	0/0	1/244 (0.4)
不全片麻痺	0/114	0/1	0/0	1/244 (0.4)
感覚鈍麻	2/114 (1.8)	0/1	0/0	3/244 (1.2)
反射減弱	2/114 (1.8)	0/1	0/0	3/244 (1.2)
不規則睡眠覚醒リズム障害	1/114 (0.9)	0/1	0/0	1/244 (0.4)
嗜眠	0/114	0/1	0/0	2/244 (0.8)
意識消失	0/114	0/1	0/0	2/244 (0.8)
腰仙部神経根障害	0/114	0/1	0/0	1/244 (0.4)
記憶障害	1/114 (0.9)	0/1	0/0	2/244 (0.8)
代謝性脳症	1/114 (0.9)	0/1	0/0	2/244 (0.8)
神経痛	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
末梢性ニューロパチー	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
オンオフ現象	8/244 (3.3)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
錯感覚	4/244 (1.6)	1/182 (0.5)	0/149	2/128 (1.6)
パーキンソン病	11/244 (4.5)	8/182 (4.4)	5/149 (3.4)	2/128 (1.6)
パーキンソニズム	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
側反弓	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	2/128 (1.6)
多発ニューロパチー	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
失神寸前の状態	0/244	1/182 (0.5)	0/149	0/128
心因性発作	1/244 (0.4)	0/182	0/149	0/128
精神運動亢進	2/244 (0.8)	0/182	0/149	0/128
反射異常	0/244	0/182	0/149	1/128 (0.8)
安静時振戦	1/244 (0.4)	0/182	0/149	0/128
坐骨神経痛	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	0/128
痙攣発作	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
感覚障害	1/244 (0.4)	0/182	0/149	0/128
感覚消失	0/244	1/182 (0.5)	1/149 (0.7)	0/128
睡眠時麻痺	0/244	1/182 (0.5)	0/149	0/128
傾眠	8/244 (3.3)	7/182 (3.8)	4/149 (2.7)	3/128 (2.3)
失神	0/244	1/182 (0.5)	0/149	1/128 (0.8)
振戦	2/244 (0.8)	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
末梢性ニューロパチー	1/114 (0.9)	0/1	0/0	2/244 (0.8)
オンオフ現象	1/114 (0.9)	0/1	0/0	8/244 (3.3)
錯感覚	2/114 (1.8)	1/1 (100)	0/0	7/244 (2.9)
パーキンソン病	2/114 (1.8)	0/1	0/0	17/244 (7.0)
パーキンソニズム	1/114 (0.9)	0/1	0/0	3/244 (1.2)
側反弓	2/114 (1.8)	0/1	0/0	3/244 (1.2)
多発ニューロパチー	1/114 (0.9)	0/1	0/0	2/244 (0.8)
失神寸前の状態	0/114	0/1	0/0	1/244 (0.4)
心因性発作	0/114	0/1	0/0	1/244 (0.4)
精神運動亢進	0/114	0/1	0/0	2/244 (0.8)
反射異常	1/114 (0.9)	0/1	0/0	1/244 (0.4)
安静時振戦	0/114	0/1	0/0	1/244 (0.4)
坐骨神経痛	0/114	0/1	0/0	3/244 (1.2)
痙攣発作	1/114 (0.9)	0/1	0/0	1/244 (0.4)
感覚障害	0/114	0/1	0/0	1/244 (0.4)
感覚消失	0/114	0/1	0/0	1/244 (0.4)
睡眠時麻痺	0/114	0/1	0/0	1/244 (0.4)
傾眠	2/114 (1.8)	0/1	0/0	12/244 (4.9)
失神	1/114 (0.9)	0/1	0/0	3/244 (1.2)
振戦	0/114	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
製品の問題	3/244 (1.2)	0/182	0/149	0/128
医療機器送達システムの問題	1/244 (0.4)	0/182	0/149	0/128
医療機器位置異常	1/244 (0.4)	0/182	0/149	0/128
医療機器機能不良	1/244 (0.4)	0/182	0/149	0/128
精神障害	90/244 (36.9)	60/182 (33.0)	49/149 (32.9)	41/128 (32.0)
異常な夢	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
感情不安定	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
激越	1/244 (0.4)	0/182	0/149	0/128
不安	22/244 (9.0)	14/182 (7.7)	14/149 (9.4)	13/128 (10.2)
不安障害	0/244	0/182	0/149	1/128 (0.8)
無感情	0/244	1/182 (0.5)	0/149	0/128
歯ぎしり	2/244 (0.8)	1/182 (0.5)	0/149	0/128
強迫行為	1/244 (0.4)	0/182	0/149	0/128
強迫性性行動	0/244	0/182	1/149 (0.7)	0/128
錯乱状態	5/244 (2.0)	3/182 (1.6)	3/149 (2.0)	3/128 (2.3)
譫妄	4/244 (1.6)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
妄想	7/244 (2.9)	5/182 (2.7)	3/149 (2.0)	2/128 (1.6)
寄生虫妄想	0/244	1/182 (0.5)	0/149	0/128
妄想性障害、詳細不明	1/244 (0.4)	1/182 (0.5)	0/149	0/128
抑うつ気分	2/244 (0.8)	3/182 (1.6)	3/149 (2.0)	2/128 (1.6)
うつ病	1/244 (0.4)	2/182 (1.1)	2/149 (1.3)	2/128 (1.6)
抑うつ症状	2/244 (0.8)	0/182	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
製品の問題	0/114	0/1	0/0	3/244 (1.2)
医療機器送達システムの問題	0/114	0/1	0/0	1/244 (0.4)
医療機器位置異常	0/114	0/1	0/0	1/244 (0.4)
医療機器機能不良	0/114	0/1	0/0	1/244 (0.4)
精神障害	29/114 (25.4)	0/1	0/0	104/244 (42.6)
異常な夢	1/114 (0.9)	0/1	0/0	1/244 (0.4)
感情不安定	0/114	0/1	0/0	2/244 (0.8)
激越	0/114	0/1	0/0	1/244 (0.4)
不安	10/114 (8.8)	0/1	0/0	28/244 (11.5)
不安障害	1/114 (0.9)	0/1	0/0	1/244 (0.4)
無感情	0/114	0/1	0/0	1/244 (0.4)
歯ぎしり	0/114	0/1	0/0	2/244 (0.8)
強迫行為	0/114	0/1	0/0	1/244 (0.4)
強迫性性行動	0/114	0/1	0/0	1/244 (0.4)
錯乱状態	0/114	0/1	0/0	8/244 (3.3)
譫妄	0/114	0/1	0/0	5/244 (2.0)
妄想	1/114 (0.9)	0/1	0/0	10/244 (4.1)
寄生虫妄想	0/114	0/1	0/0	1/244 (0.4)
妄想性障害、詳細不明	0/114	0/1	0/0	1/244 (0.4)
抑うつ気分	1/114 (0.9)	0/1	0/0	3/244 (1.2)
うつ病	1/114 (0.9)	0/1	0/0	4/244 (1.6)
抑うつ症状	0/114	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
ドーパミン調節障害症候群	0/244	0/182	0/149	1/128 (0.8)
ディスフェミア	0/244	0/182	1/149 (0.7)	0/128
睡眠異常	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
情動障害	1/244 (0.4)	1/182 (0.5)	0/149	0/128
注射恐怖	0/244	1/182 (0.5)	0/149	0/128
幻覚	33/244 (13.5)	20/182 (11.0)	14/149 (9.4)	13/128 (10.2)
幻聴	2/244 (0.8)	4/182 (2.2)	3/149 (2.0)	2/128 (1.6)
幻嗅	1/244 (0.4)	0/182	0/149	0/128
幻視	10/244 (4.1)	7/182 (3.8)	7/149 (4.7)	4/128 (3.1)
混合性幻覚	1/244 (0.4)	0/182	0/149	0/128
性欲過剰	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
錯覚	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
衝動制御障害	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
衝動行為	0/244	0/182	0/149	1/128 (0.8)
不眠症	15/244 (6.1)	9/182 (4.9)	5/149 (3.4)	5/128 (3.9)
易刺激性	2/244 (0.8)	2/182 (1.1)	0/149	0/128
嫉妬妄想	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
躁病	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
気分変化	1/244 (0.4)	0/182	0/149	0/128
気分動揺	0/244	1/182 (0.5)	0/149	0/128
悪夢	1/244 (0.4)	1/182 (0.5)	0/149	0/128
強迫観念	1/244 (0.4)	1/182 (0.5)	0/149	0/128
パニック発作	3/244 (1.2)	0/182	1/149 (0.7)	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
ドーパミン調節障害症候群	0/114	0/1	0/0	1/244 (0.4)
ディスフェミア	0/114	0/1	0/0	1/244 (0.4)
睡眠異常	1/114 (0.9)	0/1	0/0	1/244 (0.4)
情動障害	0/114	0/1	0/0	2/244 (0.8)
注射恐怖	0/114	0/1	0/0	1/244 (0.4)
幻覚	8/114 (7.0)	0/1	0/0	41/244 (16.8)
幻聴	1/114 (0.9)	0/1	0/0	6/244 (2.5)
幻嗅	0/114	0/1	0/0	1/244 (0.4)
幻視	3/114 (2.6)	0/1	0/0	15/244 (6.1)
混合性幻覚	0/114	0/1	0/0	1/244 (0.4)
性欲過剰	0/114	0/1	0/0	1/244 (0.4)
錯覚	0/114	0/1	0/0	1/244 (0.4)
衝動制御障害	1/114 (0.9)	0/1	0/0	4/244 (1.6)
衝動行為	1/114 (0.9)	0/1	0/0	1/244 (0.4)
不眠症	5/114 (4.4)	0/1	0/0	18/244 (7.4)
易刺激性	0/114	0/1	0/0	2/244 (0.8)
嫉妬妄想	0/114	0/1	0/0	1/244 (0.4)
躁病	0/114	0/1	0/0	1/244 (0.4)
気分変化	0/114	0/1	0/0	1/244 (0.4)
気分動揺	0/114	0/1	0/0	1/244 (0.4)
悪夢	0/114	0/1	0/0	2/244 (0.8)
強迫観念	0/114	0/1	0/0	1/244 (0.4)
パニック発作	1/114 (0.9)	0/1	0/0	3/244 (1.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
パニック反応	0/244	0/182	1/149 (0.7)	1/128 (0.8)
妄想症	0/244	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
睡眠の質低下	0/244	1/182 (0.5)	0/149	0/128
処置に対する不安	0/244	1/182 (0.5)	0/149	0/128
精神病性障害	3/244 (1.2)	2/182 (1.1)	3/149 (2.0)	2/128 (1.6)
精神病症状	0/244	0/182	0/149	1/128 (0.8)
レム睡眠行動障害	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
レム睡眠異常	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
睡眠障害	2/244 (0.8)	2/182 (1.1)	1/149 (0.7)	1/128 (0.8)
ねごと	1/244 (0.4)	2/182 (1.1)	0/149	0/128
常同症	0/244	0/182	0/149	1/128 (0.8)
ストレス	1/244 (0.4)	0/182	0/149	0/128
自殺念慮	2/244 (0.8)	2/182 (1.1)	1/149 (0.7)	0/128
自殺企図	0/244	0/182	0/149	1/128 (0.8)
腎および尿路障害	10/244 (4.1)	7/182 (3.8)	9/149 (6.0)	9/128 (7.0)
膀胱痙縮	0/244	0/182	1/149 (0.7)	1/128 (0.8)
膀胱結石	0/244	1/182 (0.5)	0/149	0/128
排尿困難	2/244 (0.8)	0/182	0/149	1/128 (0.8)
緊張性膀胱	0/244	0/182	0/149	1/128 (0.8)
夜間頻尿	0/244	1/182 (0.5)	1/149 (0.7)	0/128
多尿	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
パニック反応	0/114	0/1	0/0	1/244 (0.4)
妄想症	1/114 (0.9)	0/1	0/0	2/244 (0.8)
睡眠の質低下	0/114	0/1	0/0	1/244 (0.4)
処置に対する不安	0/114	0/1	0/0	1/244 (0.4)
精神病性障害	1/114 (0.9)	0/1	0/0	6/244 (2.5)
精神病症状	1/114 (0.9)	0/1	0/0	1/244 (0.4)
レム睡眠行動障害	1/114 (0.9)	0/1	0/0	2/244 (0.8)
レム睡眠異常	1/114 (0.9)	0/1	0/0	1/244 (0.4)
睡眠障害	0/114	0/1	0/0	3/244 (1.2)
ねごと	0/114	0/1	0/0	2/244 (0.8)
常同症	1/114 (0.9)	0/1	0/0	1/244 (0.4)
ストレス	0/114	0/1	0/0	1/244 (0.4)
自殺念慮	0/114	0/1	0/0	3/244 (1.2)
自殺企図	0/114	0/1	0/0	1/244 (0.4)
腎および尿路障害	6/114 (5.3)	0/1	0/0	18/244 (7.4)
膀胱痙縮	1/114 (0.9)	0/1	0/0	1/244 (0.4)
膀胱結石	0/114	0/1	0/0	1/244 (0.4)
排尿困難	1/114 (0.9)	0/1	0/0	3/244 (1.2)
緊張性膀胱	1/114 (0.9)	0/1	0/0	1/244 (0.4)
夜間頻尿	0/114	0/1	0/0	1/244 (0.4)
多尿	1/114 (0.9)	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
腎機能障害	0/244	0/182	1/149 (0.7)	0/128
尿管結石症	1/244 (0.4)	0/182	0/149	0/128
切迫性尿失禁	3/244 (1.2)	3/182 (1.6)	2/149 (1.3)	2/128 (1.6)
尿失禁	2/244 (0.8)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
尿閉	0/244	0/182	1/149 (0.7)	3/128 (2.3)
尿路障害	1/244 (0.4)	0/182	0/149	0/128
尿異常	1/244 (0.4)	0/182	0/149	0/128
尿臭異常	0/244	0/182	1/149 (0.7)	1/128 (0.8)
生殖系および乳房障害	3/244 (1.2)	4/182 (2.2)	4/149 (2.7)	4/128 (3.1)
良性前立腺肥大症	0/244	0/182	1/149 (0.7)	1/128 (0.8)
勃起不全	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
ペイロニー病	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
前立腺腫大	0/244	1/182 (0.5)	0/149	0/128
腟脱	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
呼吸器、胸郭および縦隔障害	15/244 (6.1)	7/182 (3.8)	6/149 (4.0)	4/128 (3.1)
急性呼吸不全	1/244 (0.4)	0/182	0/149	0/128
気管支拡張症	0/244	0/182	1/149 (0.7)	0/128
咳嗽	3/244 (1.2)	1/182 (0.5)	0/149	0/128
発声障害	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
腎および尿路障害 (Cont.)				
腎機能障害	0/114	0/1	0/0	1/244 (0.4)
尿管結石症	0/114	0/1	0/0	1/244 (0.4)
切迫性尿失禁	1/114 (0.9)	0/1	0/0	3/244 (1.2)
尿失禁	0/114	0/1	0/0	5/244 (2.0)
尿閉	1/114 (0.9)	0/1	0/0	3/244 (1.2)
尿路障害	0/114	0/1	0/0	1/244 (0.4)
尿異常	0/114	0/1	0/0	1/244 (0.4)
尿臭異常	0/114	0/1	0/0	1/244 (0.4)
生殖系および乳房障害	3/114 (2.6)	0/1	0/0	6/244 (2.5)
良性前立腺肥大症	0/114	0/1	0/0	1/244 (0.4)
勃起不全	1/114 (0.9)	0/1	0/0	2/244 (0.8)
ペイロニー病	1/114 (0.9)	0/1	0/0	1/244 (0.4)
前立腺腫大	0/114	0/1	0/0	1/244 (0.4)
膣脱	1/114 (0.9)	0/1	0/0	1/244 (0.4)
呼吸器、胸郭および縦隔障害	3/114 (2.6)	0/1	0/0	25/244 (10.2)
急性呼吸不全	0/114	0/1	0/0	1/244 (0.4)
気管支拡張症	0/114	0/1	0/0	1/244 (0.4)
咳嗽	0/114	0/1	0/0	3/244 (1.2)
発声障害	0/114	0/1	0/0	2/244 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	5/244 (2.0)	2/182 (1.1)	1/149 (0.7)	0/128
労作性呼吸困難	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
鼻出血	0/244	0/182	1/149 (0.7)	0/128
過換気	2/244 (0.8)	0/182	0/149	0/128
口腔咽頭痛	1/244 (0.4)	1/182 (0.5)	0/149	0/128
誤嚥性肺炎	0/244	0/182	0/149	1/128 (0.8)
湿性咳嗽	0/244	0/182	1/149 (0.7)	0/128
肺塞栓症	1/244 (0.4)	0/182	0/149	1/128 (0.8)
ラ音	0/244	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
鼻痛	1/244 (0.4)	0/182	0/149	0/128
鼻漏	2/244 (0.8)	0/182	0/149	0/128
咽喉刺激感	1/244 (0.4)	0/182	0/149	0/128
皮膚および皮下組織障害	22/244 (9.0)	13/182 (7.1)	10/149 (6.7)	10/128 (7.8)
脱毛症	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
褥瘡性潰瘍	1/244 (0.4)	1/182 (0.5)	0/149	0/128
皮膚嚢腫	1/244 (0.4)	1/182 (0.5)	0/149	1/128 (0.8)
皮膚炎	1/244 (0.4)	1/182 (0.5)	0/149	0/128
接触皮膚炎	1/244 (0.4)	0/182	0/149	1/128 (0.8)
おむつ皮膚炎	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
薬疹	1/244 (0.4)	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/114 (0.9)	0/1	0/0	8/244 (3.3)
労作性呼吸困難	1/114 (0.9)	0/1	0/0	1/244 (0.4)
鼻出血	0/114	0/1	0/0	1/244 (0.4)
過換気	0/114	0/1	0/0	2/244 (0.8)
口腔咽頭痛	0/114	0/1	0/0	2/244 (0.8)
誤嚥性肺炎	0/114	0/1	0/0	1/244 (0.4)
湿性咳嗽	0/114	0/1	0/0	1/244 (0.4)
肺塞栓症	1/114 (0.9)	0/1	0/0	2/244 (0.8)
ラ音	0/114	0/1	0/0	1/244 (0.4)
鼻痛	0/114	0/1	0/0	1/244 (0.4)
鼻漏	0/114	0/1	0/0	2/244 (0.8)
咽喉刺激感	0/114	0/1	0/0	1/244 (0.4)
皮膚および皮下組織障害	6/114 (5.3)	0/1	0/0	28/244 (11.5)
脱毛症	1/114 (0.9)	0/1	0/0	2/244 (0.8)
褥瘡性潰瘍	0/114	0/1	0/0	1/244 (0.4)
皮膚嚢腫	0/114	0/1	0/0	2/244 (0.8)
皮膚炎	0/114	0/1	0/0	1/244 (0.4)
接触皮膚炎	1/114 (0.9)	0/1	0/0	2/244 (0.8)
おむつ皮膚炎	1/114 (0.9)	0/1	0/0	1/244 (0.4)
薬疹	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	1/244 (0.4)	1/182 (0.5)	0/149	0/128
斑状出血	1/244 (0.4)	0/182	0/149	0/128
紅斑	4/244 (1.6)	0/182	0/149	0/128
爪の障害	0/244	0/182	1/149 (0.7)	1/128 (0.8)
脂肪織炎	0/244	0/182	1/149 (0.7)	1/128 (0.8)
丘疹	2/244 (0.8)	2/182 (1.1)	2/149 (1.3)	1/128 (0.8)
光線過敏性反応	1/244 (0.4)	0/182	0/149	0/128
そう痒症	1/244 (0.4)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
乾癬	0/244	1/182 (0.5)	1/149 (0.7)	0/128
発疹	2/244 (0.8)	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
紅斑性皮疹	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	1/128 (0.8)
そう痒性皮疹	2/244 (0.8)	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
皮膚刺激	1/244 (0.4)	0/182	0/149	0/128
皮膚病変	1/244 (0.4)	1/182 (0.5)	1/149 (0.7)	0/128
皮膚潰瘍	2/244 (0.8)	1/182 (0.5)	1/149 (0.7)	0/128
蕁麻疹	0/244	1/182 (0.5)	2/149 (1.3)	1/128 (0.8)
社会環境	1/244 (0.4)	1/182 (0.5)	0/149	0/128
運動不能	1/244 (0.4)	1/182 (0.5)	0/149	0/128

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
皮膚および皮下組織障害 (Cont.)				
皮膚乾燥	0/114	0/1	0/0	2/244 (0.8)
斑状出血	0/114	0/1	0/0	1/244 (0.4)
紅斑	0/114	0/1	0/0	4/244 (1.6)
爪の障害	1/114 (0.9)	0/1	0/0	1/244 (0.4)
脂肪織炎	0/114	0/1	0/0	1/244 (0.4)
丘疹	1/114 (0.9)	0/1	0/0	2/244 (0.8)
光線過敏性反応	0/114	0/1	0/0	1/244 (0.4)
そう痒症	1/114 (0.9)	0/1	0/0	3/244 (1.2)
乾癬	0/114	0/1	0/0	1/244 (0.4)
発疹	1/114 (0.9)	0/1	0/0	3/244 (1.2)
紅斑性皮疹	1/114 (0.9)	0/1	0/0	1/244 (0.4)
そう痒性皮疹	1/114 (0.9)	0/1	0/0	3/244 (1.2)
皮膚刺激	0/114	0/1	0/0	1/244 (0.4)
皮膚病変	0/114	0/1	0/0	1/244 (0.4)
皮膚潰瘍	0/114	0/1	0/0	2/244 (0.8)
蕁麻疹	0/114	0/1	0/0	2/244 (0.8)
社会環境	0/114	0/1	0/0	1/244 (0.4)
運動不能	0/114	0/1	0/0	1/244 (0.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Total (Any Dose)				
外科および内科処置	0/244	1/182 (0.5)	0/149	0/128
抜歯	0/244	1/182 (0.5)	0/149	0/128
血管障害	13/244 (5.3)	6/182 (3.3)	10/149 (6.7)	12/128 (9.4)
深部静脈血栓症	1/244 (0.4)	0/182	0/149	0/128
血腫	0/244	0/182	0/149	1/128 (0.8)
出血	0/244	1/182 (0.5)	0/149	0/128
ほてり	1/244 (0.4)	0/182	0/149	0/128
高血圧	4/244 (1.6)	0/182	1/149 (0.7)	2/128 (1.6)
高血圧クリーゼ	1/244 (0.4)	0/182	0/149	0/128
低血圧	3/244 (1.2)	1/182 (0.5)	2/149 (1.3)	2/128 (1.6)
不安定血圧	1/244 (0.4)	0/182	0/149	0/128
起立性高血圧	0/244	0/182	0/149	0/128
起立性低血圧	5/244 (2.0)	4/182 (2.2)	7/149 (4.7)	8/128 (6.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Total (Any Dose)				
外科および内科処置	0/114	0/1	0/0	1/244 (0.4)
抜歯	0/114	0/1	0/0	1/244 (0.4)
血管障害	12/114 (10.5)	0/1	0/0	26/244 (10.7)
深部静脈血栓症	0/114	0/1	0/0	1/244 (0.4)
血腫	0/114	0/1	0/0	1/244 (0.4)
出血	0/114	0/1	0/0	1/244 (0.4)
ほてり	0/114	0/1	0/0	1/244 (0.4)
高血圧	0/114	0/1	0/0	6/244 (2.5)
高血圧クリーゼ	0/114	0/1	0/0	1/244 (0.4)
低血圧	3/114 (2.6)	0/1	0/0	6/244 (2.5)
不安定血圧	0/114	0/1	0/0	1/244 (0.4)
起立性高血圧	1/114 (0.9)	0/1	0/0	1/244 (0.4)
起立性低血圧	8/114 (7.0)	0/1	0/0	12/244 (4.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
Any adverse event	120/132 (90.9)	83/97 (85.6)	67/79 (84.8)	59/70 (84.3)
血液およびリンパ系障害	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
リンパ節症	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
心臓障害	1/132 (0.8)	2/97 (2.1)	1/79 (1.3)	3/70 (4.3)
急性心筋梗塞	0/132	0/97	0/79	1/70 (1.4)
狭心症	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
心停止	0/132	0/97	0/79	1/70 (1.4)
冠動脈疾患	0/132	0/97	0/79	1/70 (1.4)
冠動脈狭窄	0/132	0/97	0/79	1/70 (1.4)
心筋梗塞	1/132 (0.8)	1/97 (1.0)	0/79	0/70
耳および迷路障害	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
感音性難聴	0/132	0/97	1/79 (1.3)	1/70 (1.4)
回転性めまい	2/132 (1.5)	1/97 (1.0)	0/79	0/70
眼障害	2/132 (1.5)	3/97 (3.1)	3/79 (3.8)	4/70 (5.7)
白内障	0/132	0/97	1/79 (1.3)	2/70 (2.9)
複視	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
ドライアイ	1/132 (0.8)	0/97	0/79	0/70
緑内障	0/132	0/97	0/79	1/70 (1.4)
網膜裂孔	0/132	2/97 (2.1)	1/79 (1.3)	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
Any adverse event	48/63 (76.2)	1/1 (100)	0/0	122/132 (92.4)
血液およびリンパ系障害	0/63	0/1	0/0	1/132 (0.8)
リンパ節症	0/63	0/1	0/0	1/132 (0.8)
心臓障害	2/63 (3.2)	0/1	0/0	4/132 (3.0)
急性心筋梗塞	0/63	0/1	0/0	1/132 (0.8)
狭心症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
心停止	0/63	0/1	0/0	1/132 (0.8)
冠動脈疾患	1/63 (1.6)	0/1	0/0	1/132 (0.8)
冠動脈狭窄	0/63	0/1	0/0	1/132 (0.8)
心筋梗塞	0/63	0/1	0/0	1/132 (0.8)
耳および迷路障害	1/63 (1.6)	0/1	0/0	4/132 (3.0)
感音性難聴	1/63 (1.6)	0/1	0/0	1/132 (0.8)
回転性めまい	0/63	0/1	0/0	3/132 (2.3)
眼障害	2/63 (3.2)	0/1	0/0	7/132 (5.3)
白内障	0/63	0/1	0/0	2/132 (1.5)
複視	1/63 (1.6)	0/1	0/0	2/132 (1.5)
ドライアイ	0/63	0/1	0/0	1/132 (0.8)
緑内障	1/63 (1.6)	0/1	0/0	1/132 (0.8)
網膜裂孔	0/63	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	1/132 (0.8)	0/97	0/79	0/70
胃腸障害	18/132 (13.6)	14/97 (14.4)	12/79 (15.2)	7/70 (10.0)
腹部膨満	0/132	1/97 (1.0)	1/79 (1.3)	0/70
腹痛	1/132 (0.8)	1/97 (1.0)	0/79	0/70
上腹部痛	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
アフタ性潰瘍	1/132 (0.8)	0/97	0/79	0/70
呼気臭	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
虚血性大腸炎	0/132	1/97 (1.0)	0/79	0/70
便秘	5/132 (3.8)	4/97 (4.1)	4/79 (5.1)	3/70 (4.3)
齲歯	0/132	0/97	1/79 (1.3)	0/70
下痢	3/132 (2.3)	2/97 (2.1)	2/79 (2.5)	0/70
口内乾燥	3/132 (2.3)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
消化不良	1/132 (0.8)	0/97	0/79	0/70
胃食道逆流性疾患	0/132	0/97	1/79 (1.3)	1/70 (1.4)
舌炎	0/132	1/97 (1.0)	1/79 (1.3)	0/70
舌痛	0/132	1/97 (1.0)	1/79 (1.3)	0/70
吐血	0/132	0/97	0/79	1/70 (1.4)
痔核	1/132 (0.8)	0/97	0/79	0/70
裂孔ヘルニア	0/132	0/97	0/79	1/70 (1.4)
胃排出不全	0/132	0/97	0/79	1/70 (1.4)
腸出血	0/132	1/97 (1.0)	0/79	0/70
過敏性腸症候群	1/132 (0.8)	1/97 (1.0)	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
眼障害 (Cont.)				
霧視	0/63	0/1	0/0	1/132 (0.8)
胃腸障害	5/63 (7.9)	0/1	0/0	27/132 (20.5)
腹部膨満	0/63	0/1	0/0	1/132 (0.8)
腹痛	0/63	0/1	0/0	2/132 (1.5)
上腹部痛	0/63	0/1	0/0	1/132 (0.8)
アフタ性潰瘍	0/63	0/1	0/0	1/132 (0.8)
呼気臭	0/63	0/1	0/0	2/132 (1.5)
虚血性大腸炎	0/63	0/1	0/0	1/132 (0.8)
便秘	3/63 (4.8)	0/1	0/0	8/132 (6.1)
齲歯	0/63	0/1	0/0	1/132 (0.8)
下痢	0/63	0/1	0/0	6/132 (4.5)
口内乾燥	0/63	0/1	0/0	3/132 (2.3)
消化不良	0/63	0/1	0/0	1/132 (0.8)
胃食道逆流性疾患	1/63 (1.6)	0/1	0/0	1/132 (0.8)
舌炎	0/63	0/1	0/0	1/132 (0.8)
舌痛	0/63	0/1	0/0	1/132 (0.8)
吐血	0/63	0/1	0/0	1/132 (0.8)
痔核	0/63	0/1	0/0	1/132 (0.8)
裂孔ヘルニア	1/63 (1.6)	0/1	0/0	1/132 (0.8)
胃排出不全	1/63 (1.6)	0/1	0/0	1/132 (0.8)
腸出血	0/63	0/1	0/0	1/132 (0.8)
過敏性腸症候群	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
胃腸障害 (Cont.)				
口唇乾燥	0/132	1/97 (1.0)	0/79	0/70
メレナ	1/132 (0.8)	2/97 (2.1)	0/79	0/70
口腔腫脹	0/132	1/97 (1.0)	0/79	0/70
悪心	5/132 (3.8)	4/97 (4.1)	2/79 (2.5)	2/70 (2.9)
口腔内不快感	0/132	1/97 (1.0)	1/79 (1.3)	0/70
口腔内痛	0/132	0/97	1/79 (1.3)	0/70
口の錯感覚	0/132	0/97	1/79 (1.3)	0/70
直腸出血	0/132	1/97 (1.0)	1/79 (1.3)	0/70
嘔吐	2/132 (1.5)	1/97 (1.0)	0/79	1/70 (1.4)
一般・全身障害および投与部位の状態	102/132 (77.3)	61/97 (62.9)	44/79 (55.7)	37/70 (52.9)
投与部位紅斑	1/132 (0.8)	0/97	0/79	0/70
無力症	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
カテーテル留置部位紅斑	1/132 (0.8)	1/97 (1.0)	0/79	0/70
カテーテル留置部位漏出	0/132	0/97	1/79 (1.3)	0/70
胸痛	0/132	0/97	0/79	1/70 (1.4)
泣き	0/132	1/97 (1.0)	0/79	0/70
不快感	1/132 (0.8)	0/97	0/79	0/70
薬剤離脱症候群	1/132 (0.8)	0/97	0/79	0/70
疲労	4/132 (3.0)	2/97 (2.1)	2/79 (2.5)	2/70 (2.9)
異常感	1/132 (0.8)	0/97	0/79	0/70
熱感	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
胃腸障害 (Cont.)				
口唇乾燥	0/63	0/1	0/0	1/132 (0.8)
メレナ	0/63	0/1	0/0	2/132 (1.5)
口腔腫脹	0/63	0/1	0/0	1/132 (0.8)
悪心	1/63 (1.6)	0/1	0/0	8/132 (6.1)
口腔内不快感	0/63	0/1	0/0	1/132 (0.8)
口腔内痛	0/63	0/1	0/0	1/132 (0.8)
口の錯感覚	0/63	0/1	0/0	1/132 (0.8)
直腸出血	0/63	0/1	0/0	1/132 (0.8)
嘔吐	0/63	0/1	0/0	3/132 (2.3)
一般・全身障害および投与部位の状態	32/63 (50.8)	0/1	0/0	106/132 (80.3)
投与部位紅斑	0/63	0/1	0/0	1/132 (0.8)
無力症	0/63	0/1	0/0	3/132 (2.3)
カテーテル留置部位紅斑	0/63	0/1	0/0	1/132 (0.8)
カテーテル留置部位漏出	0/63	0/1	0/0	1/132 (0.8)
胸痛	1/63 (1.6)	0/1	0/0	1/132 (0.8)
泣き	0/63	0/1	0/0	1/132 (0.8)
不快感	0/63	0/1	0/0	1/132 (0.8)
薬剤離脱症候群	0/63	0/1	0/0	1/132 (0.8)
疲労	2/63 (3.2)	0/1	0/0	6/132 (4.5)
異常感	0/63	0/1	0/0	1/132 (0.8)
熱感	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
歩行不能	1/132 (0.8)	0/97	0/79	0/70
低体温	1/132 (0.8)	0/97	0/79	0/70
インフルエンザ様疾患	1/132 (0.8)	0/97	0/79	0/70
注入部位内出血	7/132 (5.3)	6/97 (6.2)	4/79 (5.1)	2/70 (2.9)
注入部位皮膚炎	1/132 (0.8)	1/97 (1.0)	0/79	2/70 (2.9)
注入部位分泌物	1/132 (0.8)	0/97	0/79	0/70
注入部位変色	2/132 (1.5)	1/97 (1.0)	0/79	0/70
注入部位不快感	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	0/70
注入部位びらん	1/132 (0.8)	0/97	0/79	0/70
注入部位紅斑	60/132 (45.5)	25/97 (25.8)	14/79 (17.7)	12/70 (17.1)
注入部位皮膚剥脱	2/132 (1.5)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
注入部位血管外漏出	6/132 (4.5)	6/97 (6.2)	2/79 (2.5)	1/70 (1.4)
注入部位血腫	5/132 (3.8)	0/97	1/79 (1.3)	2/70 (2.9)
注入部位出血	3/132 (2.3)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
注入部位硬結	6/132 (4.5)	4/97 (4.1)	1/79 (1.3)	2/70 (2.9)
注入部位炎症	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
注入部位損傷	1/132 (0.8)	0/97	0/79	0/70
注入部位刺激感	0/132	0/97	1/79 (1.3)	0/70
注入部位腫瘤	5/132 (3.8)	1/97 (1.0)	1/79 (1.3)	0/70
注入部位結節	28/132 (21.2)	24/97 (24.7)	21/79 (26.6)	20/70 (28.6)
注入部位浮腫	16/132 (12.1)	5/97 (5.2)	4/79 (5.1)	3/70 (4.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
歩行不能	0/63	0/1	0/0	1/132 (0.8)
低体温	0/63	0/1	0/0	1/132 (0.8)
インフルエンザ様疾患	0/63	0/1	0/0	1/132 (0.8)
注入部位内出血	2/63 (3.2)	0/1	0/0	10/132 (7.6)
注入部位皮膚炎	1/63 (1.6)	0/1	0/0	2/132 (1.5)
注入部位分泌物	0/63	0/1	0/0	1/132 (0.8)
注入部位変色	0/63	0/1	0/0	2/132 (1.5)
注入部位不快感	0/63	0/1	0/0	3/132 (2.3)
注入部位びらん	0/63	0/1	0/0	1/132 (0.8)
注入部位紅斑	11/63 (17.5)	0/1	0/0	65/132 (49.2)
注入部位皮膚剥脱	1/63 (1.6)	0/1	0/0	3/132 (2.3)
注入部位血管外漏出	1/63 (1.6)	0/1	0/0	8/132 (6.1)
注入部位血腫	1/63 (1.6)	0/1	0/0	8/132 (6.1)
注入部位出血	1/63 (1.6)	0/1	0/0	4/132 (3.0)
注入部位硬結	2/63 (3.2)	0/1	0/0	7/132 (5.3)
注入部位炎症	0/63	0/1	0/0	3/132 (2.3)
注入部位損傷	0/63	0/1	0/0	1/132 (0.8)
注入部位刺激感	0/63	0/1	0/0	1/132 (0.8)
注入部位腫瘤	0/63	0/1	0/0	5/132 (3.8)
注入部位結節	19/63 (30.2)	0/1	0/0	34/132 (25.8)
注入部位浮腫	2/63 (3.2)	0/1	0/0	19/132 (14.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位疼痛	14/132 (10.6)	9/97 (9.3)	6/79 (7.6)	5/70 (7.1)
注入部位蒼白	2/132 (1.5)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
注入部位丘疹	2/132 (1.5)	3/97 (3.1)	1/79 (1.3)	1/70 (1.4)
注入部位そう痒感	3/132 (2.3)	1/97 (1.0)	2/79 (2.5)	0/70
注入部位発疹	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	0/70
注入部位反応	9/132 (6.8)	6/97 (6.2)	4/79 (5.1)	3/70 (4.3)
注入部位腫脹	4/132 (3.0)	1/97 (1.0)	1/79 (1.3)	0/70
注射部位内出血	2/132 (1.5)	0/97	0/79	0/70
注射部位変色	0/132	1/97 (1.0)	0/79	0/70
注射部位紅斑	6/132 (4.5)	5/97 (5.2)	3/79 (3.8)	0/70
注射部位漏出	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
注射部位炎症	2/132 (1.5)	1/97 (1.0)	0/79	0/70
注射部位結節	1/132 (0.8)	3/97 (3.1)	2/79 (2.5)	0/70
注射部位浮腫	2/132 (1.5)	0/97	0/79	1/70 (1.4)
注射部位疼痛	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
注射部位反応	0/132	0/97	1/79 (1.3)	1/70 (1.4)
注射部位腫脹	1/132 (0.8)	0/97	1/79 (1.3)	1/70 (1.4)
倦怠感	1/132 (0.8)	0/97	0/79	0/70
医療機器使用部位刺激感	1/132 (0.8)	1/97 (1.0)	0/79	0/70
医療機器使用部位そう痒感	1/132 (0.8)	0/97	0/79	0/70
小結節	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位疼痛	4/63 (6.3)	0/1	0/0	18/132 (13.6)
注入部位蒼白	1/63 (1.6)	0/1	0/0	3/132 (2.3)
注入部位丘疹	2/63 (3.2)	0/1	0/0	7/132 (5.3)
注入部位そう痒感	0/63	0/1	0/0	5/132 (3.8)
注入部位発疹	0/63	0/1	0/0	3/132 (2.3)
注入部位反応	3/63 (4.8)	0/1	0/0	13/132 (9.8)
注入部位腫脹	0/63	0/1	0/0	4/132 (3.0)
注射部位内出血	0/63	0/1	0/0	2/132 (1.5)
注射部位変色	0/63	0/1	0/0	1/132 (0.8)
注射部位紅斑	0/63	0/1	0/0	6/132 (4.5)
注射部位漏出	1/63 (1.6)	0/1	0/0	1/132 (0.8)
注射部位炎症	0/63	0/1	0/0	2/132 (1.5)
注射部位結節	0/63	0/1	0/0	3/132 (2.3)
注射部位浮腫	0/63	0/1	0/0	2/132 (1.5)
注射部位疼痛	1/63 (1.6)	0/1	0/0	2/132 (1.5)
注射部位反応	1/63 (1.6)	0/1	0/0	1/132 (0.8)
注射部位腫脹	0/63	0/1	0/0	2/132 (1.5)
倦怠感	0/63	0/1	0/0	1/132 (0.8)
医療機器使用部位刺激感	0/63	0/1	0/0	1/132 (0.8)
医療機器使用部位そう痒感	0/63	0/1	0/0	1/132 (0.8)
小結節	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
末梢性浮腫	4/132 (3.0)	3/97 (3.1)	3/79 (3.8)	0/70
疼痛	0/132	1/97 (1.0)	0/79	1/70 (1.4)
穿刺部位内出血	1/132 (0.8)	0/97	0/79	0/70
穿刺部位出血	1/132 (0.8)	0/97	0/79	0/70
穿刺部位硬結	2/132 (1.5)	1/97 (1.0)	0/79	0/70
発熱	2/132 (1.5)	0/97	0/79	0/70
口渇	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
血管穿刺部位硬結	1/132 (0.8)	0/97	0/79	0/70
肝胆道系障害	1/132 (0.8)	0/97	0/79	0/70
肝嚢胞	0/132	0/97	0/79	0/70
門脈血栓症	1/132 (0.8)	0/97	0/79	0/70
感染症および寄生虫症	38/132 (28.8)	24/97 (24.7)	16/79 (20.3)	17/70 (24.3)
ボレリア感染	1/132 (0.8)	0/97	0/79	0/70
COVID-19	0/132	0/97	0/79	1/70 (1.4)
COVID-19肺炎	0/132	0/97	1/79 (1.3)	0/70
カテーテル留置部位感染	0/132	0/97	0/79	1/70 (1.4)
蜂巣炎	1/132 (0.8)	0/97	0/79	0/70
結膜炎	1/132 (0.8)	2/97 (2.1)	0/79	0/70
真菌感染	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
一般・全身障害および投与部位の状態(Cont.)				
末梢性浮腫	0/63	0/1	0/0	5/132 (3.8)
疼痛	0/63	0/1	0/0	2/132 (1.5)
穿刺部位内出血	0/63	0/1	0/0	1/132 (0.8)
穿刺部位出血	0/63	0/1	0/0	1/132 (0.8)
穿刺部位硬結	0/63	0/1	0/0	2/132 (1.5)
発熱	0/63	0/1	0/0	2/132 (1.5)
口渇	1/63 (1.6)	0/1	0/0	1/132 (0.8)
血管穿刺部位硬結	0/63	0/1	0/0	1/132 (0.8)
肝胆道系障害	1/63 (1.6)	1/1 (100)	0/0	2/132 (1.5)
肝嚢胞	1/63 (1.6)	1/1 (100)	0/0	1/132 (0.8)
門脈血栓症	0/63	0/1	0/0	1/132 (0.8)
感染症および寄生虫症	7/63 (11.1)	0/1	0/0	58/132 (43.9)
ボレリア感染	0/63	0/1	0/0	1/132 (0.8)
COVID-19	0/63	0/1	0/0	1/132 (0.8)
COVID-19肺炎	0/63	0/1	0/0	1/132 (0.8)
カテーテル留置部位感染	1/63 (1.6)	0/1	0/0	1/132 (0.8)
蜂巣炎	0/63	0/1	0/0	1/132 (0.8)
結膜炎	0/63	0/1	0/0	2/132 (1.5)
真菌感染	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
麦粒腫	0/132	1/97 (1.0)	0/79	0/70
注入部位膿瘍	9/132 (6.8)	3/97 (3.1)	2/79 (2.5)	2/70 (2.9)
注入部位蜂巣炎	19/132 (14.4)	11/97 (11.3)	8/79 (10.1)	9/70 (12.9)
注入部位感染	1/132 (0.8)	3/97 (3.1)	0/79	2/70 (2.9)
上咽頭炎	1/132 (0.8)	2/97 (2.1)	0/79	2/70 (2.9)
肺炎	1/132 (0.8)	0/97	2/79 (2.5)	1/70 (1.4)
術後膿瘍	0/132	0/97	1/79 (1.3)	0/70
膿疱性皮疹	1/132 (0.8)	0/97	0/79	0/70
敗血症	2/132 (1.5)	1/97 (1.0)	0/79	1/70 (1.4)
敗血症性ショック	1/132 (0.8)	0/97	0/79	0/70
副鼻腔炎	1/132 (0.8)	1/97 (1.0)	0/79	0/70
ブドウ球菌感染	0/132	0/97	0/79	1/70 (1.4)
歯感染	1/132 (0.8)	1/97 (1.0)	0/79	0/70
上気道感染	1/132 (0.8)	0/97	0/79	0/70
尿路感染	5/132 (3.8)	2/97 (2.1)	1/79 (1.3)	2/70 (2.9)
水痘帯状疱疹ウイルス感染	0/132	1/97 (1.0)	0/79	0/70
傷害、中毒および処置合併症	13/132 (9.8)	8/97 (8.2)	5/79 (6.3)	5/70 (7.1)
骨挫傷	0/132	0/97	0/79	1/70 (1.4)
脳挫傷	1/132 (0.8)	0/97	0/79	0/70
挫傷	1/132 (0.8)	1/97 (1.0)	0/79	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
歯肉炎	0/63	0/1	0/0	1/132 (0.8)
麦粒腫	0/63	0/1	0/0	1/132 (0.8)
注入部位膿瘍	1/63 (1.6)	0/1	0/0	13/132 (9.8)
注入部位蜂巣炎	3/63 (4.8)	0/1	0/0	29/132 (22.0)
注入部位感染	0/63	0/1	0/0	6/132 (4.5)
上咽頭炎	1/63 (1.6)	0/1	0/0	5/132 (3.8)
肺炎	0/63	0/1	0/0	3/132 (2.3)
術後膿瘍	0/63	0/1	0/0	1/132 (0.8)
膿疱性皮疹	0/63	0/1	0/0	1/132 (0.8)
敗血症	0/63	0/1	0/0	3/132 (2.3)
敗血症性ショック	0/63	0/1	0/0	1/132 (0.8)
副鼻腔炎	0/63	0/1	0/0	1/132 (0.8)
ブドウ球菌感染	0/63	0/1	0/0	1/132 (0.8)
歯感染	0/63	0/1	0/0	1/132 (0.8)
上気道感染	0/63	0/1	0/0	1/132 (0.8)
尿路感染	1/63 (1.6)	0/1	0/0	8/132 (6.1)
水痘帯状疱疹ウイルス感染	0/63	0/1	0/0	1/132 (0.8)
傷害、中毒および処置合併症	4/63 (6.3)	0/1	0/0	21/132 (15.9)
骨挫傷	1/63 (1.6)	0/1	0/0	1/132 (0.8)
脳挫傷	0/63	0/1	0/0	1/132 (0.8)
挫傷	1/63 (1.6)	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	1/132 (0.8)	0/97	0/79	0/70
医療機器による投与の欠落	1/132 (0.8)	0/97	0/79	0/70
期限切れの製品使用	1/132 (0.8)	0/97	0/79	0/70
転倒	9/132 (6.8)	8/97 (8.2)	3/79 (3.8)	3/70 (4.3)
頭部損傷	1/132 (0.8)	1/97 (1.0)	0/79	0/70
注入に伴う反応	1/132 (0.8)	0/97	0/79	0/70
靭帯捻挫	0/132	1/97 (1.0)	0/79	0/70
処置後挫傷	1/132 (0.8)	0/97	0/79	0/70
肋骨骨折	0/132	1/97 (1.0)	1/79 (1.3)	0/70
皮膚擦過傷	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
皮膚損傷	1/132 (0.8)	0/97	0/79	0/70
皮膚裂傷	0/132	1/97 (1.0)	0/79	0/70
ストレス骨折	0/132	0/97	1/79 (1.3)	1/70 (1.4)
腱断裂	0/132	0/97	0/79	1/70 (1.4)
創傷	0/132	0/97	0/79	1/70 (1.4)
臨床検査	15/132 (11.4)	12/97 (12.4)	13/79 (16.5)	13/70 (18.6)
血中クレアチンホスホキナーゼ増加	1/132 (0.8)	0/97	0/79	0/70
血中葉酸減少	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
血中ホモシステイン増加	0/132	0/97	0/79	0/70
血圧上昇	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
傷害、中毒および処置合併症(Cont.)				
医療機器設置の問題	0/63	0/1	0/0	1/132 (0.8)
医療機器による投与の欠落	0/63	0/1	0/0	1/132 (0.8)
期限切れの製品使用	0/63	0/1	0/0	1/132 (0.8)
転倒	1/63 (1.6)	0/1	0/0	16/132 (12.1)
頭部損傷	0/63	0/1	0/0	2/132 (1.5)
注入に伴う反応	0/63	0/1	0/0	1/132 (0.8)
靱帯捻挫	0/63	0/1	0/0	1/132 (0.8)
処置後挫傷	0/63	0/1	0/0	1/132 (0.8)
肋骨骨折	0/63	0/1	0/0	1/132 (0.8)
皮膚擦過傷	0/63	0/1	0/0	1/132 (0.8)
皮膚損傷	0/63	0/1	0/0	1/132 (0.8)
皮膚裂傷	0/63	0/1	0/0	1/132 (0.8)
ストレス骨折	0/63	0/1	0/0	1/132 (0.8)
腱断裂	1/63 (1.6)	0/1	0/0	1/132 (0.8)
創傷	1/63 (1.6)	0/1	0/0	1/132 (0.8)
臨床検査	11/63 (17.5)	0/1	0/0	23/132 (17.4)
血中クレアチンホスホキナーゼ増加	0/63	0/1	0/0	1/132 (0.8)
血中葉酸減少	1/63 (1.6)	0/1	0/0	1/132 (0.8)
血中ホモシステイン増加	1/63 (1.6)	0/1	0/0	1/132 (0.8)
血圧上昇	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
血中ナトリウム減少	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
握力低下	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
ヘモグロビン減少	1/132 (0.8)	1/97 (1.0)	0/79	0/70
ビタミンB12減少	1/132 (0.8)	0/97	0/79	0/70
ビタミンB6減少	4/132 (3.0)	3/97 (3.1)	4/79 (5.1)	4/70 (5.7)
体重減少	4/132 (3.0)	4/97 (4.1)	5/79 (6.3)	5/70 (7.1)
体重増加	1/132 (0.8)	2/97 (2.1)	2/79 (2.5)	2/70 (2.9)
代謝および栄養障害	4/132 (3.0)	5/97 (5.2)	5/79 (6.3)	5/70 (7.1)
悪液質	0/132	0/97	1/79 (1.3)	0/70
食欲減退	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
脱水	0/132	1/97 (1.0)	0/79	0/70
体液貯留	1/132 (0.8)	0/97	0/79	0/70
葉酸欠乏	0/132	0/97	1/79 (1.3)	1/70 (1.4)
低ナトリウム血症	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
ビタミンB群欠乏	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
ビタミンB6欠乏	1/132 (0.8)	1/97 (1.0)	2/79 (2.5)	2/70 (2.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
臨床検査 (Cont.)				
起立血圧低下	1/63 (1.6)	0/1	0/0	1/132 (0.8)
血中ナトリウム減少	1/63 (1.6)	0/1	0/0	1/132 (0.8)
握力低下	1/63 (1.6)	0/1	0/0	1/132 (0.8)
ヘモグロビン減少	0/63	0/1	0/0	1/132 (0.8)
ビタミンB12減少	0/63	0/1	0/0	1/132 (0.8)
ビタミンB6減少	4/63 (6.3)	0/1	0/0	5/132 (3.8)
体重減少	2/63 (3.2)	0/1	0/0	10/132 (7.6)
体重増加	2/63 (3.2)	0/1	0/0	2/132 (1.5)
代謝および栄養障害	3/63 (4.8)	0/1	0/0	11/132 (8.3)
悪液質	0/63	0/1	0/0	1/132 (0.8)
食欲減退	0/63	0/1	0/0	3/132 (2.3)
脱水	0/63	0/1	0/0	1/132 (0.8)
体液貯留	0/63	0/1	0/0	1/132 (0.8)
葉酸欠乏	0/63	0/1	0/0	1/132 (0.8)
低ナトリウム血症	0/63	0/1	0/0	2/132 (1.5)
ビタミンB群欠乏	1/63 (1.6)	0/1	0/0	1/132 (0.8)
ビタミンB6欠乏	2/63 (3.2)	0/1	0/0	3/132 (2.3)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
筋骨格系および結合組織障害	14/132 (10.6)	10/97 (10.3)	11/79 (13.9)	13/70 (18.6)
関節痛	2/132 (1.5)	0/97	1/79 (1.3)	1/70 (1.4)
反応性関節炎	0/132	0/97	1/79 (1.3)	1/70 (1.4)
背部痛	4/132 (3.0)	2/97 (2.1)	4/79 (5.1)	4/70 (5.7)
滑液包炎	1/132 (0.8)	0/97	1/79 (1.3)	1/70 (1.4)
椎間板変性症	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
筋痙縮	0/132	2/97 (2.1)	1/79 (1.3)	0/70
筋力低下	3/132 (2.3)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
筋肉痛	2/132 (1.5)	0/97	0/79	0/70
頚部痛	0/132	0/97	2/79 (2.5)	2/70 (2.9)
変形性関節症	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
骨減少症	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
四肢痛	2/132 (1.5)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
横紋筋融解症	1/132 (0.8)	0/97	0/79	1/70 (1.4)
仙腸関節機能障害	1/132 (0.8)	0/97	0/79	0/70
変形性脊椎症	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
腱炎	1/132 (0.8)	0/97	0/79	0/70
弾発指	0/132	0/97	1/79 (1.3)	1/70 (1.4)
神経系障害	47/132 (35.6)	27/97 (27.8)	18/79 (22.8)	19/70 (27.1)
アカシジア	0/132	0/97	0/79	1/70 (1.4)
健忘	0/132	0/97	0/79	0/70
運動失調	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
筋骨格系および結合組織障害	11/63 (17.5)	0/1	0/0	24/132 (18.2)
関節痛	1/63 (1.6)	0/1	0/0	3/132 (2.3)
反応性関節炎	0/63	0/1	0/0	1/132 (0.8)
背部痛	4/63 (6.3)	0/1	0/0	8/132 (6.1)
滑液包炎	0/63	0/1	0/0	2/132 (1.5)
椎間板変性症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
筋痙縮	0/63	0/1	0/0	2/132 (1.5)
筋力低下	1/63 (1.6)	0/1	0/0	4/132 (3.0)
筋肉痛	0/63	0/1	0/0	2/132 (1.5)
頚部痛	2/63 (3.2)	0/1	0/0	2/132 (1.5)
変形性関節症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
骨減少症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
四肢痛	1/63 (1.6)	0/1	0/0	3/132 (2.3)
横紋筋融解症	0/63	0/1	0/0	2/132 (1.5)
仙腸関節機能障害	0/63	0/1	0/0	1/132 (0.8)
変形性脊椎症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
腱炎	0/63	0/1	0/0	1/132 (0.8)
弾発指	1/63 (1.6)	0/1	0/0	1/132 (0.8)
神経系障害	18/63 (28.6)	1/1 (100)	0/0	62/132 (47.0)
アカシジア	0/63	0/1	0/0	1/132 (0.8)
健忘	1/63 (1.6)	0/1	0/0	1/132 (0.8)
運動失調	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
運動緩慢	1/132 (0.8)	0/97	0/79	0/70
認知障害	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	2/70 (2.9)
振動覚低下	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
浮動性めまい	13/132 (9.8)	5/97 (5.2)	3/79 (3.8)	3/70 (4.3)
体位性めまい	3/132 (2.3)	3/97 (3.1)	1/79 (1.3)	0/70
味覚不全	2/132 (1.5)	0/97	0/79	0/70
ジスキネジア	8/132 (6.1)	4/97 (4.1)	2/79 (2.5)	3/70 (4.3)
起立障害	1/132 (0.8)	0/97	0/79	0/70
ジストニア	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	0/70
伸展性足底反応	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
すくみ現象	4/132 (3.0)	2/97 (2.1)	0/79	0/70
頭部不快感	1/132 (0.8)	0/97	0/79	0/70
頭痛	5/132 (3.8)	3/97 (3.1)	3/79 (3.8)	1/70 (1.4)
感覚鈍麻	0/132	0/97	1/79 (1.3)	1/70 (1.4)
反射減弱	0/132	0/97	1/79 (1.3)	1/70 (1.4)
不規則睡眠覚醒リズム障害	0/132	0/97	1/79 (1.3)	1/70 (1.4)
嗜眠	0/132	1/97 (1.0)	0/79	0/70
意識消失	0/132	1/97 (1.0)	0/79	0/70
代謝性脳症	0/132	0/97	1/79 (1.3)	1/70 (1.4)
末梢性ニューロパチー	0/132	0/97	0/79	1/70 (1.4)
オンオフ現象	4/132 (3.0)	0/97	0/79	0/70
錯感覚	2/132 (1.5)	1/97 (1.0)	0/79	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
運動緩慢	0/63	0/1	0/0	1/132 (0.8)
認知障害	3/63 (4.8)	0/1	0/0	4/132 (3.0)
振動覚低下	0/63	0/1	0/0	1/132 (0.8)
浮動性めまい	3/63 (4.8)	0/1	0/0	15/132 (11.4)
体位性めまい	0/63	0/1	0/0	5/132 (3.8)
味覚不全	0/63	0/1	0/0	2/132 (1.5)
ジスキネジア	1/63 (1.6)	0/1	0/0	12/132 (9.1)
起立障害	0/63	0/1	0/0	1/132 (0.8)
ジストニア	0/63	0/1	0/0	2/132 (1.5)
伸展性足底反応	1/63 (1.6)	0/1	0/0	1/132 (0.8)
すくみ現象	0/63	0/1	0/0	4/132 (3.0)
頭部不快感	0/63	0/1	0/0	1/132 (0.8)
頭痛	1/63 (1.6)	0/1	0/0	7/132 (5.3)
感覚鈍麻	1/63 (1.6)	0/1	0/0	1/132 (0.8)
反射減弱	2/63 (3.2)	0/1	0/0	2/132 (1.5)
不規則睡眠覚醒リズム障害	1/63 (1.6)	0/1	0/0	1/132 (0.8)
嗜眠	0/63	0/1	0/0	1/132 (0.8)
意識消失	0/63	0/1	0/0	1/132 (0.8)
代謝性脳症	1/63 (1.6)	0/1	0/0	1/132 (0.8)
末梢性ニューロパチー	1/63 (1.6)	0/1	0/0	1/132 (0.8)
オンオフ現象	0/63	0/1	0/0	4/132 (3.0)
錯感覚	1/63 (1.6)	1/1 (100)	0/0	4/132 (3.0)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
パーキンソン病	8/132 (6.1)	7/97 (7.2)	4/79 (5.1)	2/70 (2.9)
側反弓	0/132	0/97	0/79	1/70 (1.4)
精神運動亢進	1/132 (0.8)	0/97	0/79	0/70
睡眠時麻痺	0/132	1/97 (1.0)	0/79	0/70
傾眠	6/132 (4.5)	6/97 (6.2)	2/79 (2.5)	2/70 (2.9)
振戦	0/132	1/97 (1.0)	0/79	0/70
製品の問題	2/132 (1.5)	0/97	0/79	0/70
医療機器送達システムの問題	1/132 (0.8)	0/97	0/79	0/70
医療機器位置異常	1/132 (0.8)	0/97	0/79	0/70
精神障害	45/132 (34.1)	31/97 (32.0)	25/79 (31.6)	21/70 (30.0)
感情不安定	1/132 (0.8)	0/97	0/79	0/70
不安	7/132 (5.3)	6/97 (6.2)	4/79 (5.1)	5/70 (7.1)
無感情	0/132	1/97 (1.0)	0/79	0/70
歯ぎしり	2/132 (1.5)	1/97 (1.0)	0/79	0/70
強迫性性行動	0/132	0/97	1/79 (1.3)	0/70
錯乱状態	4/132 (3.0)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
譫妄	1/132 (0.8)	0/97	0/79	0/70
妄想	6/132 (4.5)	4/97 (4.1)	3/79 (3.8)	2/70 (2.9)
寄生虫妄想	0/132	1/97 (1.0)	0/79	0/70
抑うつ気分	1/132 (0.8)	2/97 (2.1)	2/79 (2.5)	1/70 (1.4)
うつ病	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
神経系障害 (Cont.)				
パーキンソン病	2/63 (3.2)	0/1	0/0	12/132 (9.1)
側反弓	1/63 (1.6)	0/1	0/0	1/132 (0.8)
精神運動亢進	0/63	0/1	0/0	1/132 (0.8)
睡眠時麻痺	0/63	0/1	0/0	1/132 (0.8)
傾眠	2/63 (3.2)	0/1	0/0	9/132 (6.8)
振戦	0/63	0/1	0/0	1/132 (0.8)
製品の問題	0/63	0/1	0/0	2/132 (1.5)
医療機器送達システムの問題	0/63	0/1	0/0	1/132 (0.8)
医療機器位置異常	0/63	0/1	0/0	1/132 (0.8)
精神障害	13/63 (20.6)	0/1	0/0	50/132 (37.9)
感情不安定	0/63	0/1	0/0	1/132 (0.8)
不安	3/63 (4.8)	0/1	0/0	10/132 (7.6)
無感情	0/63	0/1	0/0	1/132 (0.8)
歯ぎしり	0/63	0/1	0/0	2/132 (1.5)
強迫性性行動	0/63	0/1	0/0	1/132 (0.8)
錯乱状態	0/63	0/1	0/0	4/132 (3.0)
譫妄	0/63	0/1	0/0	1/132 (0.8)
妄想	1/63 (1.6)	0/1	0/0	8/132 (6.1)
寄生虫妄想	0/63	0/1	0/0	1/132 (0.8)
抑うつ気分	0/63	0/1	0/0	2/132 (1.5)
うつ病	1/63 (1.6)	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ症状	2/132 (1.5)	0/97	0/79	0/70
ドーパミン調節障害症候群	0/132	0/97	0/79	1/70 (1.4)
睡眠異常	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
情動障害	0/132	1/97 (1.0)	0/79	0/70
幻覚	17/132 (12.9)	10/97 (10.3)	6/79 (7.6)	6/70 (8.6)
幻聴	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	2/70 (2.9)
幻視	6/132 (4.5)	5/97 (5.2)	5/79 (6.3)	3/70 (4.3)
混合性幻覚	1/132 (0.8)	0/97	0/79	0/70
性欲過剰	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
錯覚	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
不眠症	9/132 (6.8)	3/97 (3.1)	2/79 (2.5)	1/70 (1.4)
易刺激性	1/132 (0.8)	1/97 (1.0)	0/79	0/70
嫉妬妄想	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
気分変化	1/132 (0.8)	0/97	0/79	0/70
悪夢	0/132	1/97 (1.0)	0/79	0/70
強迫観念	1/132 (0.8)	1/97 (1.0)	0/79	0/70
妄想症	0/132	1/97 (1.0)	2/79 (2.5)	2/70 (2.9)
睡眠の質低下	0/132	1/97 (1.0)	0/79	0/70
精神病性障害	3/132 (2.3)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
精神病症状	0/132	0/97	0/79	1/70 (1.4)
レム睡眠行動障害	1/132 (0.8)	0/97	0/79	0/70
レム睡眠異常	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ症状	0/63	0/1	0/0	2/132 (1.5)
ドーパミン調節障害症候群	0/63	0/1	0/0	1/132 (0.8)
睡眠異常	1/63 (1.6)	0/1	0/0	1/132 (0.8)
情動障害	0/63	0/1	0/0	1/132 (0.8)
幻覚	4/63 (6.3)	0/1	0/0	20/132 (15.2)
幻聴	1/63 (1.6)	0/1	0/0	3/132 (2.3)
幻視	3/63 (4.8)	0/1	0/0	10/132 (7.6)
混合性幻覚	0/63	0/1	0/0	1/132 (0.8)
性欲過剰	0/63	0/1	0/0	1/132 (0.8)
錯覚	0/63	0/1	0/0	1/132 (0.8)
不眠症	1/63 (1.6)	0/1	0/0	9/132 (6.8)
易刺激性	0/63	0/1	0/0	1/132 (0.8)
嫉妬妄想	0/63	0/1	0/0	1/132 (0.8)
気分変化	0/63	0/1	0/0	1/132 (0.8)
悪夢	0/63	0/1	0/0	1/132 (0.8)
強迫観念	0/63	0/1	0/0	1/132 (0.8)
妄想症	1/63 (1.6)	0/1	0/0	2/132 (1.5)
睡眠の質低下	0/63	0/1	0/0	1/132 (0.8)
精神病性障害	1/63 (1.6)	0/1	0/0	4/132 (3.0)
精神病症状	1/63 (1.6)	0/1	0/0	1/132 (0.8)
レム睡眠行動障害	0/63	0/1	0/0	1/132 (0.8)
レム睡眠異常	1/63 (1.6)	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
睡眠障害	1/132 (0.8)	2/97 (2.1)	1/79 (1.3)	1/70 (1.4)
ねごと	0/132	1/97 (1.0)	0/79	0/70
自殺念慮	0/132	1/97 (1.0)	0/79	0/70
自殺企図	0/132	0/97	0/79	1/70 (1.4)
腎および尿路障害	7/132 (5.3)	5/97 (5.2)	4/79 (5.1)	5/70 (7.1)
膀胱痙縮	0/132	0/97	1/79 (1.3)	1/70 (1.4)
膀胱結石	0/132	1/97 (1.0)	0/79	0/70
排尿困難	1/132 (0.8)	0/97	0/79	0/70
緊張性膀胱	0/132	0/97	0/79	1/70 (1.4)
切迫性尿失禁	3/132 (2.3)	3/97 (3.1)	2/79 (2.5)	2/70 (2.9)
尿失禁	2/132 (1.5)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
尿路障害	1/132 (0.8)	0/97	0/79	0/70
生殖系および乳房障害	0/132	1/97 (1.0)	2/79 (2.5)	2/70 (2.9)
良性前立腺肥大症	0/132	0/97	1/79 (1.3)	1/70 (1.4)
勃起不全	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
呼吸器、胸郭および縦隔障害	2/132 (1.5)	2/97 (2.1)	2/79 (2.5)	1/70 (1.4)
気管支拡張症	0/132	0/97	1/79 (1.3)	0/70
咳嗽	1/132 (0.8)	0/97	0/79	0/70

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
精神障害 (Cont.)				
睡眠障害	0/63	0/1	0/0	2/132 (1.5)
ねごと	0/63	0/1	0/0	1/132 (0.8)
自殺念慮	0/63	0/1	0/0	1/132 (0.8)
自殺企図	0/63	0/1	0/0	1/132 (0.8)
腎および尿路障害	3/63 (4.8)	0/1	0/0	11/132 (8.3)
膀胱痙縮	1/63 (1.6)	0/1	0/0	1/132 (0.8)
膀胱結石	0/63	0/1	0/0	1/132 (0.8)
排尿困難	0/63	0/1	0/0	1/132 (0.8)
緊張性膀胱	1/63 (1.6)	0/1	0/0	1/132 (0.8)
切迫性尿失禁	1/63 (1.6)	0/1	0/0	3/132 (2.3)
尿失禁	0/63	0/1	0/0	3/132 (2.3)
尿路障害	0/63	0/1	0/0	1/132 (0.8)
生殖系および乳房障害	1/63 (1.6)	0/1	0/0	2/132 (1.5)
良性前立腺肥大症	0/63	0/1	0/0	1/132 (0.8)
勃起不全	1/63 (1.6)	0/1	0/0	1/132 (0.8)
呼吸器、胸郭および縦隔障害	2/63 (3.2)	0/1	0/0	6/132 (4.5)
気管支拡張症	0/63	0/1	0/0	1/132 (0.8)
咳嗽	0/63	0/1	0/0	1/132 (0.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/132 (0.8)	0/97	0/79	0/70
労作性呼吸困難	0/132	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
口腔咽頭痛	0/132	1/97 (1.0)	0/79	0/70
皮膚および皮下組織障害	10/132 (7.6)	7/97 (7.2)	5/79 (6.3)	5/70 (7.1)
脱毛症	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
皮膚嚢腫	1/132 (0.8)	1/97 (1.0)	0/79	0/70
接触皮膚炎	1/132 (0.8)	0/97	0/79	1/70 (1.4)
おむつ皮膚炎	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	1/70 (1.4)
薬疹	1/132 (0.8)	1/97 (1.0)	0/79	0/70
皮膚乾燥	0/132	1/97 (1.0)	0/79	0/70
斑状出血	1/132 (0.8)	0/97	0/79	0/70
紅斑	1/132 (0.8)	0/97	0/79	0/70
爪の障害	0/132	0/97	1/79 (1.3)	1/70 (1.4)
そう痒症	0/132	0/97	1/79 (1.3)	1/70 (1.4)
発疹	1/132 (0.8)	0/97	1/79 (1.3)	0/70
そう痒性皮疹	1/132 (0.8)	0/97	1/79 (1.3)	0/70
皮膚潰瘍	1/132 (0.8)	1/97 (1.0)	1/79 (1.3)	0/70
蕁麻疹	0/132	1/97 (1.0)	2/79 (2.5)	1/70 (1.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
呼吸器、胸郭および縦隔障害(Cont.)				
呼吸困難	1/63 (1.6)	0/1	0/0	2/132 (1.5)
労作性呼吸困難	1/63 (1.6)	0/1	0/0	1/132 (0.8)
口腔咽頭痛	0/63	0/1	0/0	1/132 (0.8)
皮膚および皮下組織障害	3/63 (4.8)	0/1	0/0	14/132 (10.6)
脱毛症	1/63 (1.6)	0/1	0/0	2/132 (1.5)
皮膚嚢腫	0/63	0/1	0/0	1/132 (0.8)
接触皮膚炎	1/63 (1.6)	0/1	0/0	2/132 (1.5)
おむつ皮膚炎	1/63 (1.6)	0/1	0/0	1/132 (0.8)
薬疹	0/63	0/1	0/0	1/132 (0.8)
皮膚乾燥	0/63	0/1	0/0	1/132 (0.8)
斑状出血	0/63	0/1	0/0	1/132 (0.8)
紅斑	0/63	0/1	0/0	1/132 (0.8)
爪の障害	1/63 (1.6)	0/1	0/0	1/132 (0.8)
そう痒症	0/63	0/1	0/0	2/132 (1.5)
発疹	0/63	0/1	0/0	2/132 (1.5)
そう痒性皮疹	0/63	0/1	0/0	2/132 (1.5)
皮膚潰瘍	0/63	0/1	0/0	1/132 (0.8)
蕁麻疹	0/63	0/1	0/0	2/132 (1.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
Low Dose				
社会環境	1/132 (0.8)	1/97 (1.0)	0/79	0/70
運動不能	1/132 (0.8)	1/97 (1.0)	0/79	0/70
血管障害	5/132 (3.8)	2/97 (2.1)	4/79 (5.1)	7/70 (10.0)
高血圧	2/132 (1.5)	0/97	1/79 (1.3)	1/70 (1.4)
高血圧クリーゼ	1/132 (0.8)	0/97	0/79	0/70
低血圧	1/132 (0.8)	0/97	0/79	1/70 (1.4)
起立性低血圧	1/132 (0.8)	2/97 (2.1)	3/79 (3.8)	5/70 (7.1)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
Low Dose				
社会環境	0/63	0/1	0/0	1/132 (0.8)
運動不能	0/63	0/1	0/0	1/132 (0.8)
血管障害	6/63 (9.5)	0/1	0/0	11/132 (8.3)
高血圧	0/63	0/1	0/0	3/132 (2.3)
高血圧クリーゼ	0/63	0/1	0/0	1/132 (0.8)
低血圧	1/63 (1.6)	0/1	0/0	2/132 (1.5)
起立性低血圧	5/63 (7.9)	0/1	0/0	6/132 (4.5)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
Any adverse event	105/112 (93.8)	75/85 (88.2)	60/70 (85.7)	50/58 (86.2)
血液およびリンパ系障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	2/58 (3.4)
大球性貧血	0/112	0/85	0/70	1/58 (1.7)
凝血異常	1/112 (0.9)	0/85	0/70	0/58
縦隔リンパ節腫脹	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
心臓障害	4/112 (3.6)	2/85 (2.4)	2/70 (2.9)	2/58 (3.4)
心房細動	0/112	0/85	1/70 (1.4)	1/58 (1.7)
徐脈	1/112 (0.9)	0/85	0/70	0/58
心肺停止	0/112	1/85 (1.2)	0/70	0/58
冠動脈疾患	0/112	0/85	1/70 (1.4)	1/58 (1.7)
期外収縮	1/112 (0.9)	1/85 (1.2)	0/70	0/58
左室肥大	1/112 (0.9)	0/85	0/70	0/58
動悸	1/112 (0.9)	0/85	1/70 (1.4)	1/58 (1.7)
耳および迷路障害	4/112 (3.6)	2/85 (2.4)	1/70 (1.4)	1/58 (1.7)
乗物酔い	1/112 (0.9)	0/85	0/70	0/58
回転性めまい	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
頭位性回転性めまい	1/112 (0.9)	1/85 (1.2)	0/70	0/58
眼障害	3/112 (2.7)	5/85 (5.9)	6/70 (8.6)	3/58 (5.2)
白内障	1/112 (0.9)	1/85 (1.2)	2/70 (2.9)	1/58 (1.7)
複視	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
Any adverse event	42/51 (82.4)	0/0	0/0	108/112 (96.4)
血液およびリンパ系障害	2/51 (3.9)	0/0	0/0	3/112 (2.7)
大球性貧血	1/51 (2.0)	0/0	0/0	1/112 (0.9)
凝血異常	0/51	0/0	0/0	1/112 (0.9)
縦隔リンパ節腫脹	1/51 (2.0)	0/0	0/0	1/112 (0.9)
心臓障害	2/51 (3.9)	0/0	0/0	7/112 (6.3)
心房細動	1/51 (2.0)	0/0	0/0	1/112 (0.9)
徐脈	0/51	0/0	0/0	1/112 (0.9)
心肺停止	0/51	0/0	0/0	1/112 (0.9)
冠動脈疾患	1/51 (2.0)	0/0	0/0	1/112 (0.9)
期外収縮	0/51	0/0	0/0	1/112 (0.9)
左室肥大	0/51	0/0	0/0	1/112 (0.9)
動悸	1/51 (2.0)	0/0	0/0	2/112 (1.8)
耳および迷路障害	0/51	0/0	0/0	4/112 (3.6)
乗物酔い	0/51	0/0	0/0	1/112 (0.9)
回転性めまい	0/51	0/0	0/0	2/112 (1.8)
頭位性回転性めまい	0/51	0/0	0/0	1/112 (0.9)
眼障害	2/51 (3.9)	0/0	0/0	8/112 (7.1)
白内障	1/51 (2.0)	0/0	0/0	2/112 (1.8)
複視	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/112 (0.9)	2/85 (2.4)	3/70 (4.3)	2/58 (3.4)
緑内障	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
眼窩周囲痛	0/112	1/85 (1.2)	0/70	0/58
眼窩周囲腫脹	1/112 (0.9)	1/85 (1.2)	0/70	0/58
視野欠損	0/112	1/85 (1.2)	1/70 (1.4)	0/58
胃腸障害	23/112 (20.5)	13/85 (15.3)	14/70 (20.0)	10/58 (17.2)
腹部膨満	3/112 (2.7)	0/85	1/70 (1.4)	0/58
腹痛	0/112	0/85	0/70	1/58 (1.7)
上腹部痛	1/112 (0.9)	0/85	0/70	0/58
呼気臭	1/112 (0.9)	0/85	0/70	0/58
便秘	6/112 (5.4)	6/85 (7.1)	5/70 (7.1)	3/58 (5.2)
下痢	2/112 (1.8)	0/85	1/70 (1.4)	0/58
口内乾燥	5/112 (4.5)	5/85 (5.9)	3/70 (4.3)	2/58 (3.4)
嚥下障害	1/112 (0.9)	1/85 (1.2)	0/70	0/58
糞塊	1/112 (0.9)	0/85	0/70	0/58
排便回数増加	0/112	1/85 (1.2)	0/70	0/58
胃食道逆流性疾患	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
過敏性腸症候群	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
大腸ポリープ	0/112	0/85	0/70	1/58 (1.7)
悪心	8/112 (7.1)	1/85 (1.2)	4/70 (5.7)	3/58 (5.2)
口の錯感覚	1/112 (0.9)	0/85	0/70	0/58
直腸出血	0/112	0/85	1/70 (1.4)	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
眼障害 (Cont.)				
ドライアイ	1/51 (2.0)	0/0	0/0	3/112 (2.7)
緑内障	1/51 (2.0)	0/0	0/0	1/112 (0.9)
眼窩周囲痛	0/51	0/0	0/0	1/112 (0.9)
眼窩周囲腫脹	0/51	0/0	0/0	2/112 (1.8)
視野欠損	0/51	0/0	0/0	1/112 (0.9)
胃腸障害	7/51 (13.7)	0/0	0/0	29/112 (25.9)
腹部膨満	0/51	0/0	0/0	3/112 (2.7)
腹痛	0/51	0/0	0/0	1/112 (0.9)
上腹部痛	0/51	0/0	0/0	1/112 (0.9)
呼気臭	0/51	0/0	0/0	1/112 (0.9)
便秘	2/51 (3.9)	0/0	0/0	12/112 (10.7)
下痢	0/51	0/0	0/0	3/112 (2.7)
口内乾燥	2/51 (3.9)	0/0	0/0	5/112 (4.5)
嚥下障害	0/51	0/0	0/0	1/112 (0.9)
糞塊	0/51	0/0	0/0	1/112 (0.9)
排便回数増加	0/51	0/0	0/0	1/112 (0.9)
胃食道逆流性疾患	1/51 (2.0)	0/0	0/0	1/112 (0.9)
過敏性腸症候群	1/51 (2.0)	0/0	0/0	1/112 (0.9)
大腸ポリープ	0/51	0/0	0/0	1/112 (0.9)
悪心	2/51 (3.9)	0/0	0/0	11/112 (9.8)
口の錯感覚	0/51	0/0	0/0	1/112 (0.9)
直腸出血	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	1/112 (0.9)	0/85	0/70	0/58
嘔吐	2/112 (1.8)	0/85	1/70 (1.4)	1/58 (1.7)
一般・全身障害および投与部位の状態	92/112 (82.1)	66/85 (77.6)	50/70 (71.4)	40/58 (69.0)
投与部位内出血	0/112	0/85	0/70	1/58 (1.7)
投与部位漏出	2/112 (1.8)	2/85 (2.4)	1/70 (1.4)	0/58
カテーテル留置部位紅斑	1/112 (0.9)	0/85	0/70	0/58
カテーテル留置部位出血	1/112 (0.9)	0/85	0/70	0/58
カテーテル留置部位炎症	1/112 (0.9)	1/85 (1.2)	0/70	0/58
カテーテル留置部位刺激感	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
カテーテル留置部位浮腫	1/112 (0.9)	0/85	0/70	0/58
カテーテル留置部位疼痛	2/112 (1.8)	0/85	0/70	0/58
胸部不快感	0/112	1/85 (1.2)	0/70	0/58
胸痛	1/112 (0.9)	1/85 (1.2)	0/70	0/58
薬効欠如	0/112	1/85 (1.2)	0/70	0/58
薬剤離脱症候群	1/112 (0.9)	0/85	0/70	0/58
疲労	3/112 (2.7)	2/85 (2.4)	1/70 (1.4)	1/58 (1.7)
異常感	1/112 (0.9)	1/85 (1.2)	0/70	0/58
冷感	0/112	0/85	1/70 (1.4)	0/58
歩行障害	1/112 (0.9)	1/85 (1.2)	0/70	0/58
低体温	0/112	0/85	0/70	1/58 (1.7)
インフルエンザ様疾患	2/112 (1.8)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
胃腸障害 (Cont.)				
歯痛	0/51	0/0	0/0	1/112 (0.9)
嘔吐	0/51	0/0	0/0	3/112 (2.7)
一般・全身障害および投与部位の状態	32/51 (62.7)	0/0	0/0	96/112 (85.7)
投与部位内出血	1/51 (2.0)	0/0	0/0	1/112 (0.9)
投与部位漏出	0/51	0/0	0/0	2/112 (1.8)
カテーテル留置部位紅斑	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位出血	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位炎症	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位刺激感	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位浮腫	0/51	0/0	0/0	1/112 (0.9)
カテーテル留置部位疼痛	0/51	0/0	0/0	2/112 (1.8)
胸部不快感	0/51	0/0	0/0	1/112 (0.9)
胸痛	0/51	0/0	0/0	1/112 (0.9)
薬効欠如	0/51	0/0	0/0	1/112 (0.9)
薬剤離脱症候群	0/51	0/0	0/0	1/112 (0.9)
疲労	1/51 (2.0)	0/0	0/0	3/112 (2.7)
異常感	0/51	0/0	0/0	1/112 (0.9)
冷感	0/51	0/0	0/0	1/112 (0.9)
歩行障害	0/51	0/0	0/0	2/112 (1.8)
低体温	0/51	0/0	0/0	1/112 (0.9)
インフルエンザ様疾患	0/51	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	7/112 (6.3)	0/85	2/70 (2.9)	1/58 (1.7)
注入部位皮膚炎	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注入部位分泌物	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注入部位不快感	1/112 (0.9)	0/85	0/70	0/58
注入部位びらん	1/112 (0.9)	0/85	0/70	0/58
注入部位紅斑	53/112 (47.3)	32/85 (37.6)	22/70 (31.4)	16/58 (27.6)
注入部位皮膚剥脱	1/112 (0.9)	0/85	0/70	2/58 (3.4)
注入部位血管外漏出	11/112 (9.8)	3/85 (3.5)	2/70 (2.9)	2/58 (3.4)
注入部位血腫	7/112 (6.3)	4/85 (4.7)	1/70 (1.4)	0/58
注入部位出血	3/112 (2.7)	1/85 (1.2)	0/70	1/58 (1.7)
注入部位硬結	2/112 (1.8)	1/85 (1.2)	2/70 (2.9)	2/58 (3.4)
注入部位炎症	3/112 (2.7)	3/85 (3.5)	1/70 (1.4)	1/58 (1.7)
注入部位損傷	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注入部位刺激感	3/112 (2.7)	3/85 (3.5)	1/70 (1.4)	0/58
注入部位腫瘤	3/112 (2.7)	2/85 (2.4)	2/70 (2.9)	2/58 (3.4)
注入部位壊死	1/112 (0.9)	0/85	0/70	0/58
注入部位結節	25/112 (22.3)	28/85 (32.9)	22/70 (31.4)	20/58 (34.5)
注入部位浮腫	20/112 (17.9)	8/85 (9.4)	6/70 (8.6)	5/58 (8.6)
注入部位疼痛	18/112 (16.1)	11/85 (12.9)	9/70 (12.9)	5/58 (8.6)
注入部位蒼白	1/112 (0.9)	0/85	0/70	0/58
注入部位丘疹	6/112 (5.4)	3/85 (3.5)	2/70 (2.9)	2/58 (3.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位内出血	0/51	0/0	0/0	8/112 (7.1)
注入部位皮膚炎	1/51 (2.0)	0/0	0/0	2/112 (1.8)
注入部位分泌物	1/51 (2.0)	0/0	0/0	1/112 (0.9)
注入部位不快感	0/51	0/0	0/0	1/112 (0.9)
注入部位びらん	0/51	0/0	0/0	1/112 (0.9)
注入部位紅斑	9/51 (17.6)	0/0	0/0	60/112 (53.6)
注入部位皮膚剥脱	2/51 (3.9)	0/0	0/0	3/112 (2.7)
注入部位血管外漏出	0/51	0/0	0/0	12/112 (10.7)
注入部位血腫	0/51	0/0	0/0	8/112 (7.1)
注入部位出血	0/51	0/0	0/0	5/112 (4.5)
注入部位硬結	2/51 (3.9)	0/0	0/0	3/112 (2.7)
注入部位炎症	3/51 (5.9)	0/0	0/0	6/112 (5.4)
注入部位損傷	0/51	0/0	0/0	2/112 (1.8)
注入部位刺激感	0/51	0/0	0/0	4/112 (3.6)
注入部位腫瘤	2/51 (3.9)	0/0	0/0	3/112 (2.7)
注入部位壊死	0/51	0/0	0/0	1/112 (0.9)
注入部位結節	16/51 (31.4)	0/0	0/0	34/112 (30.4)
注入部位浮腫	4/51 (7.8)	0/0	0/0	28/112 (25.0)
注入部位疼痛	5/51 (9.8)	0/0	0/0	20/112 (17.9)
注入部位蒼白	0/51	0/0	0/0	1/112 (0.9)
注入部位丘疹	2/51 (3.9)	0/0	0/0	11/112 (9.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位異常感覚	2/112 (1.8)	0/85	1/70 (1.4)	0/58
注入部位そう痒感	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注入部位発疹	3/112 (2.7)	2/85 (2.4)	0/70	0/58
注入部位反応	14/112 (12.5)	5/85 (5.9)	3/70 (4.3)	6/58 (10.3)
注入部位痂皮	0/112	1/85 (1.2)	0/70	1/58 (1.7)
注入部位腫脹	2/112 (1.8)	0/85	1/70 (1.4)	0/58
注入部位小水疱	2/112 (1.8)	1/85 (1.2)	0/70	0/58
注入部位熱感	1/112 (0.9)	0/85	0/70	0/58
注射部位内出血	0/112	1/85 (1.2)	1/70 (1.4)	0/58
注射部位紅斑	7/112 (6.3)	2/85 (2.4)	3/70 (4.3)	3/58 (5.2)
注射部位漏出	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注射部位血腫	1/112 (0.9)	0/85	0/70	0/58
注射部位出血	0/112	1/85 (1.2)	0/70	0/58
注射部位炎症	2/112 (1.8)	3/85 (3.5)	2/70 (2.9)	1/58 (1.7)
注射部位結節	4/112 (3.6)	3/85 (3.5)	4/70 (5.7)	3/58 (5.2)
注射部位浮腫	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注射部位疼痛	5/112 (4.5)	1/85 (1.2)	0/70	0/58
注射部位丘疹	1/112 (0.9)	0/85	0/70	0/58
注射部位反応	1/112 (0.9)	0/85	0/70	0/58
注射部位腫脹	1/112 (0.9)	2/85 (2.4)	1/70 (1.4)	0/58
注射部位蕁麻疹	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
注入部位異常感覚	0/51	0/0	0/0	2/112 (1.8)
注入部位そう痒感	1/51 (2.0)	0/0	0/0	2/112 (1.8)
注入部位発疹	0/51	0/0	0/0	4/112 (3.6)
注入部位反応	5/51 (9.8)	0/0	0/0	18/112 (16.1)
注入部位痂皮	1/51 (2.0)	0/0	0/0	1/112 (0.9)
注入部位腫脹	0/51	0/0	0/0	2/112 (1.8)
注入部位小水疱	0/51	0/0	0/0	2/112 (1.8)
注入部位熱感	0/51	0/0	0/0	1/112 (0.9)
注射部位内出血	0/51	0/0	0/0	1/112 (0.9)
注射部位紅斑	1/51 (2.0)	0/0	0/0	8/112 (7.1)
注射部位漏出	0/51	0/0	0/0	1/112 (0.9)
注射部位血腫	0/51	0/0	0/0	1/112 (0.9)
注射部位出血	0/51	0/0	0/0	1/112 (0.9)
注射部位炎症	1/51 (2.0)	0/0	0/0	4/112 (3.6)
注射部位結節	2/51 (3.9)	0/0	0/0	6/112 (5.4)
注射部位浮腫	2/51 (3.9)	0/0	0/0	3/112 (2.7)
注射部位疼痛	0/51	0/0	0/0	6/112 (5.4)
注射部位丘疹	0/51	0/0	0/0	1/112 (0.9)
注射部位反応	0/51	0/0	0/0	1/112 (0.9)
注射部位腫脹	0/51	0/0	0/0	2/112 (1.8)
注射部位蕁麻疹	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
滴下投与部位熱傷	1/112 (0.9)	0/85	0/70	0/58
滴下投与部位痛	0/112	1/85 (1.2)	0/70	0/58
限局性浮腫	1/112 (0.9)	0/85	0/70	0/58
適用部位からの吸収不良	1/112 (0.9)	0/85	0/70	0/58
倦怠感	1/112 (0.9)	0/85	1/70 (1.4)	0/58
医療機器使用部位刺激感	2/112 (1.8)	0/85	0/70	0/58
医療機器使用部位発疹	2/112 (1.8)	0/85	0/70	0/58
非心臓性胸痛	2/112 (1.8)	0/85	0/70	0/58
末梢性浮腫	4/112 (3.6)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
末梢腫脹	3/112 (2.7)	1/85 (1.2)	1/70 (1.4)	2/58 (3.4)
穿刺部位紅斑	2/112 (1.8)	2/85 (2.4)	0/70	0/58
穿刺部位浮腫	1/112 (0.9)	0/85	0/70	0/58
穿刺部位腫脹	1/112 (0.9)	0/85	0/70	0/58
発熱	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
肝胆道系障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
脂肪肝	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
一般・全身障害および投与部位の状態(Cont.)				
滴下投与部位熱傷	0/51	0/0	0/0	1/112 (0.9)
滴下投与部位痛	0/51	0/0	0/0	1/112 (0.9)
限局性浮腫	0/51	0/0	0/0	1/112 (0.9)
適用部位からの吸収不良	0/51	0/0	0/0	1/112 (0.9)
倦怠感	0/51	0/0	0/0	2/112 (1.8)
医療機器使用部位刺激感	0/51	0/0	0/0	2/112 (1.8)
医療機器使用部位発疹	0/51	0/0	0/0	2/112 (1.8)
非心臓性胸痛	0/51	0/0	0/0	2/112 (1.8)
末梢性浮腫	1/51 (2.0)	0/0	0/0	4/112 (3.6)
末梢腫脹	2/51 (3.9)	0/0	0/0	4/112 (3.6)
穿刺部位紅斑	0/51	0/0	0/0	3/112 (2.7)
穿刺部位浮腫	0/51	0/0	0/0	1/112 (0.9)
穿刺部位腫脹	0/51	0/0	0/0	1/112 (0.9)
発熱	0/51	0/0	0/0	2/112 (1.8)
肝胆道系障害	1/51 (2.0)	0/0	0/0	1/112 (0.9)
脂肪肝	1/51 (2.0)	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
感染症および寄生虫症	43/112 (38.4)	23/85 (27.1)	19/70 (27.1)	16/58 (27.6)
無症候性COVID-19	0/112	0/85	1/70 (1.4)	1/58 (1.7)
細菌性疾患キャリアー	0/112	0/85	1/70 (1.4)	1/58 (1.7)
ウイルス性気管支炎	0/112	0/85	0/70	1/58 (1.7)
蜂巣炎	0/112	0/85	1/70 (1.4)	0/58
膀胱炎	1/112 (0.9)	0/85	0/70	0/58
爪の皮膚糸状菌症	0/112	1/85 (1.2)	1/70 (1.4)	0/58
胃腸炎	1/112 (0.9)	0/85	0/70	0/58
感染性皮膚潰瘍	1/112 (0.9)	1/85 (1.2)	0/70	0/58
インフルエンザ	0/112	0/85	0/70	1/58 (1.7)
注入部位膿瘍	9/112 (8.0)	7/85 (8.2)	4/70 (5.7)	1/58 (1.7)
注入部位蜂巣炎	21/112 (18.8)	6/85 (7.1)	7/70 (10.0)	7/58 (12.1)
注入部位感染	6/112 (5.4)	5/85 (5.9)	1/70 (1.4)	2/58 (3.4)
注入部位膿疱	1/112 (0.9)	1/85 (1.2)	0/70	0/58
注射部位蜂巣炎	2/112 (1.8)	1/85 (1.2)	0/70	1/58 (1.7)
上咽頭炎	4/112 (3.6)	1/85 (1.2)	0/70	0/58
爪真菌症	1/112 (0.9)	0/85	0/70	0/58
耳下腺膿瘍	0/112	0/85	1/70 (1.4)	0/58
肺炎	1/112 (0.9)	1/85 (1.2)	0/70	0/58
シュードモナス感染	1/112 (0.9)	1/85 (1.2)	0/70	0/58
気道感染	0/112	0/85	0/70	1/58 (1.7)
敗血症	0/112	0/85	1/70 (1.4)	0/58
ブドウ球菌感染	0/112	1/85 (1.2)	1/70 (1.4)	0/58
歯感染	0/112	0/85	0/70	1/58 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
感染症および寄生虫症	7/51 (13.7)	0/0	0/0	56/112 (50.0)
無症候性COVID-19	0/51	0/0	0/0	1/112 (0.9)
細菌性疾患キャリアー	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ウイルス性気管支炎	0/51	0/0	0/0	1/112 (0.9)
蜂巣炎	0/51	0/0	0/0	1/112 (0.9)
膀胱炎	0/51	0/0	0/0	1/112 (0.9)
爪の皮膚糸状菌症	0/51	0/0	0/0	1/112 (0.9)
胃腸炎	0/51	0/0	0/0	1/112 (0.9)
感染性皮膚潰瘍	0/51	0/0	0/0	1/112 (0.9)
インフルエンザ	1/51 (2.0)	0/0	0/0	1/112 (0.9)
注入部位膿瘍	0/51	0/0	0/0	13/112 (11.6)
注入部位蜂巣炎	2/51 (3.9)	0/0	0/0	27/112 (24.1)
注入部位感染	2/51 (3.9)	0/0	0/0	11/112 (9.8)
注入部位膿疱	0/51	0/0	0/0	1/112 (0.9)
注射部位蜂巣炎	0/51	0/0	0/0	3/112 (2.7)
上咽頭炎	0/51	0/0	0/0	5/112 (4.5)
爪真菌症	0/51	0/0	0/0	1/112 (0.9)
耳下腺膿瘍	0/51	0/0	0/0	1/112 (0.9)
肺炎	0/51	0/0	0/0	1/112 (0.9)
シュードモナス感染	0/51	0/0	0/0	1/112 (0.9)
気道感染	0/51	0/0	0/0	1/112 (0.9)
敗血症	0/51	0/0	0/0	1/112 (0.9)
ブドウ球菌感染	0/51	0/0	0/0	1/112 (0.9)
歯感染	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	6/112 (5.4)	5/85 (5.9)	4/70 (5.7)	2/58 (3.4)
傷害、中毒および処置合併症	16/112 (14.3)	10/85 (11.8)	9/70 (12.9)	6/58 (10.3)
足関節部骨折	1/112 (0.9)	1/85 (1.2)	0/70	0/58
節足動物咬傷	1/112 (0.9)	0/85	0/70	0/58
骨挫傷	0/112	1/85 (1.2)	1/70 (1.4)	0/58
挫傷	2/112 (1.8)	3/85 (3.5)	2/70 (2.9)	0/58
眼挫傷	1/112 (0.9)	0/85	0/70	0/58
顔面損傷	0/112	1/85 (1.2)	0/70	0/58
顔面骨骨折	2/112 (1.8)	0/85	0/70	0/58
転倒	13/112 (11.6)	6/85 (7.1)	6/70 (8.6)	4/58 (6.9)
頭部損傷	0/112	1/85 (1.2)	1/70 (1.4)	0/58
関節脱臼	0/112	1/85 (1.2)	1/70 (1.4)	0/58
靭帯捻挫	0/112	1/85 (1.2)	0/70	0/58
腰椎骨折	1/112 (0.9)	0/85	0/70	0/58
過量投与	0/112	0/85	1/70 (1.4)	1/58 (1.7)
処置によるめまい	1/112 (0.9)	0/85	0/70	0/58
肋骨骨折	1/112 (0.9)	0/85	0/70	1/58 (1.7)
皮膚擦過傷	0/112	1/85 (1.2)	2/70 (2.9)	0/58
皮膚裂傷	2/112 (1.8)	2/85 (2.4)	1/70 (1.4)	2/58 (3.4)
硬膜下血腫	0/112	0/85	0/70	1/58 (1.7)
サンバーン	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	1/51 (2.0)	0/0	0/0	11/112 (9.8)
傷害、中毒および処置合併症	2/51 (3.9)	0/0	0/0	26/112 (23.2)
足関節部骨折	0/51	0/0	0/0	1/112 (0.9)
節足動物咬傷	0/51	0/0	0/0	1/112 (0.9)
骨挫傷	0/51	0/0	0/0	1/112 (0.9)
挫傷	0/51	0/0	0/0	6/112 (5.4)
眼挫傷	0/51	0/0	0/0	1/112 (0.9)
顔面損傷	0/51	0/0	0/0	1/112 (0.9)
顔面骨骨折	0/51	0/0	0/0	2/112 (1.8)
転倒	1/51 (2.0)	0/0	0/0	23/112 (20.5)
頭部損傷	0/51	0/0	0/0	2/112 (1.8)
関節脱臼	0/51	0/0	0/0	1/112 (0.9)
靭帯捻挫	0/51	0/0	0/0	1/112 (0.9)
腰椎骨折	0/51	0/0	0/0	1/112 (0.9)
過量投与	0/51	0/0	0/0	1/112 (0.9)
処置によるめまい	0/51	0/0	0/0	1/112 (0.9)
肋骨骨折	1/51 (2.0)	0/0	0/0	2/112 (1.8)
皮膚擦過傷	0/51	0/0	0/0	2/112 (1.8)
皮膚裂傷	0/51	0/0	0/0	6/112 (5.4)
硬膜下血腫	0/51	0/0	0/0	1/112 (0.9)
サンバーン	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/112	1/85 (1.2)	1/70 (1.4)	0/58
過少量投与	0/112	0/85	1/70 (1.4)	0/58
臨床検査	15/112 (13.4)	15/85 (17.6)	14/70 (20.0)	10/58 (17.2)
血中クレアチンホスホキナーゼ増加	1/112 (0.9)	0/85	0/70	0/58
血中クレアチニン減少	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
血中葉酸減少	0/112	0/85	0/70	1/58 (1.7)
血中ホモシステイン増加	1/112 (0.9)	1/85 (1.2)	2/70 (2.9)	2/58 (3.4)
血中リン減少	0/112	1/85 (1.2)	0/70	0/58
血圧上昇	1/112 (0.9)	0/85	0/70	0/58
C-反応性蛋白増加	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
ヘモグロビン減少	0/112	0/85	0/70	1/58 (1.7)
リンパ球数減少	1/112 (0.9)	0/85	0/70	0/58
単球数増加	1/112 (0.9)	0/85	0/70	0/58
好中球数増加	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
プロトロンビン時間延長	0/112	0/85	0/70	0/58
赤血球数減少	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
ビタミンB12減少	0/112	0/85	1/70 (1.4)	1/58 (1.7)
ビタミンB6減少	5/112 (4.5)	5/85 (5.9)	5/70 (7.1)	5/58 (8.6)
ビタミンD減少	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
体重減少	8/112 (7.1)	10/85 (11.8)	9/70 (12.9)	5/58 (8.6)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
傷害、中毒および処置合併症(Cont.)				
腱断裂	0/51	0/0	0/0	1/112 (0.9)
過少量投与	0/51	0/0	0/0	1/112 (0.9)
臨床検査	10/51 (19.6)	0/0	0/0	22/112 (19.6)
血中クレアチンホスホキナーゼ増加	0/51	0/0	0/0	1/112 (0.9)
血中クレアチニン減少	1/51 (2.0)	0/0	0/0	1/112 (0.9)
血中葉酸減少	2/51 (3.9)	0/0	0/0	2/112 (1.8)
血中ホモシステイン増加	2/51 (3.9)	0/0	0/0	2/112 (1.8)
血中リン減少	0/51	0/0	0/0	1/112 (0.9)
血圧上昇	0/51	0/0	0/0	1/112 (0.9)
C-反応性蛋白増加	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ヘモグロビン減少	0/51	0/0	0/0	1/112 (0.9)
リンパ球数減少	0/51	0/0	0/0	1/112 (0.9)
単球数増加	0/51	0/0	0/0	1/112 (0.9)
好中球数増加	1/51 (2.0)	0/0	0/0	2/112 (1.8)
プロトロンビン時間延長	1/51 (2.0)	0/0	0/0	1/112 (0.9)
赤血球数減少	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ビタミンB12減少	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ビタミンB6減少	5/51 (9.8)	0/0	0/0	6/112 (5.4)
ビタミンD減少	0/51	0/0	0/0	1/112 (0.9)
体重減少	4/51 (7.8)	0/0	0/0	12/112 (10.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
臨床検査 (Cont.)				
白血球数増加	2/112 (1.8)	0/85	0/70	0/58
代謝および栄養障害	12/112 (10.7)	9/85 (10.6)	8/70 (11.4)	5/58 (8.6)
食欲減退	2/112 (1.8)	2/85 (2.4)	1/70 (1.4)	0/58
脱水	2/112 (1.8)	1/85 (1.2)	0/70	0/58
糖尿病	0/112	0/85	1/70 (1.4)	1/58 (1.7)
水分過負荷	1/112 (0.9)	0/85	0/70	0/58
体液貯留	0/112	0/85	0/70	1/58 (1.7)
葉酸欠乏	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
耐糖能障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
高コレステロール血症	0/112	1/85 (1.2)	0/70	0/58
高血糖	1/112 (0.9)	0/85	0/70	0/58
高ホモシステイン血症	0/112	0/85	1/70 (1.4)	0/58
低カリウム血症	2/112 (1.8)	0/85	0/70	1/58 (1.7)
栄養障害	1/112 (0.9)	0/85	0/70	0/58
ビタミンB群欠乏	0/112	0/85	1/70 (1.4)	1/58 (1.7)
ビタミンB12欠乏	0/112	0/85	1/70 (1.4)	0/58
ビタミンB6欠乏	4/112 (3.6)	4/85 (4.7)	4/70 (5.7)	2/58 (3.4)
筋骨格系および結合組織障害	13/112 (11.6)	8/85 (9.4)	9/70 (12.9)	5/58 (8.6)
関節痛	2/112 (1.8)	3/85 (3.5)	1/70 (1.4)	1/58 (1.7)
反応性関節炎	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
臨床検査 (Cont.)				
白血球数増加	0/51	0/0	0/0	2/112 (1.8)
代謝および栄養障害	4/51 (7.8)	0/0	0/0	17/112 (15.2)
食欲減退	0/51	0/0	0/0	2/112 (1.8)
脱水	0/51	0/0	0/0	3/112 (2.7)
糖尿病	0/51	0/0	0/0	1/112 (0.9)
水分過負荷	0/51	0/0	0/0	1/112 (0.9)
体液貯留	1/51 (2.0)	0/0	0/0	1/112 (0.9)
葉酸欠乏	0/51	0/0	0/0	1/112 (0.9)
耐糖能障害	1/51 (2.0)	0/0	0/0	1/112 (0.9)
高コレステロール血症	0/51	0/0	0/0	1/112 (0.9)
高血糖	0/51	0/0	0/0	1/112 (0.9)
高ホモシステイン血症	0/51	0/0	0/0	1/112 (0.9)
低カリウム血症	0/51	0/0	0/0	3/112 (2.7)
栄養障害	0/51	0/0	0/0	1/112 (0.9)
ビタミンB群欠乏	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ビタミンB12欠乏	1/51 (2.0)	0/0	0/0	2/112 (1.8)
ビタミンB6欠乏	2/51 (3.9)	0/0	0/0	5/112 (4.5)
筋骨格系および結合組織障害	5/51 (9.8)	0/0	0/0	20/112 (17.9)
関節痛	1/51 (2.0)	0/0	0/0	3/112 (2.7)
反応性関節炎	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
背部痛	2/112 (1.8)	2/85 (2.4)	2/70 (2.9)	1/58 (1.7)
骨痛	0/112	0/85	1/70 (1.4)	0/58
外骨腫	0/112	1/85 (1.2)	1/70 (1.4)	0/58
椎間関節症候群	0/112	1/85 (1.2)	1/70 (1.4)	0/58
椎間板突出	0/112	1/85 (1.2)	1/70 (1.4)	0/58
関節滲出液	0/112	1/85 (1.2)	1/70 (1.4)	0/58
関節腫脹	1/112 (0.9)	1/85 (1.2)	0/70	0/58
四肢不快感	0/112	0/85	1/70 (1.4)	0/58
筋萎縮	0/112	1/85 (1.2)	1/70 (1.4)	0/58
筋痙縮	2/112 (1.8)	2/85 (2.4)	0/70	0/58
筋力低下	0/112	0/85	1/70 (1.4)	1/58 (1.7)
筋骨格硬直	1/112 (0.9)	0/85	0/70	0/58
筋肉痛	1/112 (0.9)	0/85	0/70	0/58
骨炎	1/112 (0.9)	0/85	0/70	0/58
変形性関節症	0/112	2/85 (2.4)	3/70 (4.3)	1/58 (1.7)
四肢痛	3/112 (2.7)	1/85 (1.2)	1/70 (1.4)	0/58
関節周囲炎	0/112	0/85	1/70 (1.4)	1/58 (1.7)
姿勢異常	1/112 (0.9)	0/85	0/70	0/58
肩回旋筋腱板症候群	0/112	1/85 (1.2)	1/70 (1.4)	0/58
腱障害	0/112	1/85 (1.2)	1/70 (1.4)	0/58
斜頚	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
筋骨格系および結合組織障害(Cont.)				
背部痛	1/51 (2.0)	0/0	0/0	4/112 (3.6)
骨痛	0/51	0/0	0/0	1/112 (0.9)
外骨腫	0/51	0/0	0/0	1/112 (0.9)
椎間関節症候群	0/51	0/0	0/0	1/112 (0.9)
椎間板突出	0/51	0/0	0/0	1/112 (0.9)
関節滲出液	1/51 (2.0)	0/0	0/0	2/112 (1.8)
関節腫脹	0/51	0/0	0/0	1/112 (0.9)
四肢不快感	0/51	0/0	0/0	1/112 (0.9)
筋萎縮	0/51	0/0	0/0	1/112 (0.9)
筋痙縮	0/51	0/0	0/0	3/112 (2.7)
筋力低下	0/51	0/0	0/0	1/112 (0.9)
筋骨格硬直	0/51	0/0	0/0	1/112 (0.9)
筋肉痛	0/51	0/0	0/0	1/112 (0.9)
骨炎	0/51	0/0	0/0	1/112 (0.9)
変形性関節症	2/51 (3.9)	0/0	0/0	4/112 (3.6)
四肢痛	0/51	0/0	0/0	3/112 (2.7)
関節周囲炎	1/51 (2.0)	0/0	0/0	1/112 (0.9)
姿勢異常	0/51	0/0	0/0	1/112 (0.9)
肩回旋筋腱板症候群	0/51	0/0	0/0	1/112 (0.9)
腱障害	0/51	0/0	0/0	1/112 (0.9)
斜頚	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
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）	1/112 (0.9)	2/85 (2.4)	3/70 (4.3)	1/58 (1.7)
基底細胞癌	0/112	2/85 (2.4)	2/70 (2.9)	0/58
脂漏性角化症	0/112	0/85	1/70 (1.4)	1/58 (1.7)
皮膚有棘細胞癌	1/112 (0.9)	0/85	0/70	0/58
神経系障害	32/112 (28.6)	22/85 (25.9)	23/70 (32.9)	18/58 (31.0)
失語症	0/112	0/85	1/70 (1.4)	0/58
平衡障害	1/112 (0.9)	0/85	2/70 (2.9)	2/58 (3.4)
運動緩慢	0/112	0/85	1/70 (1.4)	0/58
手根管症候群	0/112	0/85	1/70 (1.4)	1/58 (1.7)
大脳萎縮	0/112	0/85	0/70	1/58 (1.7)
脳出血	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
脳圧排効果	0/112	0/85	0/70	1/58 (1.7)
脳血管発作	0/112	1/85 (1.2)	0/70	0/58
認知障害	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
注意力障害	1/112 (0.9)	1/85 (1.2)	0/70	0/58
浮動性めまい	10/112 (8.9)	5/85 (5.9)	3/70 (4.3)	2/58 (3.4)
構語障害	1/112 (0.9)	1/85 (1.2)	2/70 (2.9)	1/58 (1.7)
味覚不全	0/112	0/85	0/70	1/58 (1.7)
ジスキネジア	3/112 (2.7)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
ジストニア	2/112 (1.8)	3/85 (3.5)	3/70 (4.3)	4/58 (6.9)
脳症	1/112 (0.9)	0/85	0/70	0/58
てんかん	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
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）	0/51	0/0	0/0	4/112 (3.6)
基底細胞癌	0/51	0/0	0/0	2/112 (1.8)
脂漏性角化症	0/51	0/0	0/0	1/112 (0.9)
皮膚有棘細胞癌	0/51	0/0	0/0	1/112 (0.9)
神経系障害	16/51 (31.4)	0/0	0/0	48/112 (42.9)
失語症	0/51	0/0	0/0	1/112 (0.9)
平衡障害	3/51 (5.9)	0/0	0/0	4/112 (3.6)
運動緩慢	0/51	0/0	0/0	1/112 (0.9)
手根管症候群	1/51 (2.0)	0/0	0/0	1/112 (0.9)
大脳萎縮	1/51 (2.0)	0/0	0/0	1/112 (0.9)
脳出血	1/51 (2.0)	0/0	0/0	1/112 (0.9)
脳圧排効果	0/51	0/0	0/0	1/112 (0.9)
脳血管発作	0/51	0/0	0/0	1/112 (0.9)
認知障害	1/51 (2.0)	0/0	0/0	2/112 (1.8)
注意力障害	0/51	0/0	0/0	1/112 (0.9)
浮動性めまい	2/51 (3.9)	0/0	0/0	10/112 (8.9)
構語障害	0/51	0/0	0/0	3/112 (2.7)
味覚不全	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ジスキネジア	1/51 (2.0)	0/0	0/0	6/112 (5.4)
ジストニア	4/51 (7.8)	0/0	0/0	5/112 (4.5)
脳症	0/51	0/0	0/0	1/112 (0.9)
てんかん	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
本態性振戦	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
全身性強直性間代性発作	0/112	0/85	0/70	1/58 (1.7)
頭痛	4/112 (3.6)	2/85 (2.4)	2/70 (2.9)	3/58 (5.2)
片側感覚消失	1/112 (0.9)	0/85	0/70	0/58
不全片麻痺	1/112 (0.9)	0/85	0/70	0/58
感覚鈍麻	0/112	0/85	2/70 (2.9)	1/58 (1.7)
反射減弱	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
嗜眠	0/112	0/85	1/70 (1.4)	0/58
意識消失	0/112	1/85 (1.2)	0/70	0/58
腰仙部神経根障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
記憶障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
代謝性脳症	1/112 (0.9)	0/85	0/70	0/58
神経痛	0/112	1/85 (1.2)	0/70	0/58
末梢性ニューロパチー	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
オンオフ現象	4/112 (3.6)	2/85 (2.4)	1/70 (1.4)	1/58 (1.7)
錯感覚	2/112 (1.8)	0/85	0/70	1/58 (1.7)
パーキンソン病	3/112 (2.7)	1/85 (1.2)	1/70 (1.4)	0/58
パーキンソニズム	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
側反弓	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
多発ニューロパチー	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
失神寸前の状態	0/112	1/85 (1.2)	0/70	0/58
心因性発作	1/112 (0.9)	0/85	0/70	0/58
精神運動亢進	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
本態性振戦	0/51	0/0	0/0	1/112 (0.9)
全身性強直性間代性発作	0/51	0/0	0/0	1/112 (0.9)
頭痛	3/51 (5.9)	0/0	0/0	7/112 (6.3)
片側感覚消失	0/51	0/0	0/0	1/112 (0.9)
不全片麻痺	0/51	0/0	0/0	1/112 (0.9)
感覚鈍麻	1/51 (2.0)	0/0	0/0	2/112 (1.8)
反射減弱	0/51	0/0	0/0	1/112 (0.9)
嗜眠	0/51	0/0	0/0	1/112 (0.9)
意識消失	0/51	0/0	0/0	1/112 (0.9)
腰仙部神経根障害	0/51	0/0	0/0	1/112 (0.9)
記憶障害	1/51 (2.0)	0/0	0/0	2/112 (1.8)
代謝性脳症	0/51	0/0	0/0	1/112 (0.9)
神経痛	0/51	0/0	0/0	1/112 (0.9)
末梢性ニューロパチー	0/51	0/0	0/0	1/112 (0.9)
オンオフ現象	1/51 (2.0)	0/0	0/0	4/112 (3.6)
錯感覚	1/51 (2.0)	0/0	0/0	3/112 (2.7)
パーキンソン病	0/51	0/0	0/0	5/112 (4.5)
パーキンソニズム	1/51 (2.0)	0/0	0/0	3/112 (2.7)
側反弓	1/51 (2.0)	0/0	0/0	2/112 (1.8)
多発ニューロパチー	1/51 (2.0)	0/0	0/0	2/112 (1.8)
失神寸前の状態	0/51	0/0	0/0	1/112 (0.9)
心因性発作	0/51	0/0	0/0	1/112 (0.9)
精神運動亢進	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
反射異常	0/112	0/85	0/70	1/58 (1.7)
安静時振戦	1/112 (0.9)	0/85	0/70	0/58
坐骨神経痛	2/112 (1.8)	2/85 (2.4)	2/70 (2.9)	0/58
痙攣発作	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
感覚障害	1/112 (0.9)	0/85	0/70	0/58
感覚消失	0/112	1/85 (1.2)	1/70 (1.4)	0/58
傾眠	2/112 (1.8)	1/85 (1.2)	2/70 (2.9)	1/58 (1.7)
失神	0/112	1/85 (1.2)	0/70	1/58 (1.7)
振戦	2/112 (1.8)	0/85	0/70	0/58
製品の問題	1/112 (0.9)	0/85	0/70	0/58
医療機器機能不良	1/112 (0.9)	0/85	0/70	0/58
精神障害	45/112 (40.2)	29/85 (34.1)	24/70 (34.3)	20/58 (34.5)
異常な夢	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
感情不安定	0/112	1/85 (1.2)	1/70 (1.4)	0/58
激越	1/112 (0.9)	0/85	0/70	0/58
不安	15/112 (13.4)	8/85 (9.4)	10/70 (14.3)	8/58 (13.8)
不安障害	0/112	0/85	0/70	1/58 (1.7)
強迫行為	1/112 (0.9)	0/85	0/70	0/58
錯乱状態	1/112 (0.9)	1/85 (1.2)	2/70 (2.9)	2/58 (3.4)
譫妄	3/112 (2.7)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
妄想	1/112 (0.9)	1/85 (1.2)	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
神経系障害 (Cont.)				
反射異常	1/51 (2.0)	0/0	0/0	1/112 (0.9)
安静時振戦	0/51	0/0	0/0	1/112 (0.9)
坐骨神経痛	0/51	0/0	0/0	3/112 (2.7)
痙攣発作	1/51 (2.0)	0/0	0/0	1/112 (0.9)
感覚障害	0/51	0/0	0/0	1/112 (0.9)
感覚消失	0/51	0/0	0/0	1/112 (0.9)
傾眠	0/51	0/0	0/0	3/112 (2.7)
失神	1/51 (2.0)	0/0	0/0	3/112 (2.7)
振戦	0/51	0/0	0/0	2/112 (1.8)
製品の問題	0/51	0/0	0/0	1/112 (0.9)
医療機器機能不良	0/51	0/0	0/0	1/112 (0.9)
精神障害	16/51 (31.4)	0/0	0/0	54/112 (48.2)
異常な夢	1/51 (2.0)	0/0	0/0	1/112 (0.9)
感情不安定	0/51	0/0	0/0	1/112 (0.9)
激越	0/51	0/0	0/0	1/112 (0.9)
不安	7/51 (13.7)	0/0	0/0	18/112 (16.1)
不安障害	1/51 (2.0)	0/0	0/0	1/112 (0.9)
強迫行為	0/51	0/0	0/0	1/112 (0.9)
錯乱状態	0/51	0/0	0/0	4/112 (3.6)
譫妄	0/51	0/0	0/0	4/112 (3.6)
妄想	0/51	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
妄想性障害、詳細不明	1/112 (0.9)	1/85 (1.2)	0/70	0/58
抑うつ気分	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
うつ病	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
ディスフェミア	0/112	0/85	1/70 (1.4)	0/58
情動障害	1/112 (0.9)	0/85	0/70	0/58
注射恐怖	0/112	1/85 (1.2)	0/70	0/58
幻覚	16/112 (14.3)	10/85 (11.8)	8/70 (11.4)	7/58 (12.1)
幻聴	1/112 (0.9)	3/85 (3.5)	2/70 (2.9)	0/58
幻嗅	1/112 (0.9)	0/85	0/70	0/58
幻視	4/112 (3.6)	2/85 (2.4)	2/70 (2.9)	1/58 (1.7)
衝動制御障害	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
衝動行為	0/112	0/85	0/70	1/58 (1.7)
不眠症	6/112 (5.4)	6/85 (7.1)	3/70 (4.3)	4/58 (6.9)
易刺激性	1/112 (0.9)	1/85 (1.2)	0/70	0/58
躁病	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
気分動揺	0/112	1/85 (1.2)	0/70	0/58
悪夢	1/112 (0.9)	0/85	0/70	0/58
パニック発作	3/112 (2.7)	0/85	1/70 (1.4)	1/58 (1.7)
パニック反応	0/112	0/85	1/70 (1.4)	1/58 (1.7)
処置に対する不安	0/112	1/85 (1.2)	0/70	0/58
精神病性障害	0/112	1/85 (1.2)	2/70 (2.9)	1/58 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
妄想性障害、詳細不明	0/51	0/0	0/0	1/112 (0.9)
抑うつ気分	1/51 (2.0)	0/0	0/0	1/112 (0.9)
うつ病	0/51	0/0	0/0	2/112 (1.8)
ディスフェミア	0/51	0/0	0/0	1/112 (0.9)
情動障害	0/51	0/0	0/0	1/112 (0.9)
注射恐怖	0/51	0/0	0/0	1/112 (0.9)
幻覚	4/51 (7.8)	0/0	0/0	21/112 (18.8)
幻聴	0/51	0/0	0/0	3/112 (2.7)
幻嗅	0/51	0/0	0/0	1/112 (0.9)
幻視	0/51	0/0	0/0	5/112 (4.5)
衝動制御障害	1/51 (2.0)	0/0	0/0	4/112 (3.6)
衝動行為	1/51 (2.0)	0/0	0/0	1/112 (0.9)
不眠症	4/51 (7.8)	0/0	0/0	9/112 (8.0)
易刺激性	0/51	0/0	0/0	1/112 (0.9)
躁病	0/51	0/0	0/0	1/112 (0.9)
気分動揺	0/51	0/0	0/0	1/112 (0.9)
悪夢	0/51	0/0	0/0	1/112 (0.9)
パニック発作	1/51 (2.0)	0/0	0/0	3/112 (2.7)
パニック反応	0/51	0/0	0/0	1/112 (0.9)
処置に対する不安	0/51	0/0	0/0	1/112 (0.9)
精神病性障害	0/51	0/0	0/0	2/112 (1.8)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
レム睡眠行動障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
睡眠障害	1/112 (0.9)	0/85	0/70	0/58
ねごと	1/112 (0.9)	1/85 (1.2)	0/70	0/58
常同症	0/112	0/85	0/70	1/58 (1.7)
ストレス	1/112 (0.9)	0/85	0/70	0/58
自殺念慮	2/112 (1.8)	1/85 (1.2)	1/70 (1.4)	0/58
腎および尿路障害	3/112 (2.7)	2/85 (2.4)	5/70 (7.1)	4/58 (6.9)
排尿困難	1/112 (0.9)	0/85	0/70	1/58 (1.7)
夜間頻尿	0/112	1/85 (1.2)	1/70 (1.4)	0/58
多尿	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
腎機能障害	0/112	0/85	1/70 (1.4)	0/58
尿管結石症	1/112 (0.9)	0/85	0/70	0/58
尿失禁	0/112	0/85	1/70 (1.4)	1/58 (1.7)
尿閉	0/112	0/85	1/70 (1.4)	3/58 (5.2)
尿異常	1/112 (0.9)	0/85	0/70	0/58
尿臭異常	0/112	0/85	1/70 (1.4)	1/58 (1.7)
生殖系および乳房障害	3/112 (2.7)	3/85 (3.5)	2/70 (2.9)	2/58 (3.4)
勃起不全	1/112 (0.9)	0/85	0/70	0/58
ペイロニー病	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
精神障害 (Cont.)				
レム睡眠行動障害	1/51 (2.0)	0/0	0/0	1/112 (0.9)
睡眠障害	0/51	0/0	0/0	1/112 (0.9)
ねごと	0/51	0/0	0/0	1/112 (0.9)
常同症	1/51 (2.0)	0/0	0/0	1/112 (0.9)
ストレス	0/51	0/0	0/0	1/112 (0.9)
自殺念慮	0/51	0/0	0/0	2/112 (1.8)
腎および尿路障害	3/51 (5.9)	0/0	0/0	7/112 (6.3)
排尿困難	1/51 (2.0)	0/0	0/0	2/112 (1.8)
夜間頻尿	0/51	0/0	0/0	1/112 (0.9)
多尿	1/51 (2.0)	0/0	0/0	1/112 (0.9)
腎機能障害	0/51	0/0	0/0	1/112 (0.9)
尿管結石症	0/51	0/0	0/0	1/112 (0.9)
尿失禁	0/51	0/0	0/0	2/112 (1.8)
尿閉	1/51 (2.0)	0/0	0/0	3/112 (2.7)
尿異常	0/51	0/0	0/0	1/112 (0.9)
尿臭異常	0/51	0/0	0/0	1/112 (0.9)
生殖系および乳房障害	2/51 (3.9)	0/0	0/0	4/112 (3.6)
勃起不全	0/51	0/0	0/0	1/112 (0.9)
ペイロニー病	1/51 (2.0)	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
生殖系および乳房障害(Cont.)				
前立腺腫大	0/112	1/85 (1.2)	0/70	0/58
膣脱	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
呼吸器、胸郭および縦隔障害	13/112 (11.6)	5/85 (5.9)	4/70 (5.7)	3/58 (5.2)
急性呼吸不全	1/112 (0.9)	0/85	0/70	0/58
咳嗽	2/112 (1.8)	1/85 (1.2)	0/70	0/58
発声障害	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
呼吸困難	4/112 (3.6)	2/85 (2.4)	1/70 (1.4)	0/58
鼻出血	0/112	0/85	1/70 (1.4)	0/58
過換気	2/112 (1.8)	0/85	0/70	0/58
口腔咽頭痛	1/112 (0.9)	0/85	0/70	0/58
誤嚥性肺炎	0/112	0/85	0/70	1/58 (1.7)
湿性咳嗽	0/112	0/85	1/70 (1.4)	0/58
肺塞栓症	1/112 (0.9)	0/85	0/70	1/58 (1.7)
ラ音	0/112	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
鼻痛	1/112 (0.9)	0/85	0/70	0/58
鼻漏	2/112 (1.8)	0/85	0/70	0/58
咽喉刺激感	1/112 (0.9)	0/85	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
生殖系および乳房障害(Cont.)				
前立腺腫大	0/51	0/0	0/0	1/112 (0.9)
腟脱	1/51 (2.0)	0/0	0/0	1/112 (0.9)
呼吸器、胸郭および縦隔障害	1/51 (2.0)	0/0	0/0	19/112 (17.0)
急性呼吸不全	0/51	0/0	0/0	1/112 (0.9)
咳嗽	0/51	0/0	0/0	2/112 (1.8)
発声障害	0/51	0/0	0/0	2/112 (1.8)
呼吸困難	0/51	0/0	0/0	6/112 (5.4)
鼻出血	0/51	0/0	0/0	1/112 (0.9)
過換気	0/51	0/0	0/0	2/112 (1.8)
口腔咽頭痛	0/51	0/0	0/0	1/112 (0.9)
誤嚥性肺炎	0/51	0/0	0/0	1/112 (0.9)
湿性咳嗽	0/51	0/0	0/0	1/112 (0.9)
肺塞栓症	1/51 (2.0)	0/0	0/0	2/112 (1.8)
ラ音	0/51	0/0	0/0	1/112 (0.9)
鼻痛	0/51	0/0	0/0	1/112 (0.9)
鼻漏	0/51	0/0	0/0	2/112 (1.8)
咽喉刺激感	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N_eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N_eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
皮膚および皮下組織障害	12/112 (10.7)	6/85 (7.1)	5/70 (7.1)	5/58 (8.6)
褥瘡性潰瘍	1/112 (0.9)	1/85 (1.2)	0/70	0/58
皮膚嚢腫	0/112	0/85	0/70	1/58 (1.7)
皮膚炎	1/112 (0.9)	1/85 (1.2)	0/70	0/58
皮膚乾燥	1/112 (0.9)	0/85	0/70	0/58
紅斑	3/112 (2.7)	0/85	0/70	0/58
脂肪織炎	0/112	0/85	1/70 (1.4)	1/58 (1.7)
丘疹	2/112 (1.8)	2/85 (2.4)	2/70 (2.9)	1/58 (1.7)
光線過敏性反応	1/112 (0.9)	0/85	0/70	0/58
そう痒症	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
乾癬	0/112	1/85 (1.2)	1/70 (1.4)	0/58
発疹	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
紅斑性皮疹	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
そう痒性皮疹	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	1/58 (1.7)
皮膚刺激	1/112 (0.9)	0/85	0/70	0/58
皮膚病変	1/112 (0.9)	1/85 (1.2)	1/70 (1.4)	0/58
皮膚潰瘍	1/112 (0.9)	0/85	0/70	0/58
外科および内科処置	0/112	1/85 (1.2)	0/70	0/58
抜歯	0/112	1/85 (1.2)	0/70	0/58

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
皮膚および皮下組織障害	3/51 (5.9)	0/0	0/0	14/112 (12.5)
褥瘡性潰瘍	0/51	0/0	0/0	1/112 (0.9)
皮膚嚢腫	0/51	0/0	0/0	1/112 (0.9)
皮膚炎	0/51	0/0	0/0	1/112 (0.9)
皮膚乾燥	0/51	0/0	0/0	1/112 (0.9)
紅斑	0/51	0/0	0/0	3/112 (2.7)
脂肪織炎	0/51	0/0	0/0	1/112 (0.9)
丘疹	1/51 (2.0)	0/0	0/0	2/112 (1.8)
光線過敏性反応	0/51	0/0	0/0	1/112 (0.9)
そう痒症	1/51 (2.0)	0/0	0/0	1/112 (0.9)
乾癬	0/51	0/0	0/0	1/112 (0.9)
発疹	1/51 (2.0)	0/0	0/0	1/112 (0.9)
紅斑性皮疹	1/51 (2.0)	0/0	0/0	1/112 (0.9)
そう痒性皮疹	1/51 (2.0)	0/0	0/0	1/112 (0.9)
皮膚刺激	0/51	0/0	0/0	1/112 (0.9)
皮膚病変	0/51	0/0	0/0	1/112 (0.9)
皮膚潰瘍	0/51	0/0	0/0	1/112 (0.9)
外科および内科処置	0/51	0/0	0/0	1/112 (0.9)
抜歯	0/51	0/0	0/0	1/112 (0.9)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 1 to 90 (N=244) n/N_eval (%)	 Days 91 to 180 (N=182) n/N_eval (%)	 Days 181 to 270 (N=149) n/N_eval (%)	 Days 271 to 360 (N=128) n/N_eval (%)
High Dose				
血管障害	8/112 (7.1)	4/85 (4.7)	6/70 (8.6)	5/58 (8.6)
深部静脈血栓症	1/112 (0.9)	0/85	0/70	0/58
血腫	0/112	0/85	0/70	1/58 (1.7)
出血	0/112	1/85 (1.2)	0/70	0/58
ほてり	1/112 (0.9)	0/85	0/70	0/58
高血圧	2/112 (1.8)	0/85	0/70	1/58 (1.7)
低血圧	2/112 (1.8)	1/85 (1.2)	2/70 (2.9)	1/58 (1.7)
不安定血圧	1/112 (0.9)	0/85	0/70	0/58
起立性高血圧	0/112	0/85	0/70	0/58
起立性低血圧	4/112 (3.6)	2/85 (2.4)	4/70 (5.7)	3/58 (5.2)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

TABLE 14.3__1.16.2

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

Dose Category System Organ Class MedDRA 24.0 Preferred Term	ABBV-951 Treatment Period Days 361 to 450 (N=114) n/N_eval (%)	 Days 451 to 540 (N=1) n/N_eval (%)	 After Day 540 (N=0) n/N_eval (%)	 At Any Time (N=244) n/N_eval (%)
High Dose				
血管障害	6/51 (11.8)	0/0	0/0	15/112 (13.4)
深部静脈血栓症	0/51	0/0	0/0	1/112 (0.9)
血腫	0/51	0/0	0/0	1/112 (0.9)
出血	0/51	0/0	0/0	1/112 (0.9)
ほてり	0/51	0/0	0/0	1/112 (0.9)
高血圧	0/51	0/0	0/0	3/112 (2.7)
低血圧	2/51 (3.9)	0/0	0/0	4/112 (3.6)
不安定血圧	0/51	0/0	0/0	1/112 (0.9)
起立性高血圧	1/51 (2.0)	0/0	0/0	1/112 (0.9)
起立性低血圧	3/51 (5.9)	0/0	0/0	6/112 (5.4)

Note: Subjects are counted once in each row based on the onset day of their first event, regardless of the number of events they may have had.
N = Number of subjects who received an ABBV-951 infusion during the time interval.
N eval = Number of subjects who received an ABBV-951 infusion during the time interval.
n = Number of subjects in the N eval who a) had an occurrence of the event in that time interval, b) had an occurrence in a previous time interval that was ongoing in the current time interval, or c) discontinued treatment during the time interval and had an occurrence during the 30 days following their last ABBV-951 infusion.

Program Source Code: [redacted]

表42　有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 04:28 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.1.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period	N=22	N=5	N=27
Subjects with:			
Any TEAE	20 (90.9)	5 (100)	25 (92.6)
Any severe TEAE	3 (13.6)	1 (20.0)	4 (14.8)
Any TEAE that is considered associated with study drug$	20 (90.9)	5 (100)	25 (92.6)
Any TEAE that is considered associated with product complaint$	17 (77.3)	3 (60.0)	20 (74.1)
ABBV-951	10 (45.5)	2 (40.0)	12 (44.4)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	7 (31.8)	3 (60.0)	10 (37.0)
[redacted] infusion set 6 mm	6 (27.3)	1 (20.0)	7 (25.9)
[redacted] infusion set 9 mm	1 (4.5)	3 (60.0)	4 (14.8)
Neria guard infusion set (total)	4 (18.2)	0	4 (14.8)
Neria guard infusion set 6 mm	1 (4.5)	0	1 (3.7)
Neria guard infusion set 9 mm	3 (13.6)	0	3 (11.1)
[redacted]	0	0	0
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	0	0
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	6 (27.3)	1 (20.0)	7 (25.9)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	6 (27.3)	1 (20.0)	7 (25.9)

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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Entire study period	N=110	N=107	N=217
Subjects with:			
Any TEAE	102 (92.7)	103 (96.3)	205 (94.5)
Any severe TEAE	23 (20.9)	35 (32.7)	58 (26.7)
Any TEAE that is considered associated with study drug$	98 (89.1)	101 (94.4)	199 (91.7)
Any TEAE that is considered associated with product complaint$	74 (67.3)	77 (72.0)	151 (69.6)
ABBV-951	42 (38.2)	41 (38.3)	83 (38.2)
Infusion pump	9 (8.2)	8 (7.5)	17 (7.8)
Vial adapter	0	1 (0.9)	1 (0.5)
Syringes	0	0	0
[redacted] infusion set (total)	44 (40.0)	37 (34.6)	81 (37.3)
[redacted] infusion set 6 mm	31 (28.2)	25 (23.4)	56 (25.8)
[redacted] infusion set 9 mm	24 (21.8)	20 (18.7)	44 (20.3)
Neria guard infusion set (total)	10 (9.1)	16 (15.0)	26 (12.0)
Neria guard infusion set 6 mm	7 (6.4)	9 (8.4)	16 (7.4)
Neria guard infusion set 9 mm	6 (5.5)	12 (11.2)	18 (8.3)
[redacted]	3 (2.7)	4 (3.7)	7 (3.2)
Any TEAE that is considered associated with loading dose$	2 (1.8)	5 (4.7)	7 (3.2)
Any TEAE that is considered associated with rescue dose$	4 (3.6)	8 (7.5)	12 (5.5)
Any TEAE that is considered associated with COVID-19 infection	2 (1.8)	1 (0.9)	3 (1.4)
Any TEAE leading to prematurely discontinuation of study drug	26 (23.6)	29 (27.1)	55 (25.3)
Any TEAE leading to death (fatal TEAE)	0	3 (2.8)	3 (1.4)
Any serious TEAE	25 (22.7)	29 (27.1)	54 (24.9)

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.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	3 (13.6)	0	3 (11.1)
Possible	0	0	0
Probable	1 (4.5)	0	1 (3.7)
Causal relationship	2 (9.1)	0	2 (7.4)
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$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	11 (10.0)	8 (7.5)	19 (8.8)
Possible	6 (5.5)	5 (4.7)	11 (5.1)
Probable	4 (3.6)	3 (2.8)	7 (3.2)
Causal relationship	5 (4.5)	2 (1.9)	7 (3.2)
Any SAE that is considered associated with [redacted] infusion set$	1 (0.9)	1 (0.9)	2 (0.9)
Possible	1 (0.9)	1 (0.9)	2 (0.9)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (1.8)	1 (0.9)	3 (1.4)
Possible	1 (0.9)	1 (0.9)	2 (0.9)
Probable	0	0	0
Causal relationship	1 (0.9)	0	1 (0.5)
Any SAE that is considered associated with product complaint$	11 (10.0)	7 (6.5)	18 (8.3)
ABBV-951	4 (3.6)	3 (2.8)	7 (3.2)
Infusion pump	2 (1.8)	1 (0.9)	3 (1.4)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (2.7)	2 (1.9)	5 (2.3)
[redacted] infusion set 6 mm	2 (1.8)	1 (0.9)	3 (1.4)
[redacted] infusion set 9 mm	1 (0.9)	1 (0.9)	2 (0.9)
Neria guard infusion set (total)	2 (1.8)	1 (0.9)	3 (1.4)
Neria guard infusion set 6 mm	2 (1.8)	1 (0.9)	3 (1.4)
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.J

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

	Japan		
	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 (4.5)	0	1 (3.7)
AESI: hallucinations/psychosis	10 (45.5)	2 (40.0)	12 (44.4)
AESI: somnolence	0	0	0
AESI: infusion site related infections	3 (13.6)	2 (40.0)	5 (18.5)
AESI: infusion site related non infection reactions	17 (77.3)	3 (60.0)	20 (74.1)
AESI: falls and associated injuries	8 (36.4)	3 (60.0)	11 (40.7)

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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	5 (4.7)	5 (2.3)
All TE-deaths	0	3 (2.8)	3 (1.4)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (1.8)	6 (5.6)	8 (3.7)
AESI: weight loss	11 (10.0)	13 (12.1)	24 (11.1)
AESI: hallucinations/psychosis	22 (20.0)	25 (23.4)	47 (21.7)
AESI: somnolence	9 (8.2)	3 (2.8)	12 (5.5)
AESI: infusion site related infections	38 (34.5)	41 (38.3)	79 (36.4)
AESI: infusion site related non infection reactions	86 (78.2)	93 (86.9)	179 (82.5)
AESI: falls and associated injuries	27 (24.5)	33 (30.8)	60 (27.6)

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.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period	N=22	N=5	N=27
Subjects with:			
Any TEAE	15 (68.2)	4 (80.0)	19 (70.4)
Any severe TEAE	3 (13.6)	0	3 (11.1)
Any TEAE that is considered associated with study drug$	15 (68.2)	4 (80.0)	19 (70.4)
Any TEAE that is considered associated with product complaint$	12 (54.5)	2 (40.0)	14 (51.9)
ABBV-951	7 (31.8)	0	7 (25.9)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	5 (22.7)	2 (40.0)	7 (25.9)
[redacted] infusion set 6 mm	5 (22.7)	0	5 (18.5)
[redacted] infusion set 9 mm	0	2 (40.0)	2 (7.4)
Neria guard infusion set (total)	1 (4.5)	0	1 (3.7)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	1 (4.5)	0	1 (3.7)
[redacted]	0	0	0
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	0	0
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	4 (18.2)	1 (20.0)	5 (18.5)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	4 (18.2)	0	4 (14.8)

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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Optimization period	N=110	N=107	N=217
Subjects with:			
Any TEAE	90 (81.8)	93 (86.9)	183 (84.3)
Any severe TEAE	8 (7.3)	10 (9.3)	18 (8.3)
Any TEAE that is considered associated with study drug$	81 (73.6)	91 (85.0)	172 (79.3)
Any TEAE that is considered associated with product complaint$	55 (50.0)	61 (57.0)	116 (53.5)
ABBV-951	31 (28.2)	32 (29.9)	63 (29.0)
Infusion pump	3 (2.7)	2 (1.9)	5 (2.3)
Vial adapter	0	1 (0.9)	1 (0.5)
Syringes	0	0	0
[redacted] infusion set (total)	32 (29.1)	29 (27.1)	61 (28.1)
[redacted] infusion set 6 mm	22 (20.0)	15 (14.0)	37 (17.1)
[redacted] infusion set 9 mm	15 (13.6)	15 (14.0)	30 (13.8)
Neria guard infusion set (total)	5 (4.5)	7 (6.5)	12 (5.5)
Neria guard infusion set 6 mm	3 (2.7)	5 (4.7)	8 (3.7)
Neria guard infusion set 9 mm	2 (1.8)	4 (3.7)	6 (2.8)
[redacted]	2 (1.8)	2 (1.9)	4 (1.8)
Any TEAE that is considered associated with loading dose$	2 (1.8)	3 (2.8)	5 (2.3)
Any TEAE that is considered associated with rescue dose$	2 (1.8)	2 (1.9)	4 (1.8)
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	12 (10.9)	9 (8.4)	21 (9.7)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	7 (6.4)	6 (5.6)	13 (6.0)

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.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	2 (9.1)	0	2 (7.4)
Possible	0	0	0
Probable	0	0	0
Causal relationship	2 (9.1)	0	2 (7.4)
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$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	4 (3.6)	2 (1.9)	6 (2.8)
Possible	3 (2.7)	1 (0.9)	4 (1.8)
Probable	0	1 (0.9)	1 (0.5)
Causal relationship	1 (0.9)	0	1 (0.5)
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 (2.7)	2 (1.9)	5 (2.3)
ABBV-951	2 (1.8)	0	2 (0.9)
Infusion pump	1 (0.9)	0	1 (0.5)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	2 (1.9)	2 (0.9)
[redacted] infusion set 6 mm	0	1 (0.9)	1 (0.5)
[redacted] infusion set 9 mm	0	1 (0.9)	1 (0.5)
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.J

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

	Japan		
	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	0	0	0
AESI: hallucinations/psychosis	6 (27.3)	2 (40.0)	8 (29.6)
AESI: somnolence	0	0	0
AESI: infusion site related infections	0	0	0
AESI: infusion site related non infection reactions	12 (54.5)	2 (40.0)	14 (51.9)
AESI: falls and associated injuries	4 (18.2)	1 (20.0)	5 (18.5)

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.J

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

	Non-Japan		
	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 (0.9)	1 (0.9)	2 (0.9)
AESI: hallucinations/psychosis	11 (10.0)	6 (5.6)	17 (7.8)
AESI: somnolence	2 (1.8)	2 (1.9)	4 (1.8)
AESI: infusion site related infections	11 (10.0)	18 (16.8)	29 (13.4)
AESI: infusion site related non infection reactions	75 (68.2)	80 (74.8)	155 (71.4)
AESI: falls and associated injuries	15 (13.6)	18 (16.8)	33 (15.2)

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.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Subjects with:			
Any TEAE	15 (88.2)	3 (100)	18 (90.0)
Any severe TEAE	0	1 (33.3)	1 (5.0)
Any TEAE that is considered associated with study drug$	15 (88.2)	2 (66.7)	17 (85.0)
Any TEAE that is considered associated with product complaint$	9 (52.9)	3 (100)	12 (60.0)
ABBV-951	6 (35.3)	2 (66.7)	8 (40.0)
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	2 (11.8)	2 (66.7)	4 (20.0)
[redacted] infusion set 6 mm	1 (5.9)	1 (33.3)	2 (10.0)
[redacted] infusion set 9 mm	1 (5.9)	1 (33.3)	2 (10.0)
Neria guard infusion set (total)	3 (17.6)	0	3 (15.0)
Neria guard infusion set 6 mm	1 (5.9)	0	1 (5.0)
Neria guard infusion set 9 mm	2 (11.8)	0	2 (10.0)
[redacted]	0	0	0
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	0	0
Any TEAE that is considered associated with COVID-19 infection	0	0	0
Any TEAE leading to prematurely discontinuation of study drug	2 (11.8)	0	2 (10.0)
Any TEAE leading to death (fatal TEAE)	0	0	0
Any serious TEAE	2 (11.8)	1 (33.3)	3 (15.0)

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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Maintenance period	N=94	N=92	N=186
Subjects with:			
Any TEAE	83 (88.3)	85 (92.4)	168 (90.3)
Any severe TEAE	18 (19.1)	27 (29.3)	45 (24.2)
Any TEAE that is considered associated with study drug$	74 (78.7)	81 (88.0)	155 (83.3)
Any TEAE that is considered associated with product complaint$	56 (59.6)	59 (64.1)	115 (61.8)
ABBV-951	25 (26.6)	33 (35.9)	58 (31.2)
Infusion pump	6 (6.4)	6 (6.5)	12 (6.5)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	31 (33.0)	26 (28.3)	57 (30.6)
[redacted] infusion set 6 mm	19 (20.2)	15 (16.3)	34 (18.3)
[redacted] infusion set 9 mm	17 (18.1)	15 (16.3)	32 (17.2)
Neria guard infusion set (total)	10 (10.6)	13 (14.1)	23 (12.4)
Neria guard infusion set 6 mm	5 (5.3)	7 (7.6)	12 (6.5)
Neria guard infusion set 9 mm	6 (6.4)	10 (10.9)	16 (8.6)
[redacted]	1 (1.1)	2 (2.2)	3 (1.6)
Any TEAE that is considered associated with loading dose$	0	2 (2.2)	2 (1.1)
Any TEAE that is considered associated with rescue dose$	2 (2.1)	6 (6.5)	8 (4.3)
Any TEAE that is considered associated with COVID-19 infection	2 (2.1)	1 (1.1)	3 (1.6)
Any TEAE leading to prematurely discontinuation of study drug	14 (14.9)	20 (21.7)	34 (18.3)
Any TEAE leading to death (fatal TEAE)	0	3 (3.3)	3 (1.6)
Any serious TEAE	19 (20.2)	25 (27.2)	44 (23.7)

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.J

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

	Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	1 (5.9)	0	1 (5.0)
Possible	0	0	0
Probable	1 (5.9)	0	1 (5.0)
Causal relationship	0	0	0
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$	0	0	0
ABBV-951	0	0	0
Infusion pump	0	0	0
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	0	0	0
[redacted] infusion set 6 mm	0	0	0
[redacted] infusion set 9 mm	0	0	0
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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
Any SAE that is considered associated with infusion pump$	7 (7.4)	7 (7.6)	14 (7.5)
Possible	3 (3.2)	4 (4.3)	7 (3.8)
Probable	4 (4.3)	2 (2.2)	6 (3.2)
Causal relationship	4 (4.3)	2 (2.2)	6 (3.2)
Any SAE that is considered associated with [redacted] infusion set$	1 (1.1)	1 (1.1)	2 (1.1)
Possible	1 (1.1)	1 (1.1)	2 (1.1)
Probable	0	0	0
Causal relationship	0	0	0
Any SAE that is considered associated with neria guards infusion set$	2 (2.1)	1 (1.1)	3 (1.6)
Possible	1 (1.1)	1 (1.1)	2 (1.1)
Probable	0	0	0
Causal relationship	1 (1.1)	0	1 (0.5)
Any SAE that is considered associated with product complaint$	8 (8.5)	5 (5.4)	13 (7.0)
ABBV-951	2 (2.1)	3 (3.3)	5 (2.7)
Infusion pump	1 (1.1)	1 (1.1)	2 (1.1)
Vial adapter	0	0	0
Syringes	0	0	0
[redacted] infusion set (total)	3 (3.2)	0	3 (1.6)
[redacted] infusion set 6 mm	2 (2.1)	0	2 (1.1)
[redacted] infusion set 9 mm	1 (1.1)	0	1 (0.5)
Neria guard infusion set (total)	2 (2.1)	1 (1.1)	3 (1.6)
Neria guard infusion set 6 mm	2 (2.1)	1 (1.1)	3 (1.6)
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.J

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

	Japan		
	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 (5.9)	0	1 (5.0)
AESI: hallucinations/psychosis	8 (47.1)	0	8 (40.0)
AESI: somnolence	0	0	0
AESI: infusion site related infections	3 (17.6)	2 (66.7)	5 (25.0)
AESI: infusion site related non infection reactions	10 (58.8)	3 (100)	13 (65.0)
AESI: falls and associated injuries	5 (29.4)	2 (66.7)	7 (35.0)

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.J

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

	Non-Japan		
	Dose Category		
	Low Dose n (%)	High Dose n (%)	All Subjects n (%)
All deaths#	0	3 (3.3)	3 (1.6)
All TE-deaths	0	3 (3.3)	3 (1.6)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	2 (2.1)	6 (6.5)	8 (4.3)
AESI: weight loss	10 (10.6)	12 (13.0)	22 (11.8)
AESI: hallucinations/psychosis	15 (16.0)	21 (22.8)	36 (19.4)
AESI: somnolence	8 (8.5)	1 (1.1)	9 (4.8)
AESI: infusion site related infections	30 (31.9)	31 (33.7)	61 (32.8)
AESI: infusion site related non infection reactions	54 (57.4)	67 (72.8)	121 (65.1)
AESI: falls and associated injuries	16 (17.0)	22 (23.9)	38 (20.4)

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43　すべての有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 04:29 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.2.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period	N=22	N=5	N=27	N=110	N=107	N=217
Any adverse event	20 (90.9)	5 (100)	25 (92.6)	102 (92.7)	103 (96.3)	205 (94.5)
血液およびリンパ系障害	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
大球性貧血	0	0	0	0	1 (0.9)	1 (0.5)
凝血異常	0	0	0	0	1 (0.9)	1 (0.5)
リンパ節症	0	0	0	1 (0.9)	0	1 (0.5)
縦隔リンパ節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
心臓障害	0	0	0	4 (3.6)	7 (6.5)	11 (5.1)
急性心筋梗塞	0	0	0	1 (0.9)	0	1 (0.5)
狭心症	0	0	0	1 (0.9)	0	1 (0.5)
心房細動	0	0	0	0	1 (0.9)	1 (0.5)
徐脈	0	0	0	0	1 (0.9)	1 (0.5)
心停止	0	0	0	1 (0.9)	0	1 (0.5)
心肺停止	0	0	0	0	1 (0.9)	1 (0.5)
冠動脈疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
冠動脈狭窄	0	0	0	1 (0.9)	0	1 (0.5)
期外収縮	0	0	0	0	1 (0.9)	1 (0.5)
左室肥大	0	0	0	0	1 (0.9)	1 (0.5)
心筋梗塞	0	0	0	1 (0.9)	0	1 (0.5)
動悸	0	0	0	0	2 (1.9)	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
耳および迷路障害	1 (4.5)	0	1 (3.7)	3 (2.7)	4 (3.7)	7 (3.2)
感音性難聴	1 (4.5)	0	1 (3.7)	0	0	0
乗物酔い	0	0	0	0	1 (0.9)	1 (0.5)
回転性めまい	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
頭位性回転性めまい	0	0	0	0	1 (0.9)	1 (0.5)
眼障害	1 (4.5)	1 (20.0)	2 (7.4)	6 (5.5)	7 (6.5)	13 (6.0)
白内障	1 (4.5)	1 (20.0)	2 (7.4)	1 (0.9)	1 (0.9)	2 (0.9)
複視	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
ドライアイ	0	1 (20.0)	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
緑内障	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
眼窩周囲痛	0	0	0	0	1 (0.9)	1 (0.5)
眼窩周囲腫脹	0	0	0	0	2 (1.9)	2 (0.9)
網膜裂孔	0	0	0	2 (1.8)	0	2 (0.9)
霧視	0	0	0	1 (0.9)	0	1 (0.5)
視野欠損	0	0	0	0	1 (0.9)	1 (0.5)
胃腸障害	6 (27.3)	1 (20.0)	7 (25.9)	21 (19.1)	28 (26.2)	49 (22.6)
腹部膨満	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
腹痛	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
上腹部痛	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
アフタ性潰瘍	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害 (Cont.)						
呼気臭	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
虚血性大腸炎	0	0	0	1 (0.9)	0	1 (0.5)
便秘	2 (9.1)	0	2 (7.4)	6 (5.5)	12 (11.2)	18 (8.3)
齲歯	1 (4.5)	0	1 (3.7)	0	0	0
下痢	3 (13.6)	1 (20.0)	4 (14.8)	3 (2.7)	2 (1.9)	5 (2.3)
口内乾燥	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
消化不良	0	0	0	1 (0.9)	0	1 (0.5)
嚥下障害	0	0	0	0	1 (0.9)	1 (0.5)
糞塊	0	0	0	0	1 (0.9)	1 (0.5)
排便回数増加	0	0	0	0	1 (0.9)	1 (0.5)
胃食道逆流性疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
舌炎	0	0	0	1 (0.9)	0	1 (0.5)
舌痛	0	0	0	1 (0.9)	0	1 (0.5)
吐血	0	0	0	1 (0.9)	0	1 (0.5)
痔核	0	0	0	1 (0.9)	0	1 (0.5)
裂孔ヘルニア	0	0	0	1 (0.9)	0	1 (0.5)
胃排出不全	0	0	0	1 (0.9)	0	1 (0.5)
腸出血	0	0	0	1 (0.9)	0	1 (0.5)
過敏性腸症候群	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
大腸ポリープ	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害 (Cont.)						
口唇乾燥	1 (4.5)	0	1 (3.7)	0	0	0
メレナ	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
口腔腫脹	0	0	0	1 (0.9)	0	1 (0.5)
悪心	2 (9.1)	0	2 (7.4)	6 (5.5)	11 (10.3)	17 (7.8)
口腔内不快感	0	0	0	1 (0.9)	0	1 (0.5)
口腔内痛	0	0	0	1 (0.9)	0	1 (0.5)
口の錯感覚	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
直腸出血	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
歯痛	0	0	0	0	1 (0.9)	1 (0.5)
嘔吐	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
一般・全身障害および投与部位の状態	17 (77.3)	3 (60.0)	20 (74.1)	89 (80.9)	93 (86.9)	182 (83.9)
投与部位内出血	0	0	0	0	1 (0.9)	1 (0.5)
投与部位紅斑	1 (4.5)	0	1 (3.7)	0	0	0
投与部位漏出	0	0	0	0	2 (1.9)	2 (0.9)
無力症	0	0	0	3 (2.7)	0	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
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	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
カテーテル留置部位漏出	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位出血	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位炎症	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位刺激感	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	0	2 (1.9)	2 (0.9)
胸部不快感	0	0	0	0	1 (0.9)	1 (0.5)
胸痛	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
泣き	0	0	0	1 (0.9)	0	1 (0.5)
不快感	0	0	0	1 (0.9)	0	1 (0.5)
薬効欠如	0	0	0	0	1 (0.9)	1 (0.5)
薬剤離脱症候群	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
疲労	0	0	0	6 (5.5)	3 (2.8)	9 (4.1)
異常感	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
冷感	0	0	0	0	1 (0.9)	1 (0.5)
熱感	0	0	0	1 (0.9)	0	1 (0.5)
歩行障害	0	0	0	0	2 (1.9)	2 (0.9)
歩行不能	0	0	0	1 (0.9)	0	1 (0.5)
低体温	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
インフルエンザ様疾患	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
注入部位内出血	1 (4.5)	0	1 (3.7)	9 (8.2)	8 (7.5)	17 (7.8)
注入部位皮膚炎	2 (9.1)	0	2 (7.4)	0	2 (1.9)	2 (0.9)
注入部位分泌物	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位変色	0	0	0	2 (1.8)	0	2 (0.9)
注入部位不快感	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
注入部位びらん	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位紅斑	7 (31.8)	3 (60.0)	10 (37.0)	58 (52.7)	57 (53.3)	115 (53.0)
注入部位皮膚剥脱	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
注入部位血管外漏出	0	0	0	8 (7.3)	12 (11.2)	20 (9.2)
注入部位血腫	0	0	0	8 (7.3)	8 (7.5)	16 (7.4)
注入部位出血	0	0	0	4 (3.6)	5 (4.7)	9 (4.1)
注入部位硬結	4 (18.2)	1 (20.0)	5 (18.5)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位炎症	0	0	0	3 (2.7)	6 (5.6)	9 (4.1)
注入部位損傷	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注入部位刺激感	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
注入部位腫瘤	2 (9.1)	1 (20.0)	3 (11.1)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位壊死	0	0	0	0	1 (0.9)	1 (0.5)
注入部位結節	0	0	0	34 (30.9)	34 (31.8)	68 (31.3)
注入部位浮腫	0	0	0	19 (17.3)	28 (26.2)	47 (21.7)
注入部位疼痛	1 (4.5)	0	1 (3.7)	17 (15.5)	20 (18.7)	37 (17.1)
注入部位蒼白	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
注入部位丘疹	0	0	0	7 (6.4)	11 (10.3)	18 (8.3)
注入部位異常感覚	0	0	0	0	2 (1.9)	2 (0.9)
注入部位そう痒感	0	0	0	5 (4.5)	2 (1.9)	7 (3.2)
注入部位発疹	1 (4.5)	1 (20.0)	2 (7.4)	2 (1.8)	3 (2.8)	5 (2.3)
注入部位反応	0	0	0	13 (11.8)	18 (16.8)	31 (14.3)
注入部位痂皮	0	0	0	0	1 (0.9)	1 (0.5)
注入部位腫脹	1 (4.5)	0	1 (3.7)	3 (2.7)	2 (1.9)	5 (2.3)
注入部位小水疱	0	0	0	0	2 (1.9)	2 (0.9)
注入部位熱感	0	0	0	0	1 (0.9)	1 (0.5)
注射部位内出血	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注射部位変色	0	0	0	1 (0.9)	0	1 (0.5)
注射部位紅斑	1 (4.5)	0	1 (3.7)	5 (4.5)	8 (7.5)	13 (6.0)
注射部位漏出	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注射部位血腫	0	0	0	0	1 (0.9)	1 (0.5)
注射部位出血	0	0	0	0	1 (0.9)	1 (0.5)
注射部位炎症	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
注射部位結節	0	0	0	3 (2.7)	6 (5.6)	9 (4.1)
注射部位浮腫	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)
注射部位疼痛	0	0	0	2 (1.8)	6 (5.6)	8 (3.7)
注射部位丘疹	0	0	0	0	1 (0.9)	1 (0.5)
注射部位反応	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射部位腫脹	1 (4.5)	1 (20.0)	2 (7.4)	1 (0.9)	1 (0.9)	2 (0.9)
注射部位蕁麻疹	0	0	0	0	1 (0.9)	1 (0.5)
滴下投与部位熱傷	0	0	0	0	1 (0.9)	1 (0.5)
滴下投与部位痛	0	0	0	0	1 (0.9)	1 (0.5)
限局性浮腫	0	1 (20.0)	1 (3.7)	0	0	0
適用部位からの吸収不良	0	0	0	0	1 (0.9)	1 (0.5)
倦怠感	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
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	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
医療機器使用部位そう痒感	0	0	0	1 (0.9)	0	1 (0.5)
医療機器使用部位発疹	0	0	0	0	2 (1.9)	2 (0.9)
小結節	0	0	0	1 (0.9)	0	1 (0.5)
非心臓性胸痛	0	0	0	0	2 (1.9)	2 (0.9)
末梢性浮腫	1 (4.5)	1 (20.0)	2 (7.4)	4 (3.6)	3 (2.8)	7 (3.2)
疼痛	0	0	0	2 (1.8)	0	2 (0.9)
末梢腫脹	0	0	0	0	4 (3.7)	4 (1.8)
穿刺部位内出血	1 (4.5)	0	1 (3.7)	0	0	0
穿刺部位紅斑	0	0	0	0	3 (2.8)	3 (1.4)
穿刺部位出血	0	0	0	1 (0.9)	0	1 (0.5)
穿刺部位硬結	2 (9.1)	0	2 (7.4)	0	0	0
穿刺部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位腫脹	0	0	0	0	1 (0.9)	1 (0.5)
発熱	1 (4.5)	0	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
口渇	1 (4.5)	0	1 (3.7)	0	0	0
血管穿刺部位硬結	1 (4.5)	0	1 (3.7)	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
肝胆道系障害	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
肝嚢胞	0	0	0	1 (0.9)	0	1 (0.5)
脂肪肝	0	0	0	0	1 (0.9)	1 (0.5)
門脈血栓症	0	0	0	1 (0.9)	0	1 (0.5)
感染症および寄生虫症	5 (22.7)	2 (40.0)	7 (25.9)	53 (48.2)	54 (50.5)	107 (49.3)
無症候性COVID-19	0	0	0	0	1 (0.9)	1 (0.5)
細菌性疾患キャリアー	0	0	0	0	1 (0.9)	1 (0.5)
ボレリア感染	0	0	0	1 (0.9)	0	1 (0.5)
ウイルス性気管支炎	0	0	0	0	1 (0.9)	1 (0.5)
COVID-19	0	0	0	1 (0.9)	0	1 (0.5)
COVID-19肺炎	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位感染	0	0	0	1 (0.9)	0	1 (0.5)
蜂巣炎	0	1 (20.0)	1 (3.7)	1 (0.9)	0	1 (0.5)
結膜炎	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
膀胱炎	0	0	0	0	1 (0.9)	1 (0.5)
爪の皮膚糸状菌症	0	1 (20.0)	1 (3.7)	0	0	0
真菌感染	0	0	0	1 (0.9)	0	1 (0.5)
胃腸炎	0	0	0	0	1 (0.9)	1 (0.5)
歯肉炎	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
麦粒腫	1 (4.5)	0	1 (3.7)	0	0	0
感染性皮膚潰瘍	0	0	0	0	1 (0.9)	1 (0.5)
インフルエンザ	0	0	0	0	1 (0.9)	1 (0.5)
注入部位膿瘍	0	0	0	13 (11.8)	13 (12.1)	26 (12.0)
注入部位蜂巣炎	3 (13.6)	1 (20.0)	4 (14.8)	26 (23.6)	26 (24.3)	52 (24.0)
注入部位感染	0	0	0	6 (5.5)	11 (10.3)	17 (7.8)
注入部位膿疱	0	0	0	0	1 (0.9)	1 (0.5)
注射部位蜂巣炎	0	0	0	0	3 (2.8)	3 (1.4)
上咽頭炎	0	1 (20.0)	1 (3.7)	5 (4.5)	4 (3.7)	9 (4.1)
爪真菌症	0	0	0	0	1 (0.9)	1 (0.5)
耳下腺膿瘍	0	0	0	0	1 (0.9)	1 (0.5)
肺炎	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
術後膿瘍	1 (4.5)	0	1 (3.7)	0	0	0
シュードモナス感染	0	0	0	0	1 (0.9)	1 (0.5)
膿疱性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
気道感染	0	0	0	0	1 (0.9)	1 (0.5)
敗血症	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
敗血症性ショック	0	0	0	1 (0.9)	0	1 (0.5)
副鼻腔炎	0	0	0	1 (0.9)	0	1 (0.5)
ブドウ球菌感染	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
歯感染	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
上気道感染	0	0	0	1 (0.9)	0	1 (0.5)
尿路感染	0	0	0	8 (7.3)	11 (10.3)	19 (8.8)
水痘帯状疱疹ウイルス感染	0	0	0	1 (0.9)	0	1 (0.5)
傷害、中毒および処置合併症	6 (27.3)	2 (40.0)	8 (29.6)	15 (13.6)	24 (22.4)	39 (18.0)
足関節部骨折	0	0	0	0	1 (0.9)	1 (0.5)
節足動物咬傷	0	0	0	0	1 (0.9)	1 (0.5)
骨挫傷	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
脳挫傷	1 (4.5)	0	1 (3.7)	0	0	0
挫傷	1 (4.5)	0	1 (3.7)	1 (0.9)	6 (5.6)	7 (3.2)
医療機器設置の問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器による投与の欠落	0	0	0	1 (0.9)	0	1 (0.5)
期限切れの製品使用	0	0	0	1 (0.9)	0	1 (0.5)
眼挫傷	0	0	0	0	1 (0.9)	1 (0.5)
顔面損傷	0	0	0	0	1 (0.9)	1 (0.5)
顔面骨骨折	0	0	0	0	2 (1.9)	2 (0.9)
転倒	6 (27.3)	2 (40.0)	8 (29.6)	10 (9.1)	21 (19.6)	31 (14.3)
頭部損傷	1 (4.5)	0	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
注入に伴う反応	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
傷害、中毒および処置合併症 (Cont.)						
関節脱臼	0	0	0	0	1 (0.9)	1 (0.5)
靱帯捻挫	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
腰椎骨折	0	0	0	0	1 (0.9)	1 (0.5)
過量投与	0	0	0	0	1 (0.9)	1 (0.5)
処置後挫傷	0	0	0	1 (0.9)	0	1 (0.5)
処置によるめまい	0	0	0	0	1 (0.9)	1 (0.5)
肋骨骨折	1 (4.5)	1 (20.0)	2 (7.4)	0	1 (0.9)	1 (0.5)
皮膚擦過傷	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
皮膚損傷	1 (4.5)	0	1 (3.7)	0	0	0
皮膚裂傷	0	0	0	1 (0.9)	6 (5.6)	7 (3.2)
ストレス骨折	0	0	0	1 (0.9)	0	1 (0.5)
硬膜下血腫	0	0	0	0	1 (0.9)	1 (0.5)
サンバーン	0	0	0	0	1 (0.9)	1 (0.5)
腱断裂	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
過少量投与	0	0	0	0	1 (0.9)	1 (0.5)
創傷	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
臨床検査	3 (13.6)	0	3 (11.1)	20 (18.2)	22 (20.6)	42 (19.4)
血中クレアチンホスホキナーゼ増加	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
血中クレアチニン減少	0	0	0	0	1 (0.9)	1 (0.5)
血中葉酸減少	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
血中ホモシステイン増加	1 (4.5)	0	1 (3.7)	0	2 (1.9)	2 (0.9)
血中リン減少	0	0	0	0	1 (0.9)	1 (0.5)
血圧上昇	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
起立血圧低下	0	0	0	1 (0.9)	0	1 (0.5)
血中ナトリウム減少	0	0	0	1 (0.9)	0	1 (0.5)
C-反応性蛋白増加	0	0	0	0	1 (0.9)	1 (0.5)
握力低下	0	0	0	1 (0.9)	0	1 (0.5)
ヘモグロビン減少	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
リンパ球数減少	0	0	0	0	1 (0.9)	1 (0.5)
単球数増加	0	0	0	0	1 (0.9)	1 (0.5)
好中球数増加	0	0	0	0	2 (1.9)	2 (0.9)
プロトロンビン時間延長	0	0	0	0	1 (0.9)	1 (0.5)
赤血球数減少	0	0	0	0	1 (0.9)	1 (0.5)
ビタミンB12減少	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
ビタミンB6減少	0	0	0	5 (4.5)	6 (5.6)	11 (5.1)
ビタミンD減少	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
臨床検査 (Cont.)						
体重減少	1 (4.5)	0	1 (3.7)	9 (8.2)	12 (11.2)	21 (9.7)
体重増加	0	0	0	2 (1.8)	0	2 (0.9)
白血球数増加	0	0	0	0	2 (1.9)	2 (0.9)
代謝および栄養障害	2 (9.1)	1 (20.0)	3 (11.1)	9 (8.2)	16 (15.0)	25 (11.5)
悪液質	0	0	0	1 (0.9)	0	1 (0.5)
食欲減退	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
脱水	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
糖尿病	0	0	0	0	1 (0.9)	1 (0.5)
水分過負荷	0	0	0	0	1 (0.9)	1 (0.5)
体液貯留	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
葉酸欠乏	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
耐糖能障害	0	0	0	0	1 (0.9)	1 (0.5)
高コレステロール血症	0	0	0	0	1 (0.9)	1 (0.5)
高血糖	0	0	0	0	1 (0.9)	1 (0.5)
高ホモシステイン血症	0	0	0	0	1 (0.9)	1 (0.5)
低カリウム血症	0	0	0	0	3 (2.8)	3 (1.4)
低ナトリウム血症	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
栄養障害	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
代謝および栄養障害 (Cont.)						
ビタミンB群欠乏	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
ビタミンB12欠乏	0	1 (20.0)	1 (3.7)	0	1 (0.9)	1 (0.5)
ビタミンB6欠乏	1 (4.5)	1 (20.0)	2 (7.4)	2 (1.8)	4 (3.7)	6 (2.8)
筋骨格系および結合組織障害	5 (22.7)	1 (20.0)	6 (22.2)	19 (17.3)	19 (17.8)	38 (17.5)
関節痛	0	1 (20.0)	1 (3.7)	3 (2.7)	2 (1.9)	5 (2.3)
反応性関節炎	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
背部痛	1 (4.5)	0	1 (3.7)	7 (6.4)	4 (3.7)	11 (5.1)
骨痛	0	0	0	0	1 (0.9)	1 (0.5)
滑液包炎	0	0	0	2 (1.8)	0	2 (0.9)
外骨腫	0	0	0	0	1 (0.9)	1 (0.5)
椎間関節症候群	0	0	0	0	1 (0.9)	1 (0.5)
椎間板変性症	0	0	0	1 (0.9)	0	1 (0.5)
椎間板突出	0	0	0	0	1 (0.9)	1 (0.5)
関節滲出液	0	0	0	0	2 (1.9)	2 (0.9)
関節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
四肢不快感	0	0	0	0	1 (0.9)	1 (0.5)
筋萎縮	0	0	0	0	1 (0.9)	1 (0.5)
筋痙縮	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
筋骨格系および結合組織障害 (Cont.)						
筋力低下	0	0	0	4 (3.6)	1 (0.9)	5 (2.3)
筋骨格硬直	0	0	0	0	1 (0.9)	1 (0.5)
筋肉痛	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
頚部痛	0	0	0	2 (1.8)	0	2 (0.9)
骨炎	0	0	0	0	1 (0.9)	1 (0.5)
変形性関節症	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
骨減少症	0	0	0	1 (0.9)	0	1 (0.5)
四肢痛	2 (9.1)	0	2 (7.4)	1 (0.9)	3 (2.8)	4 (1.8)
関節周囲炎	0	0	0	0	1 (0.9)	1 (0.5)
姿勢異常	0	0	0	0	1 (0.9)	1 (0.5)
横紋筋融解症	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
肩回旋筋腱板症候群	0	0	0	0	1 (0.9)	1 (0.5)
仙腸関節機能障害	0	0	0	1 (0.9)	0	1 (0.5)
変形性脊椎症	0	0	0	1 (0.9)	0	1 (0.5)
腱障害	0	0	0	0	1 (0.9)	1 (0.5)
腱炎	0	0	0	1 (0.9)	0	1 (0.5)
斜頚	0	0	0	0	1 (0.9)	1 (0.5)
弾発指	1 (4.5)	0	1 (3.7)	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
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）	0	0	0	0	4 (3.7)	4 (1.8)
基底細胞癌	0	0	0	0	2 (1.9)	2 (0.9)
脂漏性角化症	0	0	0	0	1 (0.9)	1 (0.5)
皮膚有棘細胞癌	0	0	0	0	1 (0.9)	1 (0.5)
神経系障害	10 (45.5)	2 (40.0)	12 (44.4)	52 (47.3)	46 (43.0)	98 (45.2)
アカシジア	0	0	0	1 (0.9)	0	1 (0.5)
健忘	0	0	0	1 (0.9)	0	1 (0.5)
失語症	0	0	0	0	1 (0.9)	1 (0.5)
運動失調	1 (4.5)	0	1 (3.7)	0	0	0
平衡障害	0	0	0	0	4 (3.7)	4 (1.8)
運動緩慢	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
手根管症候群	0	0	0	0	1 (0.9)	1 (0.5)
大脳萎縮	0	0	0	0	1 (0.9)	1 (0.5)
脳出血	0	0	0	0	1 (0.9)	1 (0.5)
脳圧排効果	0	0	0	0	1 (0.9)	1 (0.5)
脳血管発作	0	0	0	0	1 (0.9)	1 (0.5)
認知障害	0	0	0	4 (3.6)	2 (1.9)	6 (2.8)
振動覚低下	0	0	0	1 (0.9)	0	1 (0.5)
注意力障害	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
浮動性めまい	2 (9.1)	1 (20.0)	3 (11.1)	13 (11.8)	9 (8.4)	22 (10.1)
体位性めまい	0	0	0	5 (4.5)	0	5 (2.3)
構語障害	0	0	0	0	3 (2.8)	3 (1.4)
味覚不全	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
ジスキネジア	0	0	0	12 (10.9)	6 (5.6)	18 (8.3)
起立障害	0	0	0	1 (0.9)	0	1 (0.5)
ジストニア	0	0	0	2 (1.8)	5 (4.7)	7 (3.2)
脳症	0	0	0	0	1 (0.9)	1 (0.5)
てんかん	0	0	0	0	1 (0.9)	1 (0.5)
本態性振戦	0	0	0	0	1 (0.9)	1 (0.5)
伸展性足底反応	0	0	0	1 (0.9)	0	1 (0.5)
すくみ現象	0	0	0	4 (3.6)	0	4 (1.8)
全身性強直性間代性発作	0	0	0	0	1 (0.9)	1 (0.5)
頭部不快感	0	0	0	1 (0.9)	0	1 (0.5)
頭痛	2 (9.1)	0	2 (7.4)	5 (4.5)	7 (6.5)	12 (5.5)
片側感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
不全片麻痺	0	0	0	0	1 (0.9)	1 (0.5)
感覚鈍麻	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
反射減弱	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
不規則睡眠覚醒リズム障害	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
嗜眠	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
意識消失	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
腰仙部神経根障害	0	0	0	0	1 (0.9)	1 (0.5)
記憶障害	0	0	0	0	2 (1.9)	2 (0.9)
代謝性脳症	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
神経痛	0	0	0	0	1 (0.9)	1 (0.5)
末梢性ニューロパチー	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
オンオフ現象	0	0	0	4 (3.6)	4 (3.7)	8 (3.7)
錯感覚	0	0	0	4 (3.6)	3 (2.8)	7 (3.2)
パーキンソン病	4 (18.2)	0	4 (14.8)	8 (7.3)	5 (4.7)	13 (6.0)
パーキンソニズム	0	1 (20.0)	1 (3.7)	0	2 (1.9)	2 (0.9)
側反弓	1 (4.5)	0	1 (3.7)	0	2 (1.9)	2 (0.9)
多発ニューロパチー	0	0	0	0	2 (1.9)	2 (0.9)
失神寸前の状態	0	0	0	0	1 (0.9)	1 (0.5)
心因性発作	0	0	0	0	1 (0.9)	1 (0.5)
精神運動亢進	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
反射異常	0	0	0	0	1 (0.9)	1 (0.5)
安静時振戦	0	0	0	0	1 (0.9)	1 (0.5)
坐骨神経痛	0	0	0	0	3 (2.8)	3 (1.4)
痙攣発作	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
感覚障害	0	0	0	0	1 (0.9)	1 (0.5)
感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
睡眠時麻痺	0	0	0	1 (0.9)	0	1 (0.5)
傾眠	0	0	0	9 (8.2)	3 (2.8)	12 (5.5)
失神	0	0	0	0	3 (2.8)	3 (1.4)
振戦	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
製品の問題	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
医療機器送達システムの問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器位置異常	0	0	0	1 (0.9)	0	1 (0.5)
医療機器機能不良	0	0	0	0	1 (0.9)	1 (0.5)
精神障害	11 (50.0)	3 (60.0)	14 (51.9)	39 (35.5)	51 (47.7)	90 (41.5)
異常な夢	0	0	0	0	1 (0.9)	1 (0.5)
感情不安定	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
激越	0	0	0	0	1 (0.9)	1 (0.5)
不安	0	0	0	10 (9.1)	18 (16.8)	28 (12.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
不安障害	0	1 (20.0)	1 (3.7)	0	0	0
無感情	0	0	0	1 (0.9)	0	1 (0.5)
歯ぎしり	0	0	0	2 (1.8)	0	2 (0.9)
強迫行為	0	0	0	0	1 (0.9)	1 (0.5)
強迫性性行動	0	0	0	1 (0.9)	0	1 (0.5)
錯乱状態	0	0	0	4 (3.6)	4 (3.7)	8 (3.7)
譫妄	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
妄想	5 (22.7)	0	5 (18.5)	3 (2.7)	2 (1.9)	5 (2.3)
寄生虫妄想	0	0	0	1 (0.9)	0	1 (0.5)
妄想性障害、詳細不明	0	0	0	0	1 (0.9)	1 (0.5)
抑うつ気分	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
うつ病	0	1 (20.0)	1 (3.7)	2 (1.8)	1 (0.9)	3 (1.4)
抑うつ症状	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
ドーパミン調節障害症候群	0	0	0	1 (0.9)	0	1 (0.5)
ディスフェミア	0	0	0	0	1 (0.9)	1 (0.5)
睡眠異常	0	0	0	1 (0.9)	0	1 (0.5)
情動障害	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射恐怖	0	0	0	0	1 (0.9)	1 (0.5)
幻覚	8 (36.4)	1 (20.0)	9 (33.3)	12 (10.9)	20 (18.7)	32 (14.7)
幻聴	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
幻嗅	0	0	0	0	1 (0.9)	1 (0.5)
幻視	1 (4.5)	1 (20.0)	2 (7.4)	9 (8.2)	4 (3.7)	13 (6.0)
混合性幻覚	0	0	0	1 (0.9)	0	1 (0.5)
性欲過剰	0	0	0	1 (0.9)	0	1 (0.5)
錯覚	0	0	0	1 (0.9)	0	1 (0.5)
衝動制御障害	0	0	0	0	4 (3.7)	4 (1.8)
衝動行為	0	0	0	0	1 (0.9)	1 (0.5)
不眠症	1 (4.5)	0	1 (3.7)	8 (7.3)	9 (8.4)	17 (7.8)
易刺激性	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
嫉妬妄想	1 (4.5)	0	1 (3.7)	0	0	0
躁病	0	0	0	0	1 (0.9)	1 (0.5)
気分変化	0	0	0	1 (0.9)	0	1 (0.5)
気分動揺	0	0	0	0	1 (0.9)	1 (0.5)
悪夢	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
強迫観念	0	0	0	1 (0.9)	0	1 (0.5)
パニック発作	0	0	0	0	3 (2.8)	3 (1.4)
パニック反応	0	0	0	0	1 (0.9)	1 (0.5)
妄想症	0	0	0	2 (1.8)	0	2 (0.9)
睡眠の質低下	0	0	0	1 (0.9)	0	1 (0.5)
処置に対する不安	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
精神病性障害	0	0	0	4 (3.6)	2 (1.9)	6 (2.8)
精神病症状	0	0	0	1 (0.9)	0	1 (0.5)
レム睡眠行動障害	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
レム睡眠異常	1 (4.5)	0	1 (3.7)	0	0	0
睡眠障害	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
ねごと	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
常同症	0	0	0	0	1 (0.9)	1 (0.5)
ストレス	0	0	0	0	1 (0.9)	1 (0.5)
自殺念慮	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
自殺企図	0	0	0	1 (0.9)	0	1 (0.5)
腎および尿路障害	2 (9.1)	0	2 (7.4)	9 (8.2)	7 (6.5)	16 (7.4)
膀胱痙縮	0	0	0	1 (0.9)	0	1 (0.5)
膀胱結石	1 (4.5)	0	1 (3.7)	0	0	0
排尿困難	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
緊張性膀胱	0	0	0	1 (0.9)	0	1 (0.5)
夜間頻尿	0	0	0	0	1 (0.9)	1 (0.5)
多尿	0	0	0	0	1 (0.9)	1 (0.5)
腎機能障害	0	0	0	0	1 (0.9)	1 (0.5)
尿管結石症	0	0	0	0	1 (0.9)	1 (0.5)
切迫性尿失禁	0	0	0	3 (2.7)	0	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
腎および尿路障害 (Cont.)						
尿失禁	1 (4.5)	0	1 (3.7)	2 (1.8)	2 (1.9)	4 (1.8)
尿閉	0	0	0	0	3 (2.8)	3 (1.4)
尿路障害	0	0	0	1 (0.9)	0	1 (0.5)
尿異常	0	0	0	0	1 (0.9)	1 (0.5)
尿臭異常	0	0	0	0	1 (0.9)	1 (0.5)
生殖系および乳房障害	1 (4.5)	0	1 (3.7)	1 (0.9)	4 (3.7)	5 (2.3)
良性前立腺肥大症	1 (4.5)	0	1 (3.7)	0	0	0
勃起不全	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
ペイロニー病	0	0	0	0	1 (0.9)	1 (0.5)
前立腺腫大	0	0	0	0	1 (0.9)	1 (0.5)
膣脱	0	0	0	0	1 (0.9)	1 (0.5)
呼吸器、胸郭および縦隔障害	0	0	0	6 (5.5)	19 (17.8)	25 (11.5)
急性呼吸不全	0	0	0	0	1 (0.9)	1 (0.5)
気管支拡張症	0	0	0	1 (0.9)	0	1 (0.5)
咳嗽	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
発声障害	0	0	0	0	2 (1.9)	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
呼吸器、胸郭および縦隔障害 (Cont.)						
呼吸困難	0	0	0	2 (1.8)	6 (5.6)	8 (3.7)
労作性呼吸困難	0	0	0	1 (0.9)	0	1 (0.5)
鼻出血	0	0	0	0	1 (0.9)	1 (0.5)
過換気	0	0	0	0	2 (1.9)	2 (0.9)
口腔咽頭痛	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
誤嚥性肺炎	0	0	0	0	1 (0.9)	1 (0.5)
湿性咳嗽	0	0	0	0	1 (0.9)	1 (0.5)
肺塞栓症	0	0	0	0	2 (1.9)	2 (0.9)
ラ音	0	0	0	0	1 (0.9)	1 (0.5)
鼻痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻漏	0	0	0	0	2 (1.9)	2 (0.9)
咽喉刺激感	0	0	0	0	1 (0.9)	1 (0.5)
皮膚および皮下組織障害	4 (18.2)	1 (20.0)	5 (18.5)	10 (9.1)	13 (12.1)	23 (10.6)
脱毛症	0	0	0	2 (1.8)	0	2 (0.9)
褥瘡性潰瘍	0	0	0	0	1 (0.9)	1 (0.5)
皮膚嚢腫	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
皮膚炎	0	0	0	0	1 (0.9)	1 (0.5)
接触皮膚炎	0	0	0	2 (1.8)	0	2 (0.9)
おむつ皮膚炎	1 (4.5)	0	1 (3.7)	0	0	0
薬疹	0	0	0	1 (0.9)	0	1 (0.5)
皮膚乾燥	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
斑状出血	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
皮膚および皮下組織障害 (Cont.)						
紅斑	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
爪の障害	0	0	0	1 (0.9)	0	1 (0.5)
脂肪織炎	0	0	0	0	1 (0.9)	1 (0.5)
丘疹	0	0	0	0	2 (1.9)	2 (0.9)
光線過敏性反応	0	0	0	0	1 (0.9)	1 (0.5)
そう痒症	0	1 (20.0)	1 (3.7)	2 (1.8)	0	2 (0.9)
乾癬	0	0	0	0	1 (0.9)	1 (0.5)
発疹	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
紅斑性皮疹	0	0	0	0	1 (0.9)	1 (0.5)
そう痒性皮疹	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
皮膚刺激	0	0	0	0	1 (0.9)	1 (0.5)
皮膚病変	0	0	0	0	1 (0.9)	1 (0.5)
皮膚潰瘍	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
蕁麻疹	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
社会環境	0	0	0	1 (0.9)	0	1 (0.5)
運動不能	0	0	0	1 (0.9)	0	1 (0.5)
外科および内科処置	0	1 (20.0)	1 (3.7)	0	0	0
抜歯	0	1 (20.0)	1 (3.7)	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
血管障害	0	0	0	11 (10.0)	15 (14.0)	26 (12.0)
深部静脈血栓症	0	0	0	0	1 (0.9)	1 (0.5)
血腫	0	0	0	0	1 (0.9)	1 (0.5)
出血	0	0	0	0	1 (0.9)	1 (0.5)
ほてり	0	0	0	0	1 (0.9)	1 (0.5)
高血圧	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
高血圧クリーゼ	0	0	0	1 (0.9)	0	1 (0.5)
低血圧	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
不安定血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性高血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性低血圧	0	0	0	6 (5.5)	6 (5.6)	12 (5.5)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period	N=22	N=5	N=27	N=110	N=107	N=217
Any adverse event	15 (68.2)	4 (80.0)	19 (70.4)	90 (81.8)	93 (86.9)	183 (84.3)
心臓障害	0	0	0	0	2 (1.9)	2 (0.9)
徐脈	0	0	0	0	1 (0.9)	1 (0.5)
動悸	0	0	0	0	1 (0.9)	1 (0.5)
耳および迷路障害	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
乗物酔い	0	0	0	0	1 (0.9)	1 (0.5)
回転性めまい	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
眼障害	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
複視	0	0	0	0	1 (0.9)	1 (0.5)
眼窩周囲腫脹	0	0	0	0	1 (0.9)	1 (0.5)
霧視	0	0	0	1 (0.9)	0	1 (0.5)
胃腸障害	2 (9.1)	0	2 (7.4)	11 (10.0)	15 (14.0)	26 (12.0)
腹部膨満	0	0	0	0	2 (1.9)	2 (0.9)
腹痛	0	0	0	1 (0.9)	0	1 (0.5)
上腹部痛	0	0	0	0	1 (0.9)	1 (0.5)
アフタ性潰瘍	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
胃腸障害 (Cont.)						
呼気臭	0	0	0	2 (1.8)	0	2 (0.9)
便秘	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
下痢	1 (4.5)	0	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
口内乾燥	0	0	0	2 (1.8)	3 (2.8)	5 (2.3)
消化不良	0	0	0	1 (0.9)	0	1 (0.5)
胃食道逆流性疾患	0	0	0	0	1 (0.9)	1 (0.5)
痔核	0	0	0	1 (0.9)	0	1 (0.5)
過敏性腸症候群	0	0	0	0	1 (0.9)	1 (0.5)
悪心	1 (4.5)	0	1 (3.7)	4 (3.6)	5 (4.7)	9 (4.1)
嘔吐	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
一般・全身障害および投与部位の状態	12 (54.5)	2 (40.0)	14 (51.9)	78 (70.9)	80 (74.8)	158 (72.8)
投与部位紅斑	1 (4.5)	0	1 (3.7)	0	0	0
無力症	0	0	0	1 (0.9)	0	1 (0.5)
カテーテル留置部位紅斑	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位炎症	0	0	0	0	1 (0.9)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	0	2 (1.9)	2 (0.9)
不快感	0	0	0	1 (0.9)	0	1 (0.5)
薬剤離脱症候群	0	0	0	1 (0.9)	0	1 (0.5)
疲労	0	0	0	3 (2.7)	2 (1.9)	5 (2.3)
異常感	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
熱感	0	0	0	1 (0.9)	0	1 (0.5)
歩行障害	0	0	0	0	1 (0.9)	1 (0.5)
歩行不能	0	0	0	1 (0.9)	0	1 (0.5)
低体温	0	0	0	1 (0.9)	0	1 (0.5)
インフルエンザ様疾患	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位内出血	0	0	0	3 (2.7)	7 (6.5)	10 (4.6)
注入部位分泌物	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注入部位変色	0	0	0	2 (1.8)	0	2 (0.9)
注入部位不快感	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注入部位びらん	0	0	0	0	1 (0.9)	1 (0.5)
注入部位紅斑	5 (22.7)	2 (40.0)	7 (25.9)	45 (40.9)	43 (40.2)	88 (40.6)
注入部位皮膚剥脱	0	0	0	0	1 (0.9)	1 (0.5)
注入部位血管外漏出	0	0	0	4 (3.6)	7 (6.5)	11 (5.1)
注入部位血腫	0	0	0	4 (3.6)	4 (3.7)	8 (3.7)
注入部位出血	0	0	0	0	3 (2.8)	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注入部位硬結	3 (13.6)	0	3 (11.1)	1 (0.9)	1 (0.9)	2 (0.9)
注入部位炎症	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
注入部位腫瘤	2 (9.1)	0	2 (7.4)	2 (1.8)	1 (0.9)	3 (1.4)
注入部位壊死	0	0	0	0	1 (0.9)	1 (0.5)
注入部位結節	0	0	0	20 (18.2)	18 (16.8)	38 (17.5)
注入部位浮腫	0	0	0	14 (12.7)	16 (15.0)	30 (13.8)
注入部位疼痛	1 (4.5)	0	1 (3.7)	12 (10.9)	14 (13.1)	26 (12.0)
注入部位蒼白	0	0	0	2 (1.8)	0	2 (0.9)
注入部位丘疹	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)
注入部位異常感覚	0	0	0	0	1 (0.9)	1 (0.5)
注入部位そう痒感	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
注入部位発疹	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
注入部位反応	0	0	0	9 (8.2)	12 (11.2)	21 (9.7)
注入部位腫脹	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
注射部位内出血	0	0	0	1 (0.9)	0	1 (0.5)
注射部位紅斑	1 (4.5)	0	1 (3.7)	4 (3.6)	5 (4.7)	9 (4.1)
注射部位漏出	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
注射部位血腫	0	0	0	0	1 (0.9)	1 (0.5)
注射部位炎症	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
注射部位結節	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
注射部位浮腫	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
注射部位疼痛	0	0	0	2 (1.8)	4 (3.7)	6 (2.8)
注射部位反応	0	0	0	0	1 (0.9)	1 (0.5)
注射部位腫脹	0	0	0	1 (0.9)	0	1 (0.5)
滴下投与部位熱傷	0	0	0	0	1 (0.9)	1 (0.5)
限局性浮腫	0	1 (20.0)	1 (3.7)	0	0	0
適用部位からの吸収不良	0	0	0	0	1 (0.9)	1 (0.5)
倦怠感	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
医療機器使用部位刺激感	0	0	0	0	1 (0.9)	1 (0.5)
医療機器使用部位そう痒感	0	0	0	1 (0.9)	0	1 (0.5)
医療機器使用部位発疹	0	0	0	0	1 (0.9)	1 (0.5)
小結節	0	0	0	1 (0.9)	0	1 (0.5)
末梢性浮腫	0	1 (20.0)	1 (3.7)	1 (0.9)	2 (1.9)	3 (1.4)
末梢腫脹	0	0	0	0	2 (1.9)	2 (0.9)
穿刺部位内出血	1 (4.5)	0	1 (3.7)	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
一般・全身障害および投与部位の状態 (Cont.)						
穿刺部位紅斑	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位出血	0	0	0	1 (0.9)	0	1 (0.5)
穿刺部位硬結	1 (4.5)	0	1 (3.7)	0	0	0
穿刺部位浮腫	0	0	0	0	1 (0.9)	1 (0.5)
穿刺部位腫脹	0	0	0	0	1 (0.9)	1 (0.5)
発熱	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
口渇	1 (4.5)	0	1 (3.7)	0	0	0
肝胆道系障害	0	0	0	1 (0.9)	0	1 (0.5)
門脈血栓症	0	0	0	1 (0.9)	0	1 (0.5)
感染症および寄生虫症	0	0	0	17 (15.5)	27 (25.2)	44 (20.3)
ボレリア感染	0	0	0	1 (0.9)	0	1 (0.5)
膀胱炎	0	0	0	0	1 (0.9)	1 (0.5)
真菌感染	0	0	0	1 (0.9)	0	1 (0.5)
胃腸炎	0	0	0	0	1 (0.9)	1 (0.5)
注入部位膿瘍	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
注入部位蜂巣炎	0	0	0	10 (9.1)	13 (12.1)	23 (10.6)
注入部位感染	0	0	0	1 (0.9)	3 (2.8)	4 (1.8)
注射部位蜂巣炎	0	0	0	0	1 (0.9)	1 (0.5)
上咽頭炎	0	0	0	0	3 (2.8)	3 (1.4)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
感染症および寄生虫症 (Cont.)						
爪真菌症	0	0	0	0	1 (0.9)	1 (0.5)
肺炎	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
膿疱性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
敗血症	0	0	0	1 (0.9)	0	1 (0.5)
敗血症性ショック	0	0	0	1 (0.9)	0	1 (0.5)
尿路感染	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
傷害、中毒および処置合併症	2 (9.1)	1 (20.0)	3 (11.1)	8 (7.3)	10 (9.3)	18 (8.3)
挫傷	0	0	0	1 (0.9)	0	1 (0.5)
医療機器設置の問題	0	0	0	1 (0.9)	0	1 (0.5)
医療機器による投与の欠落	0	0	0	1 (0.9)	0	1 (0.5)
顔面骨骨折	0	0	0	0	2 (1.9)	2 (0.9)
転倒	2 (9.1)	1 (20.0)	3 (11.1)	5 (4.5)	8 (7.5)	13 (6.0)
頭部損傷	0	0	0	1 (0.9)	0	1 (0.5)
注入に伴う反応	0	0	0	1 (0.9)	0	1 (0.5)
腰椎骨折	0	0	0	0	1 (0.9)	1 (0.5)
処置後挫傷	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
傷害、中毒および処置合併症 (Cont.)						
処置によるめまい	0	0	0	0	1 (0.9)	1 (0.5)
肋骨骨折	0	0	0	0	1 (0.9)	1 (0.5)
皮膚擦過傷	0	0	0	1 (0.9)	0	1 (0.5)
皮膚裂傷	0	0	0	0	2 (1.9)	2 (0.9)
臨床検査	0	0	0	3 (2.7)	5 (4.7)	8 (3.7)
血圧上昇	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
起立血圧低下	0	0	0	1 (0.9)	0	1 (0.5)
リンパ球数減少	0	0	0	0	1 (0.9)	1 (0.5)
単球数増加	0	0	0	0	1 (0.9)	1 (0.5)
好中球数増加	0	0	0	0	1 (0.9)	1 (0.5)
ビタミンB12減少	0	0	0	1 (0.9)	0	1 (0.5)
ビタミンB6減少	0	0	0	0	2 (1.9)	2 (0.9)
体重減少	0	0	0	0	1 (0.9)	1 (0.5)
白血球数増加	0	0	0	0	1 (0.9)	1 (0.5)
代謝および栄養障害	0	0	0	1 (0.9)	5 (4.7)	6 (2.8)
食欲減退	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
脱水	0	0	0	0	1 (0.9)	1 (0.5)
耐糖能障害	0	0	0	0	1 (0.9)	1 (0.5)
高血糖	0	0	0	0	1 (0.9)	1 (0.5)
低カリウム血症	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
筋骨格系および結合組織障害	2 (9.1)	0	2 (7.4)	8 (7.3)	8 (7.5)	16 (7.4)
関節痛	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
反応性関節炎	0	0	0	0	1 (0.9)	1 (0.5)
背部痛	0	0	0	3 (2.7)	1 (0.9)	4 (1.8)
関節腫脹	0	0	0	0	1 (0.9)	1 (0.5)
筋力低下	0	0	0	2 (1.8)	0	2 (0.9)
筋骨格硬直	0	0	0	0	1 (0.9)	1 (0.5)
筋肉痛	1 (4.5)	0	1 (3.7)	1 (0.9)	1 (0.9)	2 (0.9)
四肢痛	0	0	0	0	1 (0.9)	1 (0.5)
姿勢異常	0	0	0	0	1 (0.9)	1 (0.5)
横紋筋融解症	1 (4.5)	0	1 (3.7)	0	0	0
仙腸関節機能障害	0	0	0	1 (0.9)	0	1 (0.5)
斜頚	0	0	0	0	1 (0.9)	1 (0.5)
神経系障害	6 (27.3)	1 (20.0)	7 (25.9)	30 (27.3)	25 (23.4)	55 (25.3)
運動失調	1 (4.5)	0	1 (3.7)	0	0	0
平衡障害	0	0	0	0	1 (0.9)	1 (0.5)
運動緩慢	0	0	0	1 (0.9)	0	1 (0.5)
認知障害	0	0	0	2 (1.8)	0	2 (0.9)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
浮動性めまい	2 (9.1)	0	2 (7.4)	8 (7.3)	8 (7.5)	16 (7.4)
体位性めまい	0	0	0	3 (2.7)	0	3 (1.4)
構語障害	0	0	0	0	1 (0.9)	1 (0.5)
味覚不全	0	0	0	2 (1.8)	0	2 (0.9)
ジスキネジア	0	0	0	6 (5.5)	3 (2.8)	9 (4.1)
起立障害	0	0	0	1 (0.9)	0	1 (0.5)
ジストニア	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
本態性振戦	0	0	0	0	1 (0.9)	1 (0.5)
すくみ現象	0	0	0	3 (2.7)	0	3 (1.4)
頭部不快感	0	0	0	1 (0.9)	0	1 (0.5)
頭痛	1 (4.5)	0	1 (3.7)	3 (2.7)	2 (1.9)	5 (2.3)
片側感覚消失	0	0	0	0	1 (0.9)	1 (0.5)
不全片麻痺	0	0	0	0	1 (0.9)	1 (0.5)
代謝性脳症	0	0	0	0	1 (0.9)	1 (0.5)
オンオフ現象	0	0	0	3 (2.7)	3 (2.8)	6 (2.8)
錯感覚	0	0	0	0	1 (0.9)	1 (0.5)
パーキンソン病	2 (9.1)	0	2 (7.4)	3 (2.7)	3 (2.8)	6 (2.8)
パーキンソニズム	0	1 (20.0)	1 (3.7)	0	0	0
精神運動亢進	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
安静時振戦	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
神経系障害 (Cont.)						
坐骨神経痛	0	0	0	0	2 (1.9)	2 (0.9)
傾眠	0	0	0	2 (1.8)	2 (1.9)	4 (1.8)
振戦	0	0	0	0	2 (1.9)	2 (0.9)
製品の問題	0	0	0	0	1 (0.9)	1 (0.5)
医療機器機能不良	0	0	0	0	1 (0.9)	1 (0.5)
精神障害	7 (31.8)	2 (40.0)	9 (33.3)	24 (21.8)	22 (20.6)	46 (21.2)
異常な夢	0	0	0	0	1 (0.9)	1 (0.5)
感情不安定	0	0	0	1 (0.9)	0	1 (0.5)
不安	0	0	0	2 (1.8)	8 (7.5)	10 (4.6)
歯ぎしり	0	0	0	2 (1.8)	0	2 (0.9)
錯乱状態	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
譫妄	0	0	0	1 (0.9)	2 (1.9)	3 (1.4)
妄想	1 (4.5)	0	1 (3.7)	0	1 (0.9)	1 (0.5)
抑うつ気分	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
抑うつ症状	1 (4.5)	0	1 (3.7)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
精神障害 (Cont.)						
睡眠異常	0	0	0	1 (0.9)	0	1 (0.5)
情動障害	0	0	0	0	1 (0.9)	1 (0.5)
幻覚	5 (22.7)	1 (20.0)	6 (22.2)	8 (7.3)	4 (3.7)	12 (5.5)
幻聴	0	0	0	0	1 (0.9)	1 (0.5)
幻視	0	1 (20.0)	1 (3.7)	4 (3.6)	0	4 (1.8)
不眠症	0	0	0	7 (6.4)	3 (2.8)	10 (4.6)
易刺激性	0	0	0	1 (0.9)	0	1 (0.5)
嫉妬妄想	1 (4.5)	0	1 (3.7)	0	0	0
気分変化	0	0	0	1 (0.9)	0	1 (0.5)
強迫観念	0	0	0	1 (0.9)	0	1 (0.5)
パニック発作	0	0	0	0	3 (2.8)	3 (1.4)
精神病性障害	0	0	0	2 (1.8)	0	2 (0.9)
レム睡眠行動障害	0	0	0	1 (0.9)	0	1 (0.5)
睡眠障害	0	0	0	0	1 (0.9)	1 (0.5)
ねごと	0	0	0	0	1 (0.9)	1 (0.5)
腎および尿路障害	1 (4.5)	0	1 (3.7)	5 (4.5)	1 (0.9)	6 (2.8)
排尿困難	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
切迫性尿失禁	0	0	0	2 (1.8)	0	2 (0.9)
尿失禁	1 (4.5)	0	1 (3.7)	1 (0.9)	0	1 (0.5)
尿路障害	0	0	0	1 (0.9)	0	1 (0.5)
尿異常	0	0	0	0	1 (0.9)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
生殖系および乳房障害	0	0	0	0	1 (0.9)	1 (0.5)
勃起不全	0	0	0	0	1 (0.9)	1 (0.5)
呼吸器、胸郭および縦隔障害	0	0	0	1 (0.9)	7 (6.5)	8 (3.7)
急性呼吸不全	0	0	0	0	1 (0.9)	1 (0.5)
咳嗽	0	0	0	1 (0.9)	1 (0.9)	2 (0.9)
呼吸困難	0	0	0	0	1 (0.9)	1 (0.5)
過換気	0	0	0	0	1 (0.9)	1 (0.5)
口腔咽頭痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻痛	0	0	0	0	1 (0.9)	1 (0.5)
鼻漏	0	0	0	0	1 (0.9)	1 (0.5)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)	5 (4.5)	5 (4.7)	10 (4.6)
脱毛症	0	0	0	1 (0.9)	0	1 (0.5)
接触皮膚炎	0	0	0	1 (0.9)	0	1 (0.5)
皮膚乾燥	0	0	0	0	1 (0.9)	1 (0.5)
斑状出血	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27	N=110	N=107	N=217
皮膚および皮下組織障害 (Cont.)						
紅斑	0	0	0	0	1 (0.9)	1 (0.5)
光線過敏性反応	0	0	0	0	1 (0.9)	1 (0.5)
発疹	1 (4.5)	0	1 (3.7)	0	0	0
そう痒性皮疹	0	0	0	1 (0.9)	0	1 (0.5)
皮膚刺激	0	0	0	0	1 (0.9)	1 (0.5)
皮膚病変	0	0	0	0	1 (0.9)	1 (0.5)
皮膚潰瘍	0	0	0	1 (0.9)	0	1 (0.5)
社会環境	0	0	0	1 (0.9)	0	1 (0.5)
運動不能	0	0	0	1 (0.9)	0	1 (0.5)
血管障害	0	0	0	3 (2.7)	7 (6.5)	10 (4.6)
ほてり	0	0	0	0	1 (0.9)	1 (0.5)
高血圧	0	0	0	2 (1.8)	1 (0.9)	3 (1.4)
低血圧	0	0	0	0	2 (1.9)	2 (0.9)
不安定血圧	0	0	0	0	1 (0.9)	1 (0.5)
起立性低血圧	0	0	0	1 (0.9)	4 (3.7)	5 (2.3)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period	N=17	N=3	N=20	N=94	N=92	N=186
Any adverse event	15 (88.2)	3 (100)	18 (90.0)	83 (88.3)	85 (92.4)	168 (90.3)
血液およびリンパ系障害	0	0	0	1 (1.1)	3 (3.3)	4 (2.2)
大球性貧血	0	0	0	0	1 (1.1)	1 (0.5)
凝血異常	0	0	0	0	1 (1.1)	1 (0.5)
リンパ節症	0	0	0	1 (1.1)	0	1 (0.5)
縦隔リンパ節腫脹	0	0	0	0	1 (1.1)	1 (0.5)
心臓障害	0	0	0	4 (4.3)	5 (5.4)	9 (4.8)
急性心筋梗塞	0	0	0	1 (1.1)	0	1 (0.5)
狭心症	0	0	0	1 (1.1)	0	1 (0.5)
心房細動	0	0	0	0	1 (1.1)	1 (0.5)
心停止	0	0	0	1 (1.1)	0	1 (0.5)
心肺停止	0	0	0	0	1 (1.1)	1 (0.5)
冠動脈疾患	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
冠動脈狭窄	0	0	0	1 (1.1)	0	1 (0.5)
期外収縮	0	0	0	0	1 (1.1)	1 (0.5)
左室肥大	0	0	0	0	1 (1.1)	1 (0.5)
心筋梗塞	0	0	0	1 (1.1)	0	1 (0.5)
動悸	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
耳および迷路障害	1 (5.9)	0	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
感音性難聴	1 (5.9)	0	1 (5.0)	0	0	0
回転性めまい	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
頭位性回転性めまい	0	0	0	0	1 (1.1)	1 (0.5)
眼障害	1 (5.9)	1 (33.3)	2 (10.0)	6 (6.4)	5 (5.4)	11 (5.9)
白内障	1 (5.9)	1 (33.3)	2 (10.0)	1 (1.1)	1 (1.1)	2 (1.1)
複視	0	0	0	2 (2.1)	0	2 (1.1)
ドライアイ	0	1 (33.3)	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
緑内障	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
眼窩周囲痛	0	0	0	0	1 (1.1)	1 (0.5)
眼窩周囲腫脹	0	0	0	0	1 (1.1)	1 (0.5)
網膜裂孔	0	0	0	2 (2.1)	0	2 (1.1)
視野欠損	0	0	0	0	1 (1.1)	1 (0.5)
胃腸障害	6 (35.3)	1 (33.3)	7 (35.0)	11 (11.7)	20 (21.7)	31 (16.7)
腹部膨満	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
腹痛	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
上腹部痛	1 (5.9)	0	1 (5.0)	0	0	0
呼気臭	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
胃腸障害 (Cont.)						
虚血性大腸炎	0	0	0	1 (1.1)	0	1 (0.5)
便秘	2 (11.8)	0	2 (10.0)	4 (4.3)	10 (10.9)	14 (7.5)
齲歯	1 (5.9)	0	1 (5.0)	0	0	0
下痢	2 (11.8)	1 (33.3)	3 (15.0)	2 (2.1)	0	2 (1.1)
口内乾燥	0	0	0	1 (1.1)	3 (3.3)	4 (2.2)
嚥下障害	0	0	0	0	1 (1.1)	1 (0.5)
糞塊	0	0	0	0	1 (1.1)	1 (0.5)
排便回数増加	0	0	0	0	1 (1.1)	1 (0.5)
胃食道逆流性疾患	0	0	0	1 (1.1)	0	1 (0.5)
舌炎	0	0	0	1 (1.1)	0	1 (0.5)
舌痛	0	0	0	1 (1.1)	0	1 (0.5)
吐血	0	0	0	1 (1.1)	0	1 (0.5)
裂孔ヘルニア	0	0	0	1 (1.1)	0	1 (0.5)
胃排出不全	0	0	0	1 (1.1)	0	1 (0.5)
腸出血	0	0	0	1 (1.1)	0	1 (0.5)
過敏性腸症候群	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
大腸ポリープ	0	0	0	0	1 (1.1)	1 (0.5)
口唇乾燥	1 (5.9)	0	1 (5.0)	0	0	0
メレナ	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
口腔腫脹	0	0	0	1 (1.1)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
胃腸障害 (Cont.)						
悪心	2 (11.8)	0	2 (10.0)	2 (2.1)	7 (7.6)	9 (4.8)
口腔内不快感	0	0	0	1 (1.1)	0	1 (0.5)
口腔内痛	0	0	0	1 (1.1)	0	1 (0.5)
口の錯感覚	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
直腸出血	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
歯痛	0	0	0	0	1 (1.1)	1 (0.5)
嘔吐	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
一般・全身障害および投与部位の状態	11 (64.7)	3 (100)	14 (70.0)	55 (58.5)	68 (73.9)	123 (66.1)
投与部位内出血	0	0	0	0	1 (1.1)	1 (0.5)
投与部位漏出	0	0	0	0	2 (2.2)	2 (1.1)
無力症	0	0	0	2 (2.1)	0	2 (1.1)
カテーテル留置部位紅斑	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
カテーテル留置部位漏出	0	0	0	1 (1.1)	0	1 (0.5)
カテーテル留置部位出血	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位刺激感	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位浮腫	0	0	0	0	1 (1.1)	1 (0.5)
カテーテル留置部位疼痛	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
胸部不快感	0	0	0	0	1 (1.1)	1 (0.5)
胸痛	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
泣き	0	0	0	1 (1.1)	0	1 (0.5)
薬効欠如	0	0	0	0	1 (1.1)	1 (0.5)
薬剤離脱症候群	0	0	0	0	1 (1.1)	1 (0.5)
疲労	0	0	0	3 (3.2)	1 (1.1)	4 (2.2)
異常感	0	0	0	0	1 (1.1)	1 (0.5)
冷感	0	0	0	0	1 (1.1)	1 (0.5)
歩行障害	0	0	0	0	1 (1.1)	1 (0.5)
低体温	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
インフルエンザ様疾患	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
注入部位内出血	1 (5.9)	0	1 (5.0)	6 (6.4)	2 (2.2)	8 (4.3)
注入部位皮膚炎	2 (11.8)	0	2 (10.0)	0	2 (2.2)	2 (1.1)
注入部位分泌物	0	0	0	0	1 (1.1)	1 (0.5)
注入部位不快感	0	0	0	1 (1.1)	0	1 (0.5)
注入部位びらん	0	0	0	1 (1.1)	0	1 (0.5)
注入部位紅斑	4 (23.5)	1 (33.3)	5 (25.0)	31 (33.0)	42 (45.7)	73 (39.2)
注入部位皮膚剥脱	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
注入部位血管外漏出	0	0	0	5 (5.3)	6 (6.5)	11 (5.9)
注入部位血腫	0	0	0	4 (4.3)	4 (4.3)	8 (4.3)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
注入部位出血	0	0	0	4 (4.3)	2 (2.2)	6 (3.2)
注入部位硬結	3 (17.6)	1 (33.3)	4 (20.0)	2 (2.1)	1 (1.1)	3 (1.6)
注入部位炎症	0	0	0	2 (2.1)	6 (6.5)	8 (4.3)
注入部位損傷	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
注入部位刺激感	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
注入部位腫瘤	0	1 (33.3)	1 (5.0)	1 (1.1)	1 (1.1)	2 (1.1)
注入部位結節	0	0	0	20 (21.3)	25 (27.2)	45 (24.2)
注入部位浮腫	0	0	0	8 (8.5)	18 (19.6)	26 (14.0)
注入部位疼痛	0	0	0	8 (8.5)	11 (12.0)	19 (10.2)
注入部位蒼白	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注入部位丘疹	0	0	0	6 (6.4)	8 (8.7)	14 (7.5)
注入部位異常感覚	0	0	0	0	2 (2.2)	2 (1.1)
注入部位そう痒感	0	0	0	3 (3.2)	1 (1.1)	4 (2.2)
注入部位発疹	0	1 (33.3)	1 (5.0)	1 (1.1)	2 (2.2)	3 (1.6)
注入部位反応	0	0	0	8 (8.5)	11 (12.0)	19 (10.2)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
一般・全身障害および投与部位の状態 (Cont.)						
注入部位痂皮	0	0	0	0	1 (1.1)	1 (0.5)
注入部位腫脹	1 (5.9)	0	1 (5.0)	1 (1.1)	1 (1.1)	2 (1.1)
注入部位小水疱	0	0	0	0	2 (2.2)	2 (1.1)
注入部位熱感	0	0	0	0	1 (1.1)	1 (0.5)
注射部位内出血	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注射部位変色	0	0	0	1 (1.1)	0	1 (0.5)
注射部位紅斑	1 (5.9)	0	1 (5.0)	4 (4.3)	5 (5.4)	9 (4.8)
注射部位出血	0	0	0	0	1 (1.1)	1 (0.5)
注射部位炎症	0	0	0	2 (2.1)	4 (4.3)	6 (3.2)
注射部位結節	0	0	0	3 (3.2)	5 (5.4)	8 (4.3)
注射部位浮腫	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
注射部位疼痛	0	0	0	0	2 (2.2)	2 (1.1)
注射部位丘疹	0	0	0	0	1 (1.1)	1 (0.5)
注射部位反応	0	0	0	1 (1.1)	0	1 (0.5)
注射部位腫脹	1 (5.9)	1 (33.3)	2 (10.0)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
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	0	0	0	1 (1.1)	1 (0.5)
滴下投与部位痛	0	0	0	0	1 (1.1)	1 (0.5)
倦怠感	0	0	0	0	1 (1.1)	1 (0.5)
医療機器使用部位刺激感	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
医療機器使用部位発疹	0	0	0	0	1 (1.1)	1 (0.5)
非心臓性胸痛	0	0	0	0	2 (2.2)	2 (1.1)
末梢性浮腫	1 (5.9)	0	1 (5.0)	3 (3.2)	1 (1.1)	4 (2.2)
疼痛	0	0	0	2 (2.1)	0	2 (1.1)
末梢腫脹	0	0	0	0	3 (3.3)	3 (1.6)
穿刺部位紅斑	0	0	0	0	2 (2.2)	2 (1.1)
穿刺部位硬結	2 (11.8)	0	2 (10.0)	0	0	0
発熱	0	0	0	0	1 (1.1)	1 (0.5)
血管穿刺部位硬結	1 (5.9)	0	1 (5.0)	0	0	0
肝胆道系障害	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
肝嚢胞	0	0	0	1 (1.1)	0	1 (0.5)
脂肪肝	0	0	0	0	1 (1.1)	1 (0.5)
感染症および寄生虫症	5 (29.4)	2 (66.7)	7 (35.0)	41 (43.6)	43 (46.7)	84 (45.2)
無症候性COVID-19	0	0	0	0	1 (1.1)	1 (0.5)
細菌性疾患キャリアー	0	0	0	0	1 (1.1)	1 (0.5)
ウイルス性気管支炎	0	0	0	0	1 (1.1)	1 (0.5)
COVID-19	0	0	0	1 (1.1)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
感染症および寄生虫症 (Cont.)						
COVID-19肺炎	0	0	0	1 (1.1)	0	1 (0.5)
カテーテル留置部位感染	0	0	0	1 (1.1)	0	1 (0.5)
蜂巣炎	0	1 (33.3)	1 (5.0)	1 (1.1)	0	1 (0.5)
結膜炎	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
爪の皮膚糸状菌症	0	1 (33.3)	1 (5.0)	0	0	0
歯肉炎	0	0	0	1 (1.1)	0	1 (0.5)
麦粒腫	1 (5.9)	0	1 (5.0)	0	0	0
感染性皮膚潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
インフルエンザ	0	0	0	0	1 (1.1)	1 (0.5)
注入部位膿瘍	0	0	0	10 (10.6)	9 (9.8)	19 (10.2)
注入部位蜂巣炎	3 (17.6)	1 (33.3)	4 (20.0)	18 (19.1)	18 (19.6)	36 (19.4)
注入部位感染	0	0	0	5 (5.3)	9 (9.8)	14 (7.5)
注入部位膿疱	0	0	0	0	1 (1.1)	1 (0.5)
注射部位蜂巣炎	0	0	0	0	2 (2.2)	2 (1.1)
上咽頭炎	0	1 (33.3)	1 (5.0)	5 (5.3)	1 (1.1)	6 (3.2)
耳下腺膿瘍	0	0	0	0	1 (1.1)	1 (0.5)
肺炎	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
術後膿瘍	1 (5.9)	0	1 (5.0)	0	0	0
シュードモナス感染	0	0	0	0	1 (1.1)	1 (0.5)
気道感染	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
感染症および寄生虫症 (Cont.)						
敗血症	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
副鼻腔炎	0	0	0	1 (1.1)	0	1 (0.5)
ブドウ球菌感染	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
歯感染	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
上気道感染	0	0	0	1 (1.1)	0	1 (0.5)
尿路感染	0	0	0	5 (5.3)	11 (12.0)	16 (8.6)
水痘帯状疱疹ウイルス感染	0	0	0	1 (1.1)	0	1 (0.5)
傷害、中毒および処置合併症	5 (29.4)	1 (33.3)	6 (30.0)	8 (8.5)	19 (20.7)	27 (14.5)
足関節部骨折	0	0	0	0	1 (1.1)	1 (0.5)
節足動物咬傷	0	0	0	0	1 (1.1)	1 (0.5)
骨挫傷	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
脳挫傷	1 (5.9)	0	1 (5.0)	0	0	0
挫傷	1 (5.9)	0	1 (5.0)	0	6 (6.5)	6 (3.2)
期限切れの製品使用	0	0	0	1 (1.1)	0	1 (0.5)
眼挫傷	0	0	0	0	1 (1.1)	1 (0.5)
顔面損傷	0	0	0	0	1 (1.1)	1 (0.5)
転倒	5 (29.4)	1 (33.3)	6 (30.0)	6 (6.4)	16 (17.4)	22 (11.8)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
傷害、中毒および処置合併症 (Cont.)						
頭部損傷	1 (5.9)	0	1 (5.0)	0	2 (2.2)	2 (1.1)
関節脱臼	0	0	0	0	1 (1.1)	1 (0.5)
靱帯捻挫	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
過量投与	0	0	0	0	1 (1.1)	1 (0.5)
肋骨骨折	1 (5.9)	1 (33.3)	2 (10.0)	0	0	0
皮膚擦過傷	0	0	0	0	2 (2.2)	2 (1.1)
皮膚損傷	1 (5.9)	0	1 (5.0)	0	0	0
皮膚裂傷	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
ストレス骨折	0	0	0	1 (1.1)	0	1 (0.5)
硬膜下血腫	0	0	0	0	1 (1.1)	1 (0.5)
サンバーン	0	0	0	0	1 (1.1)	1 (0.5)
腱断裂	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
過少量投与	0	0	0	0	1 (1.1)	1 (0.5)
創傷	0	0	0	1 (1.1)	0	1 (0.5)
臨床検査	3 (17.6)	0	3 (15.0)	17 (18.1)	17 (18.5)	34 (18.3)
血中クレアチンホスホキナーゼ増加	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
血中クレアチニン減少	0	0	0	0	1 (1.1)	1 (0.5)
血中葉酸減少	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
血中ホモシステイン増加	1 (5.9)	0	1 (5.0)	0	2 (2.2)	2 (1.1)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
臨床検査 (Cont.)						
血中リン減少	0	0	0	0	1 (1.1)	1 (0.5)
血中ナトリウム減少	0	0	0	1 (1.1)	0	1 (0.5)
C-反応性蛋白増加	0	0	0	0	1 (1.1)	1 (0.5)
握力低下	0	0	0	1 (1.1)	0	1 (0.5)
ヘモグロビン減少	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
好中球数増加	0	0	0	0	1 (1.1)	1 (0.5)
プロトロンビン時間延長	0	0	0	0	1 (1.1)	1 (0.5)
赤血球数減少	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB12減少	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB6減少	0	0	0	5 (5.3)	4 (4.3)	9 (4.8)
ビタミンD減少	0	0	0	0	1 (1.1)	1 (0.5)
体重減少	1 (5.9)	0	1 (5.0)	9 (9.6)	11 (12.0)	20 (10.8)
体重増加	0	0	0	2 (2.1)	0	2 (1.1)
白血球数増加	0	0	0	0	1 (1.1)	1 (0.5)
代謝および栄養障害	2 (11.8)	1 (33.3)	3 (15.0)	8 (8.5)	13 (14.1)	21 (11.3)
悪液質	0	0	0	1 (1.1)	0	1 (0.5)
食欲減退	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
脱水	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
糖尿病	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
代謝および栄養障害 (Cont.)						
水分過負荷	0	0	0	0	1 (1.1)	1 (0.5)
体液貯留	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
葉酸欠乏	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
高コレステロール血症	0	0	0	0	1 (1.1)	1 (0.5)
高ホモシステイン血症	0	0	0	0	1 (1.1)	1 (0.5)
低カリウム血症	0	0	0	0	2 (2.2)	2 (1.1)
低ナトリウム血症	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
栄養障害	0	0	0	0	1 (1.1)	1 (0.5)
ビタミンB群欠乏	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
ビタミンB12欠乏	0	1 (33.3)	1 (5.0)	0	1 (1.1)	1 (0.5)
ビタミンB6欠乏	1 (5.9)	1 (33.3)	2 (10.0)	2 (2.1)	4 (4.3)	6 (3.2)
筋骨格系および結合組織障害	4 (23.5)	1 (33.3)	5 (25.0)	13 (13.8)	13 (14.1)	26 (14.0)
関節痛	0	1 (33.3)	1 (5.0)	1 (1.1)	0	1 (0.5)
反応性関節炎	0	0	0	1 (1.1)	0	1 (0.5)
背部痛	1 (5.9)	0	1 (5.0)	4 (4.3)	3 (3.3)	7 (3.8)
骨痛	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
筋骨格系および結合組織障害 (Cont.)						
滑液包炎	0	0	0	2 (2.1)	0	2 (1.1)
外骨腫	0	0	0	0	1 (1.1)	1 (0.5)
椎間関節症候群	0	0	0	0	1 (1.1)	1 (0.5)
椎間板変性症	0	0	0	1 (1.1)	0	1 (0.5)
椎間板突出	0	0	0	0	1 (1.1)	1 (0.5)
関節滲出液	0	0	0	0	2 (2.2)	2 (1.1)
四肢不快感	0	0	0	0	1 (1.1)	1 (0.5)
筋萎縮	0	0	0	0	1 (1.1)	1 (0.5)
筋痙縮	0	0	0	2 (2.1)	3 (3.3)	5 (2.7)
筋力低下	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
頚部痛	0	0	0	2 (2.1)	0	2 (1.1)
骨炎	0	0	0	0	1 (1.1)	1 (0.5)
変形性関節症	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
骨減少症	0	0	0	1 (1.1)	0	1 (0.5)
四肢痛	2 (11.8)	0	2 (10.0)	1 (1.1)	2 (2.2)	3 (1.6)
関節周囲炎	0	0	0	0	1 (1.1)	1 (0.5)
横紋筋融解症	0	0	0	1 (1.1)	0	1 (0.5)
肩回旋筋腱板症候群	0	0	0	0	1 (1.1)	1 (0.5)
変形性脊椎症	0	0	0	1 (1.1)	0	1 (0.5)
腱障害	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
筋骨格系および結合組織障害 (Cont.)						
腱炎	0	0	0	1 (1.1)	0	1 (0.5)
弾発指	1 (5.9)	0	1 (5.0)	0	0	0
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）	0	0	0	0	4 (4.3)	4 (2.2)
基底細胞癌	0	0	0	0	2 (2.2)	2 (1.1)
脂漏性角化症	0	0	0	0	1 (1.1)	1 (0.5)
皮膚有棘細胞癌	0	0	0	0	1 (1.1)	1 (0.5)
神経系障害	5 (29.4)	1 (33.3)	6 (30.0)	32 (34.0)	33 (35.9)	65 (34.9)
アカシジア	0	0	0	1 (1.1)	0	1 (0.5)
健忘	0	0	0	1 (1.1)	0	1 (0.5)
失語症	0	0	0	0	1 (1.1)	1 (0.5)
平衡障害	0	0	0	0	4 (4.3)	4 (2.2)
運動緩慢	0	0	0	0	1 (1.1)	1 (0.5)
手根管症候群	0	0	0	0	1 (1.1)	1 (0.5)
大脳萎縮	0	0	0	0	1 (1.1)	1 (0.5)
脳出血	0	0	0	0	1 (1.1)	1 (0.5)
脳圧排効果	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害 (Cont.)						
脳血管発作	0	0	0	0	1 (1.1)	1 (0.5)
認知障害	0	0	0	2 (2.1)	2 (2.2)	4 (2.2)
振動覚低下	0	0	0	1 (1.1)	0	1 (0.5)
注意力障害	0	0	0	0	1 (1.1)	1 (0.5)
浮動性めまい	0	1 (33.3)	1 (5.0)	6 (6.4)	1 (1.1)	7 (3.8)
体位性めまい	0	0	0	3 (3.2)	0	3 (1.6)
構語障害	0	0	0	0	2 (2.2)	2 (1.1)
味覚不全	0	0	0	0	1 (1.1)	1 (0.5)
ジスキネジア	0	0	0	7 (7.4)	3 (3.3)	10 (5.4)
ジストニア	0	0	0	1 (1.1)	4 (4.3)	5 (2.7)
脳症	0	0	0	0	1 (1.1)	1 (0.5)
てんかん	0	0	0	0	1 (1.1)	1 (0.5)
伸展性足底反応	0	0	0	1 (1.1)	0	1 (0.5)
すくみ現象	0	0	0	1 (1.1)	0	1 (0.5)
全身性強直性間代性発作	0	0	0	0	1 (1.1)	1 (0.5)
頭痛	1 (5.9)	0	1 (5.0)	2 (2.1)	6 (6.5)	8 (4.3)
感覚鈍麻	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
反射減弱	0	0	0	2 (2.1)	1 (1.1)	3 (1.6)
不規則睡眠覚醒リズム障害	0	0	0	1 (1.1)	0	1 (0.5)
嗜眠	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)

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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害 (Cont.)						
意識消失	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
腰仙部神経根障害	0	0	0	0	1 (1.1)	1 (0.5)
記憶障害	0	0	0	0	2 (2.2)	2 (1.1)
代謝性脳症	0	0	0	1 (1.1)	0	1 (0.5)
神経痛	0	0	0	0	1 (1.1)	1 (0.5)
末梢性ニューロパチー	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
オンオフ現象	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
錯感覚	0	0	0	4 (4.3)	2 (2.2)	6 (3.2)
パーキンソン病	2 (11.8)	0	2 (10.0)	5 (5.3)	2 (2.2)	7 (3.8)
パーキンソニズム	0	0	0	0	2 (2.2)	2 (1.1)
側反弓	1 (5.9)	0	1 (5.0)	0	2 (2.2)	2 (1.1)
多発ニューロパチー	0	0	0	0	2 (2.2)	2 (1.1)
失神寸前の状態	0	0	0	0	1 (1.1)	1 (0.5)
心因性発作	0	0	0	0	1 (1.1)	1 (0.5)
反射異常	0	0	0	0	1 (1.1)	1 (0.5)
坐骨神経痛	0	0	0	0	3 (3.3)	3 (1.6)
痙攣発作	0	0	0	0	1 (1.1)	1 (0.5)
感覚障害	0	0	0	0	1 (1.1)	1 (0.5)
感覚消失	0	0	0	0	1 (1.1)	1 (0.5)
睡眠時麻痺	0	0	0	1 (1.1)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
神経系障害 (Cont.)						
傾眠	0	0	0	8 (8.5)	1 (1.1)	9 (4.8)
失神	0	0	0	0	3 (3.3)	3 (1.6)
振戦	0	0	0	1 (1.1)	0	1 (0.5)
製品の問題	0	0	0	2 (2.1)	0	2 (1.1)
医療機器送達システムの問題	0	0	0	1 (1.1)	0	1 (0.5)
医療機器位置異常	0	0	0	1 (1.1)	0	1 (0.5)
精神障害	8 (47.1)	1 (33.3)	9 (45.0)	28 (29.8)	38 (41.3)	66 (35.5)
感情不安定	0	0	0	0	1 (1.1)	1 (0.5)
激越	0	0	0	0	1 (1.1)	1 (0.5)
不安	0	0	0	9 (9.6)	12 (13.0)	21 (11.3)
不安障害	0	1 (33.3)	1 (5.0)	0	0	0
無感情	0	0	0	1 (1.1)	0	1 (0.5)
強迫行為	0	0	0	0	1 (1.1)	1 (0.5)
強迫性性行動	0	0	0	1 (1.1)	0	1 (0.5)
錯乱状態	0	0	0	4 (4.3)	3 (3.3)	7 (3.8)
譫妄	0	0	0	0	2 (2.2)	2 (1.1)
妄想	4 (23.5)	0	4 (20.0)	3 (3.2)	1 (1.1)	4 (2.2)
寄生虫妄想	0	0	0	1 (1.1)	0	1 (0.5)
妄想性障害、詳細不明	0	0	0	0	1 (1.1)	1 (0.5)
抑うつ気分	0	0	0	2 (2.1)	0	2 (1.1)
うつ病	0	1 (33.3)	1 (5.0)	2 (2.1)	1 (1.1)	3 (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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
精神障害 (Cont.)						
ドーパミン調節障害症候群	0	0	0	1 (1.1)	0	1 (0.5)
ディスフェミア	0	0	0	0	1 (1.1)	1 (0.5)
睡眠異常	0	0	0	1 (1.1)	0	1 (0.5)
情動障害	0	0	0	1 (1.1)	0	1 (0.5)
注射恐怖	0	0	0	0	1 (1.1)	1 (0.5)
幻覚	5 (29.4)	0	5 (25.0)	7 (7.4)	18 (19.6)	25 (13.4)
幻聴	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
幻嗅	0	0	0	0	1 (1.1)	1 (0.5)
幻視	1 (5.9)	0	1 (5.0)	5 (5.3)	4 (4.3)	9 (4.8)
混合性幻覚	0	0	0	1 (1.1)	0	1 (0.5)
性欲過剰	0	0	0	1 (1.1)	0	1 (0.5)
錯覚	0	0	0	1 (1.1)	0	1 (0.5)
衝動制御障害	0	0	0	0	4 (4.3)	4 (2.2)
衝動行為	0	0	0	0	1 (1.1)	1 (0.5)
不眠症	1 (5.9)	0	1 (5.0)	1 (1.1)	6 (6.5)	7 (3.8)
易刺激性	0	0	0	0	1 (1.1)	1 (0.5)
躁病	0	0	0	0	1 (1.1)	1 (0.5)
気分動揺	0	0	0	0	1 (1.1)	1 (0.5)
悪夢	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
パニック発作	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
精神障害 (Cont.)						
パニック反応	0	0	0	0	1 (1.1)	1 (0.5)
妄想症	0	0	0	2 (2.1)	0	2 (1.1)
睡眠の質低下	0	0	0	1 (1.1)	0	1 (0.5)
処置に対する不安	0	0	0	0	1 (1.1)	1 (0.5)
精神病性障害	0	0	0	3 (3.2)	2 (2.2)	5 (2.7)
精神病症状	0	0	0	1 (1.1)	0	1 (0.5)
レム睡眠行動障害	0	0	0	0	1 (1.1)	1 (0.5)
レム睡眠異常	1 (5.9)	0	1 (5.0)	0	0	0
睡眠障害	0	0	0	2 (2.1)	0	2 (1.1)
ねごと	0	0	0	1 (1.1)	0	1 (0.5)
常同症	0	0	0	0	1 (1.1)	1 (0.5)
ストレス	0	0	0	0	1 (1.1)	1 (0.5)
自殺念慮	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
自殺企図	0	0	0	1 (1.1)	0	1 (0.5)
腎および尿路障害	1 (5.9)	0	1 (5.0)	4 (4.3)	7 (7.6)	11 (5.9)
膀胱痙縮	0	0	0	1 (1.1)	0	1 (0.5)
膀胱結石	1 (5.9)	0	1 (5.0)	0	0	0
排尿困難	0	0	0	0	1 (1.1)	1 (0.5)
緊張性膀胱	0	0	0	1 (1.1)	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
腎および尿路障害 (Cont.)						
夜間頻尿	0	0	0	0	1 (1.1)	1 (0.5)
多尿	0	0	0	0	1 (1.1)	1 (0.5)
腎機能障害	0	0	0	0	1 (1.1)	1 (0.5)
尿管結石症	0	0	0	0	1 (1.1)	1 (0.5)
切迫性尿失禁	0	0	0	1 (1.1)	0	1 (0.5)
尿失禁	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
尿閉	0	0	0	0	3 (3.3)	3 (1.6)
尿臭異常	0	0	0	0	1 (1.1)	1 (0.5)
生殖系および乳房障害	1 (5.9)	0	1 (5.0)	1 (1.1)	3 (3.3)	4 (2.2)
良性前立腺肥大症	1 (5.9)	0	1 (5.0)	0	0	0
勃起不全	0	0	0	1 (1.1)	0	1 (0.5)
ペイロニー病	0	0	0	0	1 (1.1)	1 (0.5)
前立腺腫大	0	0	0	0	1 (1.1)	1 (0.5)
腟脱	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
呼吸器、胸郭および縦隔障害	0	0	0	5 (5.3)	13 (14.1)	18 (9.7)
気管支拡張症	0	0	0	1 (1.1)	0	1 (0.5)
咳嗽	0	0	0	0	1 (1.1)	1 (0.5)
発声障害	0	0	0	0	2 (2.2)	2 (1.1)
呼吸困難	0	0	0	2 (2.1)	5 (5.4)	7 (3.8)
労作性呼吸困難	0	0	0	1 (1.1)	0	1 (0.5)
鼻出血	0	0	0	0	1 (1.1)	1 (0.5)
過換気	0	0	0	0	1 (1.1)	1 (0.5)
口腔咽頭痛	0	0	0	1 (1.1)	0	1 (0.5)
誤嚥性肺炎	0	0	0	0	1 (1.1)	1 (0.5)
湿性咳嗽	0	0	0	0	1 (1.1)	1 (0.5)
肺塞栓症	0	0	0	0	2 (2.2)	2 (1.1)
ラ音	0	0	0	0	1 (1.1)	1 (0.5)
鼻漏	0	0	0	0	1 (1.1)	1 (0.5)
咽喉刺激感	0	0	0	0	1 (1.1)	1 (0.5)
皮膚および皮下組織障害	4 (23.5)	1 (33.3)	5 (25.0)	6 (6.4)	9 (9.8)	15 (8.1)
脱毛症	0	0	0	1 (1.1)	0	1 (0.5)
褥瘡性潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
皮膚嚢腫	1 (5.9)	0	1 (5.0)	0	1 (1.1)	1 (0.5)
皮膚炎	0	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
皮膚および皮下組織障害 (Cont.)						
接触皮膚炎	0	0	0	1 (1.1)	0	1 (0.5)
おむつ皮膚炎	1 (5.9)	0	1 (5.0)	0	0	0
薬疹	0	0	0	1 (1.1)	0	1 (0.5)
皮膚乾燥	1 (5.9)	0	1 (5.0)	0	0	0
紅斑	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
爪の障害	0	0	0	1 (1.1)	0	1 (0.5)
脂肪織炎	0	0	0	0	1 (1.1)	1 (0.5)
丘疹	0	0	0	0	2 (2.2)	2 (1.1)
そう痒症	0	1 (33.3)	1 (5.0)	2 (2.1)	0	2 (1.1)
乾癬	0	0	0	0	1 (1.1)	1 (0.5)
発疹	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
紅斑性皮疹	0	0	0	0	1 (1.1)	1 (0.5)
そう痒性皮疹	0	0	0	1 (1.1)	1 (1.1)	2 (1.1)
皮膚潰瘍	0	0	0	0	1 (1.1)	1 (0.5)
蕁麻疹	1 (5.9)	0	1 (5.0)	1 (1.1)	0	1 (0.5)
外科および内科処置	0	1 (33.3)	1 (5.0)	0	0	0
抜歯	0	1 (33.3)	1 (5.0)	0	0	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.J

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

System Organ Class MedDRA 24.0 Preferred Term	Japan Dose Category Low Dose n (%)	Japan Dose Category High Dose n (%)	Japan All Subjects n (%)	Non-Japan Dose Category Low Dose n (%)	Non-Japan Dose Category High Dose n (%)	Non-Japan All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20	N=94	N=92	N=186
血管障害	0	0	0	10 (10.6)	9 (9.8)	19 (10.2)
深部静脈血栓症	0	0	0	0	1 (1.1)	1 (0.5)
血腫	0	0	0	0	1 (1.1)	1 (0.5)
出血	0	0	0	0	1 (1.1)	1 (0.5)
高血圧	0	0	0	1 (1.1)	2 (2.2)	3 (1.6)
高血圧クリーゼ	0	0	0	1 (1.1)	0	1 (0.5)
低血圧	0	0	0	2 (2.1)	2 (2.2)	4 (2.2)
起立性高血圧	0	0	0	0	1 (1.1)	1 (0.5)
起立性低血圧	0	0	0	6 (6.4)	3 (3.3)	9 (4.8)

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

Program Source Code: [redacted]

表44　治験薬との因果関係別の有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 04:29 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	20 (90.9)	5 (100)	25 (92.6)
Reasonable possibility	20 (90.9)	5 (100)	25 (92.6)
耳および迷路障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
感音性難聴	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
眼障害	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
白内障	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
眼障害 (Cont.)			
ドライアイ	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
胃腸障害	6 (27.3)	1 (20.0)	7 (25.9)
No reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
Reasonable possibility	1 (4.5)	0	1 (3.7)
上腹部痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
便秘	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
齲歯	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
胃腸障害 (Cont.)			
下痢	3 (13.6)	1 (20.0)	4 (14.8)
No reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
口唇乾燥	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
メレナ	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
悪心	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
一般・全身障害および投与部位の状態	17 (77.3)	3 (60.0)	20 (74.1)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	15 (68.2)	3 (60.0)	18 (66.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
投与部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位内出血	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位皮膚炎	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
注入部位紅斑	7 (31.8)	3 (60.0)	10 (37.0)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	6 (27.3)	3 (60.0)	9 (33.3)
注入部位硬結	4 (18.2)	1 (20.0)	5 (18.5)
Reasonable possibility	4 (18.2)	1 (20.0)	5 (18.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注入部位腫瘤	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
注入部位疼痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	0	1 (20.0)	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位腫脹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注射部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注射部位腫脹	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
限局性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
末梢性浮腫	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
穿刺部位内出血	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
穿刺部位硬結	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
発熱	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
口渇	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
血管穿刺部位硬結	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
感染症および寄生虫症	5 (22.7)	2 (40.0)	7 (25.9)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
蜂巣炎	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
感染症および寄生虫症 (Cont.)			
結膜炎	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
爪の皮膚糸状菌症	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
麦粒腫	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位蜂巣炎	3 (13.6)	1 (20.0)	4 (14.8)
Reasonable possibility	3 (13.6)	1 (20.0)	4 (14.8)
上咽頭炎	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
感染症および寄生虫症 (Cont.)			
術後膿瘍	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
傷害、中毒および処置合併症	6 (27.3)	2 (40.0)	8 (29.6)
No reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	1 (4.5)	0	1 (3.7)
脳挫傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
挫傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
転倒	6 (27.3)	2 (40.0)	8 (29.6)
No reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
傷害、中毒および処置合併症 (Cont.)			
頭部損傷	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
靭帯捻挫	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
肋骨骨折	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
皮膚損傷	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
臨床検査	3 (13.6)	0	3 (11.1)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	2 (9.1)	0	2 (7.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
臨床検査 (Cont.)			
血中クレアチンホスホキナーゼ増加	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
血中ホモシステイン増加	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
体重減少	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
代謝および栄養障害	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
低ナトリウム血症	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
代謝および栄養障害 (Cont.)			
ビタミンB12欠乏	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
ビタミンB6欠乏	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
筋骨格系および結合組織障害	5 (22.7)	1 (20.0)	6 (22.2)
No reasonable possibility	4 (18.2)	1 (20.0)	5 (18.5)
Reasonable possibility	1 (4.5)	0	1 (3.7)
関節痛	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
背部痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
筋骨格系および結合組織障害 (Cont.)			
筋肉痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
四肢痛	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
横紋筋融解症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
弾発指	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
神経系障害	10 (45.5)	2 (40.0)	12 (44.4)
No reasonable possibility	4 (18.2)	0	4 (14.8)
Reasonable possibility	6 (27.3)	2 (40.0)	8 (29.6)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
運動失調	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
浮動性めまい	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
頭痛	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
意識消失	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
パーキンソン病	4 (18.2)	0	4 (14.8)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
パーキンソニズム	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
側反弓	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
精神障害	11 (50.0)	3 (60.0)	14 (51.9)
No reasonable possibility	1 (4.5)	2 (40.0)	3 (11.1)
Reasonable possibility	10 (45.5)	1 (20.0)	11 (40.7)
不安障害	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
妄想	5 (22.7)	0	5 (18.5)
Reasonable possibility	5 (22.7)	0	5 (18.5)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
うつ病	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
抑うつ症状	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
幻覚	8 (36.4)	1 (20.0)	9 (33.3)
Reasonable possibility	8 (36.4)	1 (20.0)	9 (33.3)
幻視	1 (4.5)	1 (20.0)	2 (7.4)
No reasonable possibility	0	1 (20.0)	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
不眠症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
嫉妬妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
レム睡眠異常	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
腎および尿路障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	2 (9.1)	0	2 (7.4)
膀胱結石	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
尿失禁	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
生殖系および乳房障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
良性前立腺肥大症	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	4 (18.2)	1 (20.0)	5 (18.5)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
Reasonable possibility	2 (9.1)	0	2 (7.4)
皮膚嚢腫	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
おむつ皮膚炎	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
皮膚および皮下組織障害 (Cont.)			
皮膚乾燥	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
そう痒症	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
発疹	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
蕁麻疹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
外科および内科処置	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period (Cont.)	N=22	N=5	N=27
外科および内科処置 (Cont.)			
抜歯	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	15 (68.2)	4 (80.0)	19 (70.4)
Reasonable possibility	15 (68.2)	4 (80.0)	19 (70.4)
胃腸障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
下痢	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
悪心	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
一般・全身障害および投与部位の状態	12 (54.5)	2 (40.0)	14 (51.9)
No reasonable possibility	2 (9.1)	0	2 (7.4)
Reasonable possibility	10 (45.5)	2 (40.0)	12 (44.4)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
投与部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注入部位紅斑	5 (22.7)	2 (40.0)	7 (25.9)
Reasonable possibility	5 (22.7)	2 (40.0)	7 (25.9)
注入部位硬結	3 (13.6)	0	3 (11.1)
Reasonable possibility	3 (13.6)	0	3 (11.1)
注入部位腫瘤	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
注入部位疼痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
注入部位発疹	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
注射部位紅斑	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
限局性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
末梢性浮腫	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
穿刺部位内出血	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位硬結	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
発熱	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
口渇	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
傷害、中毒および処置合併症	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)
転倒	2 (9.1)	1 (20.0)	3 (11.1)
No reasonable possibility	2 (9.1)	1 (20.0)	3 (11.1)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	Dose Category High Dose n (%)	All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
筋骨格系および結合組織障害	2 (9.1)	0	2 (7.4)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
筋肉痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
神経系障害	6 (27.3)	1 (20.0)	7 (25.9)
No reasonable possibility	1 (4.5)	0	1 (3.7)
Reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
運動失調	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
神経系障害 (Cont.)			
浮動性めまい	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
頭痛	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
パーキンソン病	2 (9.1)	0	2 (7.4)
Reasonable possibility	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
Reasonable possibility	0	1 (20.0)	1 (3.7)
精神障害	7 (31.8)	2 (40.0)	9 (33.3)
No reasonable possibility	1 (4.5)	1 (20.0)	2 (7.4)
Reasonable possibility	6 (27.3)	1 (20.0)	7 (25.9)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
精神障害 (Cont.)			
妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)
抑うつ症状	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
幻覚	5 (22.7)	1 (20.0)	6 (22.2)
Reasonable possibility	5 (22.7)	1 (20.0)	6 (22.2)
幻視	0	1 (20.0)	1 (3.7)
No reasonable possibility	0	1 (20.0)	1 (3.7)
嫉妬妄想	1 (4.5)	0	1 (3.7)
Reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period (Cont.)	N=22	N=5	N=27
腎および尿路障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
尿失禁	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)
発疹	1 (4.5)	0	1 (3.7)
No reasonable possibility	1 (4.5)	0	1 (3.7)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	15 (88.2)	3 (100)	18 (90.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
Reasonable possibility	15 (88.2)	2 (66.7)	17 (85.0)
耳および迷路障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
感音性難聴	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
眼障害	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
白内障	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
眼障害 (Cont.)			
ドライアイ	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
胃腸障害	6 (35.3)	1 (33.3)	7 (35.0)
No reasonable possibility	5 (29.4)	1 (33.3)	6 (30.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
上腹部痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
便秘	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)
齲歯	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
胃腸障害 (Cont.)			
下痢	2 (11.8)	1 (33.3)	3 (15.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
口唇乾燥	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
メレナ	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
悪心	2 (11.8)	0	2 (10.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
一般・全身障害および投与部位の状態	11 (64.7)	3 (100)	14 (70.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	10 (58.8)	2 (66.7)	12 (60.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
一般・全身障害および投与部位の状態 (Cont.)			
注入部位内出血	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注入部位皮膚炎	2 (11.8)	0	2 (10.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
注入部位紅斑	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
注入部位硬結	3 (17.6)	1 (33.3)	4 (20.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
注入部位腫瘤	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
一般・全身障害および投与部位の状態 (Cont.)			
注入部位発疹	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
注入部位腫脹	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注射部位紅斑	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
注射部位腫脹	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
末梢性浮腫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
一般・全身障害および投与部位の状態 (Cont.)			
穿刺部位硬結	2 (11.8)	0	2 (10.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
血管穿刺部位硬結	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
感染症および寄生虫症	5 (29.4)	2 (66.7)	7 (35.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
蜂巣炎	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
結膜炎	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
感染症および寄生虫症 (Cont.)			
爪の皮膚糸状菌症	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
麦粒腫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
注入部位蜂巣炎	3 (17.6)	1 (33.3)	4 (20.0)
Reasonable possibility	3 (17.6)	1 (33.3)	4 (20.0)
上咽頭炎	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
術後膿瘍	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
傷害、中毒および処置合併症	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
脳挫傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
挫傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
転倒	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
頭部損傷	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
傷害、中毒および処置合併症 (Cont.)			
靱帯捻挫	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
肋骨骨折	1 (5.9)	1 (33.3)	2 (10.0)
No reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
皮膚損傷	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
臨床検査	3 (17.6)	0	3 (15.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)
血中クレアチンホスホキナーゼ増加	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
臨床検査 (Cont.)			
血中ホモシステイン増加	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
体重減少	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
代謝および栄養障害	2 (11.8)	1 (33.3)	3 (15.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
低ナトリウム血症	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
ビタミンB12欠乏	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
代謝および栄養障害 (Cont.)			
ビタミンB6欠乏	1 (5.9)	1 (33.3)	2 (10.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
筋骨格系および結合組織障害	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	4 (23.5)	1 (33.3)	5 (25.0)
関節痛	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
背部痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
四肢痛	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
筋骨格系および結合組織障害 (Cont.)			
弾発指	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
神経系障害	5 (29.4)	1 (33.3)	6 (30.0)
No reasonable possibility	4 (23.5)	0	4 (20.0)
Reasonable possibility	1 (5.9)	1 (33.3)	2 (10.0)
浮動性めまい	0	1 (33.3)	1 (5.0)
Reasonable possibility	0	1 (33.3)	1 (5.0)
頭痛	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
意識消失	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
神経系障害 (Cont.)			
パーキンソン病	2 (11.8)	0	2 (10.0)
No reasonable possibility	2 (11.8)	0	2 (10.0)
側反弓	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
精神障害	8 (47.1)	1 (33.3)	9 (45.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
Reasonable possibility	8 (47.1)	0	8 (40.0)
不安障害	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
妄想	4 (23.5)	0	4 (20.0)
Reasonable possibility	4 (23.5)	0	4 (20.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
精神障害 (Cont.)			
うつ病	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
幻覚	5 (29.4)	0	5 (25.0)
Reasonable possibility	5 (29.4)	0	5 (25.0)
幻視	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
不眠症	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
レム睡眠異常	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
腎および尿路障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
膀胱結石	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
生殖系および乳房障害	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
良性前立腺肥大症	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
皮膚および皮下組織障害	4 (23.5)	1 (33.3)	5 (25.0)
No reasonable possibility	2 (11.8)	1 (33.3)	3 (15.0)
Reasonable possibility	2 (11.8)	0	2 (10.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
皮膚および皮下組織障害 (Cont.)			
皮膚嚢腫	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)
おむつ皮膚炎	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
皮膚乾燥	1 (5.9)	0	1 (5.0)
No reasonable possibility	1 (5.9)	0	1 (5.0)
そう痒症	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
蕁麻疹	1 (5.9)	0	1 (5.0)
Reasonable possibility	1 (5.9)	0	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

TABLE 14.3 1.6.J

Subjects with Treatment-Emergent Adverse Events
by Maximum Relationship to Study Drug as Assessed by the Investigator
by Primary System Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period (Cont.)	N=17	N=3	N=20
外科および内科処置	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)
抜歯	0	1 (33.3)	1 (5.0)
No reasonable possibility	0	1 (33.3)	1 (5.0)

Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.
Subjects are counted once in each row, regardless of the number of events they may have had.

Program Source Code: [redacted]

表45　重篤な有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 16:20 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	6 (27.3)	1 (20.0)	7 (25.9)
感染症および寄生虫症	0	1 (20.0)	1 (3.7)
蜂巣炎	0	1 (20.0)	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	4 (18.2)	0	4 (14.8)
意識消失	1 (4.5)	0	1 (3.7)
パーキンソン病	3 (13.6)	0	3 (11.1)
精神障害	3 (13.6)	0	3 (11.1)
妄想	1 (4.5)	0	1 (3.7)
幻覚	3 (13.6)	0	3 (11.1)

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 1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	4 (18.2)	0	4 (14.8)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	0	2 (7.4)
パーキンソン病	2 (9.1)	0	2 (7.4)
精神障害	3 (13.6)	0	3 (11.1)
妄想	1 (4.5)	0	1 (3.7)
幻覚	3 (13.6)	0	3 (11.1)

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 1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	2 (11.8)	1 (33.3)	3 (15.0)
感染症および寄生虫症	0	1 (33.3)	1 (5.0)
蜂巣炎	0	1 (33.3)	1 (5.0)
神経系障害	2 (11.8)	0	2 (10.0)
意識消失	1 (5.9)	0	1 (5.0)
パーキンソン病	1 (5.9)	0	1 (5.0)

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

Program Source Code: [redacted]

表46　中止に至った有害事象（安全性解析対象集団，日本人部分集団）：M15-741試験

[redacted]20[redacted] 16:20 <[redacted]>
ABBV-951
STUDY M15-741 - SECOND INTERIM (CUTOFF [redacted]20[redacted])
R&D/20/1632 - CLINICAL/STATISTICAL

TABLE 14.3__1.8.1.J

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Entire study period	N=22	N=5	N=27
Any adverse event	6 (27.3)	1 (20.0)	7 (25.9)
一般・全身障害および投与部位の状態	2 (9.1)	0	2 (7.4)
注入部位腫瘤	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	0	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	1 (20.0)	3 (11.1)
パーキンソン病	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
精神障害	2 (9.1)	0	2 (7.4)
幻覚	1 (4.5)	0	1 (3.7)
幻視	1 (4.5)	0	1 (3.7)
皮膚および皮下組織障害	1 (4.5)	0	1 (3.7)
蕁麻疹	1 (4.5)	0	1 (3.7)

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 1.8.1.J

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Optimization period	N=22	N=5	N=27
Any adverse event	4 (18.2)	1 (20.0)	5 (18.5)
一般・全身障害および投与部位の状態	2 (9.1)	0	2 (7.4)
注入部位腫瘤	1 (4.5)	0	1 (3.7)
注入部位発疹	1 (4.5)	0	1 (3.7)
筋骨格系および結合組織障害	1 (4.5)	0	1 (3.7)
横紋筋融解症	1 (4.5)	0	1 (3.7)
神経系障害	2 (9.1)	1 (20.0)	3 (11.1)
パーキンソン病	2 (9.1)	0	2 (7.4)
パーキンソニズム	0	1 (20.0)	1 (3.7)
精神障害	1 (4.5)	0	1 (3.7)
幻覚	1 (4.5)	0	1 (3.7)

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 1.8.1.J

Subjects with Treatment-Emergent Adverse Events
Leading to Study Drug Premature Discontinuation (Withdrawn) by Primary System
Organ Class and Preferred Term by Time Interval
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose n (%)	 High Dose n (%)	 All Subjects n (%)
Maintenance period	N=17	N=3	N=20
Any adverse event	2 (11.8)	0	2 (10.0)
精神障害	1 (5.9)	0	1 (5.0)
幻視	1 (5.9)	0	1 (5.0)
皮膚および皮下組織障害	1 (5.9)	0	1 (5.0)
蕁麻疹	1 (5.9)	0	1 (5.0)

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

Program Source Code: [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
注入部位蜂巣炎				X
注入部位紅斑				X
耳下腺膿瘍	X			

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

Medical History	Onset Year
STROKE	19[redacted]
ASTHMA	19[redacted]
DEPRESSION	20[redacted]
HYPERTENSION	20[redacted]
SLEEP APNEA	20[redacted]
VITAMIN D DEFICIENCY	20[redacted]
OVERACTIVE BLADDER	20[redacted]
MRSA RIGHT ELBOW	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
ONSET OF MOTOR FLUCTUATION	19[redacted]
PARKINSON'S DISEASE	19[redacted]
PARKINSON'S DISEASE DIAGNOSIS	19[redacted]

Prior Procedures	Procedure Year
VASECTOMY	19[redacted]
TONSILLECTOMY	19[redacted]
DEEP BRAIN STIMULATION	20[redacted]

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

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.2	0.27	0.17	60	0.19	[redacted]/1
ABBV-951 CSCI	0.2	0.27	0.17	60	0.19	[redacted]/2
ABBV-951 CSCI	0.23	0.27	0.2	60	0.24	[redacted]/7
ABBV-951 CSCI	0.3	0.33	0.27	60	0.24	[redacted]/14
ABBV-951 CSCI	0.3	0.33	0.27	60	0.24	[redacted]/20
ABBV-951 CSCI	0.37	0.4	0.33	60	0.24	[redacted]/28
ABBV-951 CSCI	0.4	0.43	0.37	60	0.24	[redacted]/42
ABBV-951 CSCI	0.43	0.47	0.4	60	0.24	[redacted]/64
ABBV-951 CSCI	0.43	0.47	0.4	60	0.24	[redacted]/92
ABBV-951 CSCI	0.47	0.5	0.43	60	0.24	[redacted]/168
ABBV-951 CSCI	0.53	0.57	0.5	60	0.24	[redacted]/272
ABBV-951 CSCI	0.53	0.57	0.5	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	443.95		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		32.44	SC /ONCE	[redacted] / 2	
ABBV-951	816.18		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		97.32	SC /ONCE	[redacted] / 3	
ABBV-951	802.52		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		227.09	SC /ONCE	[redacted] / 4	
ABBV-951	802.52		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		227.09	SC /ONCE	[redacted] / 5	
ABBV-951	809.35		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		194.65	SC /ONCE	[redacted] / 6	
ABBV-951	809.35		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6

ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 7	
ABBV-951	879.19		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 8	
ABBV-951	1042.94		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		245.88	SC /ONCE	[redacted]20[redacted] / 9	
ABBV-951	1097.23		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951		368.82	SC /ONCE	[redacted]20[redacted] / 10	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951		327.84	SC /ONCE	[redacted]20[redacted] / 11	
ABBV-951	1101.84		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951		450.78	SC /ONCE	[redacted]20[redacted] / 12	
ABBV-951	1055.74		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1074.18		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1250.40		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	1227.86		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 16	
ABBV-951	459.48		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	321.18		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	1324.16		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	1318.53		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1312.89		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 24	
ABBV-951	1324.16		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 25	
ABBV-951	1346.70		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	1346.70		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	1312.89		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		327.84	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	1366.51		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28

ABBV-951		245.88	SC /ONCE	[redacted]20[redacted] / 29	
ABBV-951	1459.40		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 30	
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951	1494.06		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		450.78	SC /ONCE	[redacted]20[redacted] / 32	
ABBV-951	1611.88		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 33	
ABBV-951	1584.56		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		245.88	SC /ONCE	[redacted]20[redacted] / 34	
ABBV-951	1625.54		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	1591.39		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 36	
ABBV-951	1625.54		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951	1584.56		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		286.86	SC /ONCE	[redacted]20[redacted] / 38	
ABBV-951	1632.37		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		245.88	SC /ONCE	[redacted]20[redacted] / 39	
ABBV-951	1550.41		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	1625.54		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1570.9		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	1639.2		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	1668.39		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 44	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 45	
ABBV-951	1747.45		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		163.92	SC /ONCE	[redacted]20[redacted] / 46	
ABBV-951	1688.71		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		245.88	SC /ONCE	[redacted]20[redacted] / 47	

ABBV-951	1747.45		SC /CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951		204.9	SC /ONCE	[redacted] / 48	
ABBV-951	1718.08		SC /CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		163.92	SC /ONCE	[redacted] / 49	
ABBV-951	1762.14		SC /CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951		286.86	SC /ONCE	[redacted] / 50	
ABBV-951	1710.74		SC /CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951		122.94	SC /ONCE	[redacted] / 51	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951		122.94	SC /ONCE	[redacted] / 52	
ABBV-951	1688.71		SC /CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951		204.9	SC /ONCE	[redacted] / 53	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951		204.9	SC /ONCE	[redacted] / 54	
ABBV-951	1740.11		SC /CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951		122.94	SC /ONCE	[redacted] / 55	
ABBV-951	1740.11		SC /CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951		245.88	SC /ONCE	[redacted] / 56	
ABBV-951	1747.45		SC /CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951		122.94	SC /ONCE	[redacted] / 57	
ABBV-951	1696.05		SC /CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951		163.92	SC /ONCE	[redacted] / 58	
ABBV-951	1747.45		SC /CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951		81.96	SC /ONCE	[redacted] / 59	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951		122.94	SC /ONCE	[redacted] / 60	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951		204.9	SC /ONCE	[redacted] / 61	
ABBV-951	1696.05		SC /CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951		122.94	SC /ONCE	[redacted] / 62	
ABBV-951	1754.79		SC /CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951		204.9	SC /ONCE	[redacted] / 63	
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ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
ABBV-951	2006.31		SC /CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 221	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 224	
ABBV-951	1997.77		SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1997.77		SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 227	
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 228	
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 232	
ABBV-951	1980.7		SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	1955.08		SC /CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 234	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234

ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 237	
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 240	
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2014.85		SC /CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 247	
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	1989.23		SC /CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 253	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 254	
ABBV-951	2023.38		SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	1955.08		SC /CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	1989.23		SC /CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	1955.08		SC /CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	1997.77		SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	2040.46		SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1972.16		SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266

ABBV-951	2031.92		SC /CONTINUOUS	[redacted] / 267	[redacted] / 267
ABBV-951	1972.16		SC /CONTINUOUS	[redacted] / 268	[redacted] / 268
ABBV-951	2040.46		SC /CONTINUOUS	[redacted] / 269	[redacted] / 269
ABBV-951		81.96	SC /ONCE	[redacted] / 270	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted] / 270	[redacted] / 270
ABBV-951		81.96	SC /ONCE	[redacted] / 271	
ABBV-951	2040.46		SC /CONTINUOUS	[redacted] / 271	[redacted] / 271
ABBV-951		40.98	SC /ONCE	[redacted] / 272	
ABBV-951	2092.37		SC /CONTINUOUS	[redacted] / 272	[redacted] / 272
ABBV-951	2153.84		SC /CONTINUOUS	[redacted] / 273	[redacted] / 273
ABBV-951		40.98	SC /ONCE	[redacted] / 274	
ABBV-951	2090.49		SC /CONTINUOUS	[redacted] / 274	[redacted] / 274
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 275	[redacted] / 275
ABBV-951		40.98	SC /ONCE	[redacted] / 276	
ABBV-951	2072.39		SC /CONTINUOUS	[redacted] / 276	[redacted] / 276
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 277	[redacted] / 277
ABBV-951	2153.84		SC /CONTINUOUS	[redacted] / 278	[redacted] / 278
ABBV-951	2144.79		SC /CONTINUOUS	[redacted] / 279	[redacted] / 279
ABBV-951	2126.69		SC /CONTINUOUS	[redacted] / 280	[redacted] / 280
ABBV-951	1194.56		SC /CONTINUOUS	[redacted] / 281	[redacted] / 281
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 282	[redacted] / 282
ABBV-951	2135.74		SC /CONTINUOUS	[redacted] / 283	[redacted] / 283
ABBV-951	2153.84		SC /CONTINUOUS	[redacted] / 284	[redacted] / 284
ABBV-951	2045.24		SC /CONTINUOUS	[redacted] / 285	[redacted] / 285
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 286	[redacted] / 286
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 287	[redacted] / 287
ABBV-951		40.98	SC /ONCE	[redacted] / 288	
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 288	[redacted] / 288
ABBV-951	2126.69		SC /CONTINUOUS	[redacted] / 289	[redacted] / 289
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 290	[redacted] / 290
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 291	[redacted] / 291
ABBV-951	2144.79		SC /CONTINUOUS	[redacted] / 292	[redacted] / 292
ABBV-951	2126.69		SC /CONTINUOUS	[redacted] / 293	[redacted] / 293
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 294	[redacted] / 294
ABBV-951	2153.84		SC /CONTINUOUS	[redacted] / 295	[redacted] / 295
ABBV-951	2081.44		SC /CONTINUOUS	[redacted] / 296	[redacted] / 296
ABBV-951	2162.89		SC /CONTINUOUS	[redacted] / 297	[redacted] / 297

ABBV-951	2054.29	SC /CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
ABBV-951	2126.69	SC /CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951	2126.69	SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951	2117.64	SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	2144.79	SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	2135.74	SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	2171.94	SC /CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	2171.94	SC /CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951	2126.69	SC /CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951	2045.24	SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951	2144.79	SC /CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951	2117.64	SC /CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951	2081.44	SC /CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951	2171.94	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2153.84	SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	2162.89	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	2171.94	SC /CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	2144.79	SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334

ABBV-951	2144.79		SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 336	
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2153.84		SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2135.74		SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2099.54		SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2135.74		SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2117.64		SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2153.84		SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2153.84		SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 351	
ABBV-951	2144.79		SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 352	
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2153.84		SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 356	
ABBV-951	2144.79		SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 357	
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 358	
ABBV-951	2072.39		SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2081.44		SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2171.94		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	2090.49		SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	2144.79		SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	2099.54		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
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	6.000 mg	QD	Y-M: 20[redacted]
CHONDROITIN	1200 mg	BID	Y-M: 20[redacted]
GLUCOSAMINE	1500 mg	BID	Y-M: 20[redacted]
TERAZOSIN	5 mg	QD	Y-M: 20[redacted]
VITAMIN D NOS	10000 IU	QD	Y-M: 20[redacted]
VENLAFAXINE	75 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	145.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -179
CARBIDOPA;LEVODOPA	245.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -114
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 2 TABS mg	BID	Y-M: 20[redacted] / -15

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 308
CHONDROITIN	1200 mg	BID	Y-M: 20[redacted]	ONGOING
GLUCOSAMINE	1500 mg	BID	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	10000 IU	QD	Y-M: 20[redacted]	ONGOING
TERAZOSIN	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 147
VENLAFAXINE	75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 112
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 2 TABS mg	BID	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -7
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 mg	BID	Y-M: 20[redacted] / 15	Y-M: 20[redacted] / 16
CEFAZOLIN SODIUM	2 g	OTHER: ONCE	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 16
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 25
VENLAFAXINE	225 mg	QD	Y-M: 20[redacted] / 113	ONGOING
RAMIPRIL	5 mg	QD	Y-M: 20[redacted] / 147	ONGOING
AMOXICILLIN	500 mg	TID	Y-M: 20[redacted] / 233	Y-M: 20[redacted] / 234
MORPHINE	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 234	Y-M: 20[redacted] / 234
ONDANSETRON HYDROCHLORIDE	4 mg	OTHER: ONCE	Y-M: 20[redacted] / 234	Y-M: 20[redacted] / 234
AMPICILLIN SODIUM;SULBACTAM SODIUM	3 g	OTHER: CONTINUAL	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 240

VANCOMYCIN	1500 mg	OTHER: CONTINUAL	Y-M: 20[redacted] / 235	Y-M: 20[redacted] / 240
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 240	Y-M: 20[redacted] / 250

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

Event Description	RIGHT ABDOMINAL CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
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	26
Duration of AE	12 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	97
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: Serious Adverse Event

Event Description	PAROTID ABSCESS
Preferred Term	耳下腺膿瘍
AE Onset Date / RX Day	[redacted]20[redacted] / 234
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 234): LEUKOCYTES: 17.3 [3.8 - 11] 10^9/L; NEUTROPHILS/LEUKOCYTES: 87.8 [40 - 75] %

Microbiology

[redacted]20[redacted] (RX DAY 234): OTHER BODY FLUID ABSCESS CULTURE: POSITIVE-MRSA

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 234): CHEST X-RAY:NEGATIVE; CT SOFT TISSUE NECK WITH CONTRAST:MULTI SPATIAL INFECTIOUS DISEASE PROCESS PRIMARILY INVOLVING THE LEFT PAROTID GLAND EXTENDING INTO THE LEFT MASTICATOR SPACE. THERE IS OVERLYING SUBCUTANEOUS ABSCESS AND SKIN THICKENING. SOFT TISSUEHYPOATTENUATION PERIPHERAL ENHANCEMENT IS PARTIALLY CONFLUENT AND MORE WELL-DEFINED COMPARED COMPATIBLE WITH PHLEGMON/ORGANIZING ABSCESSES. SEPARATE COLLECTION IN THE RIGHT PARAHARYNGEAL SPACE, POSTER IOR TO THE RIGHT MEDIAL PTERYGOID MEASURES 1.3X2.0X2.6 CM. LARGEST ENHANCING COLLECTION IN THE LEFT SUPERFICIAL PAROTID LOBE MEASURES 1.6X2.5X3.3 CM. LEFT RETRO MANDIBULAR COLLECTION MEASURES; CT SOFT TISSUE NECK WITH CONTRAST CONTINUED FROM LOG LINE 2.:1.6X2.5X3.3 CM. LEFT RETRO MANDIBULAR COLLECTION MEASURES 1.7X2.3X3.7 CM. MILD ASYMMETRIC MUCOSAL THICKENING OF THE RIGHT OROPHARYNX.; [redacted]20[redacted] (RX DAY 238): US GUIDED ABSCESS DRAINING OF THE PAROTID:UNCOMPLICATED ASPIRATION OF THE LEFT NECK ABSCESS. APPROXIMATELY 2 CC TOTAL PURULENT FLUID WAS OBTAINED.; US HEAD NECK SOFT TISSUE:FOCUSED SONOGRAPHIC EXAMINATION OF THE LEFT LATERAL NECK DEMONSTRATES ECHOGENIC FLUID COLLECTION WITH SURROUNDING HYPEREMIA AND FINGER-LIKE EXTENSION INTO ADJACENT TISSUES. THE LARGEST DEFINED FLUID C OLLECTION MEASURES 3.4X1.7X1.0 CM JUST DEEP TO THE SKIN AND 2.8X1.3X1.5 CM DEEP TO THE SKIN. THESE LIKELY COMMUNICATE. SUBSTANCIAL EDEMA OF THE ADJACENT INFLAMED

TISSUE.

AE Stopped RX Day	254
Duration of AE	21 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	RISK FACTOR MRSA
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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，耳下腺膿瘍を発現した。

Event 3 の臨床経過：

関連する病歴は，脳卒中，喘息，扁桃摘出，パーキンソン病，うつ病，高血圧，睡眠時無呼吸，右肘 MRSA 感染，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 234 日目，被験者は耳下腺膿瘍を発現した。投与 254 日目，耳下腺膿瘍は消失した。

投与 230 日目，被験者は顔面左側の腫脹が増大したため自宅近くの緊急治療室を受診した。被験者は入院せず，アモキシシリンを処方された。被験者は左側の顔面痛及び腫脹を発現し，同時に嚥下及び会話が困難であった。投与 234 日目，被験者はかかりつけ医を受診し，直ちに耳鼻咽喉科に紹介された。同日，排膿を試みたが成功せず，被験者は緊急治療室を受診するよう指示された。同日，被験者は左側の顔面及び頚部の腫瘤のため緊急治療室を受診した。被験者に

MRSA感染歴があったため，予防としてバンコマイシンとユナシンの投与が開始された。頭部及び頚部の軟部組織の CT 検査，並びに超音波検査が実施された。被験者は耳下腺膿瘍と診断された。翌日，被験者は超音波ガイド下耳下腺膿瘍ドレナージを受け，排出液は培養に送られた。培養で MRSA 及び大量の好中球が認められたが，扁平上皮細胞は認められず，ブドウ球菌に類似したグラム陽性球菌が認められた。胸部 X 線検査などの画像検査は陰性であった。投与 243 日目，被験者の治療は経口ドキシサイクリンに移行し，退院した。
被験者にユナシン，ZOFRAN，アモキシシリン，バンコマイシン，ドキシサイクリン，及びモルヒネが投与された。

Causality for ABBV-951 (Open Label)

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1) Parotid abscess (10034019) (Parotid abscess (10034019)) [v.23.0] [10034019]

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 PAROTID ABSCESS

- Investigator: Risk factor MRSA

- AbbVie: More likely related to a history of MRSA right elbow in an advanced aged patient with concomitant use of Venlafaxine, hydrochlorothiazide and Ramipril.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] ABSCESS CULTURE: Positive MRSA

[redacted] 20[redacted] CHEST X-RAY: negative

[redacted] **20[redacted] CT SOFT TISSUE NECK WITH CONTRAST:** Multi spatial infectious disease process primarily involving the left parotid gland extending into the left masticator space. There is overlying subcutaneous abscess and skin thickening. Soft tissue hypoattenuation peripheral enhancement is partially

confluent and more well-defined compared compatible with phlegmon/organizing abscesses. Separate collection in the right paraharyngeal space, posterior to the right medial pterygoid measures 1.3x2.0x2.6 cm. Largest enhancing collection in the left superficial parotid lobe measures 1.6x2.5x3.3 cm. Left retro mandibular collection measures 1.6x2.5x3.3 cm. Left retro mandibular collection measures 1.7x2.3x3.7 cm. Mild asymmetric mucosal thickening of the right oropharynx.

[redacted] **20[redacted] NEUTROPHILS %:** 87.8% (normal 40.0 to 75.0)

[redacted] **20[redacted] US HEAD NECK SOFT TISSUE:** Focused sonographic examination of the left lateral neck demonstrates echogenic fluid collection with surrounding hyperemia and finger-like extension into adjacent tissues. The largest defined fluid collection measures 3.4x1.7x1.0 cm just deep to the skin and 2.8x1.3x1.5 cm deep to the skin. These likely communicate. Substancial edema of the adjacent inflamed tissue.

[redacted] **20[redacted] WHITE BLOOD CELLS:** 17.25 K/UL (normal 3.8 to 11.0)

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
妄想性障害，詳細不明	X			X
眼挫傷				X
転倒				X
幻覚				X
幻聴				X
幻視				X
注入部位膿瘍				X
注入部位蜂巣炎				X
注入部位皮膚炎				X
注入部位紅斑		X		X
注入部位刺激感				X
注入部位結節		X		X
注入部位浮腫		X		X
注入部位疼痛				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
POST- MENOPAUSAL	NOT REPORTED
TONSILLITIS	19[redacted]
CONSTIPATION	19[redacted]
INSOMNIA	19[redacted]
PSYCHOLOGICAL SWALLOWING DIFFICULTIES	19[redacted]
ATTENTION DEFICIT HYPERACTIVITY DISORDER	19[redacted]
APPENDICITIS	20[redacted]
BENIGN GROWTH IN ABDOMEN	20[redacted]

PARKINSONS	20[redacted]
COMPULSIVE BEHAVIOR	20[redacted]
DIFFICULTY RECALLING NAMES	20[redacted]
CERVICAL DYSTONIA	20[redacted]
SURGICAL SCAR BELOW UMBILICUS FROM BENIGN GROWTH IN ABDOMEN	20[redacted]
NEUROGENIC ORTHOSTATIC HYPOTENSION	20[redacted]
OVERACTIVE BLADDER WITH URGENCY	20[redacted]
HIGH RISK FOR FALLS	20[redacted]
ABNORMAL WEIGHTLOSS	20[redacted]
ANXIETY	20[redacted]
DRUG INDUCED DYSKINESIA	20[redacted]
NUMBNESS IN TOES	20[redacted]
RESTLESSNESS	20[redacted]
TINGLING IN BOTH LOWER EXTREMITIES	20[redacted]
HEMORRHOIDS	20[redacted]
LOSS OF APPETITE	20[redacted]
LEG WEAKNESS	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
TONSILLECTOMY	19[redacted]
ABDOMINAL SURGERY	20[redacted]
APPENDECTOMY	20[redacted]

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

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

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.3	0.37	0.44	240	0.3	[redacted]/1
ABBV-951 CSCI	0.44	0.51	0.37	120	0.3	[redacted]/3
ABBV-951 CSCI	0.44	0.51	0.37	120	0.3	[redacted]/9
ABBV-951 CSCI	0.54	0.6	0.51	60	0.3	[redacted]/17
ABBV-951 CSCI	0.54	0.6	0.51	60	0.3	[redacted]/23
ABBV-951 CSCI	0.54	0.6	0.51	60	0.3	[redacted]/29
ABBV-951 CSCI	0.45	0.51	0.39	60	0.15	[redacted]/37
ABBV-951 CSCI	0.45	0.51	0.39	60	0.15	[redacted]/43
ABBV-951 CSCI	0.6	0.63	0.54	60	0.15	[redacted]/94

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	912.65		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1803.12		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		153.67	SC /ONCE	[redacted] / 3	
ABBV-951	1807.55		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		51.22	SC /ONCE	[redacted] / 4	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		102.45	SC /ONCE	[redacted] / 5	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1682.91		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		51.22	SC /ONCE	[redacted] / 7	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1803.12		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		51.22	SC /ONCE	[redacted] / 9	
ABBV-951	1766.23		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		102.45	SC /ONCE	[redacted] / 10	
ABBV-951	1976.77		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		153.67	SC /ONCE	[redacted] / 11	
ABBV-951	130.62		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11

ABBV-951	1062.40		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1889.69		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1079.82		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 16	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1330.31		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 18	
ABBV-951	2307.17		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		461.02	SC /ONCE	[redacted]20[redacted] / 19	
ABBV-951	2443.43		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		307.35	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	2160.15		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	2028.51		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	2166.81		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2330.73		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2356.35		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 25	
ABBV-951	2212.92		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	2356.35		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		256.12	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	2366.59		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	2417.82		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 29	
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34

ABBV-951	1872.27		SC /CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	2089.98		SC /CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	2089.98		SC /CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	2080.24		SC /CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	1715.01		SC /CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	1010.15		SC /CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	1785.19		SC /CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951		102.45	SC /ONCE	[redacted] / 42	
ABBV-951	2063.85		SC /CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	2089.98		SC /CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		25.61	SC /ONCE	[redacted] / 44	
ABBV-951	1933.23		SC /CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	2029.02		SC /CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	1985.48		SC /CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951		25.61	SC /ONCE	[redacted] / 47	
ABBV-951	2055.14		SC /CONTINUOUS	[redacted] / 47	[redacted] / 47
ABBV-951	2063.85		SC /CONTINUOUS	[redacted] / 48	[redacted] / 48
ABBV-951		25.61	SC /ONCE	[redacted] / 49	
ABBV-951	2046.43		SC /CONTINUOUS	[redacted] / 49	[redacted] / 49
ABBV-951	2089.98		SC /CONTINUOUS	[redacted] / 50	[redacted] / 50
ABBV-951	1959.35		SC /CONTINUOUS	[redacted] / 51	[redacted] / 51
ABBV-951	1950.64		SC /CONTINUOUS	[redacted] / 52	[redacted] / 52
ABBV-951	2029.02		SC /CONTINUOUS	[redacted] / 53	[redacted] / 53
ABBV-951	2029.02		SC /CONTINUOUS	[redacted] / 54	[redacted] / 54
ABBV-951	2029.02		SC /CONTINUOUS	[redacted] / 55	[redacted] / 55
ABBV-951	1968.06		SC /CONTINUOUS	[redacted] / 56	[redacted] / 56
ABBV-951	2011.60		SC /CONTINUOUS	[redacted] / 57	[redacted] / 57
ABBV-951	1698.10		SC /CONTINUOUS	[redacted] / 58	[redacted] / 58
ABBV-951	2089.98		SC /CONTINUOUS	[redacted] / 59	[redacted] / 59
ABBV-951	2063.85		SC /CONTINUOUS	[redacted] / 60	[redacted] / 60
ABBV-951		25.61	SC /ONCE	[redacted] / 61	
ABBV-951	1941.93		SC /CONTINUOUS	[redacted] / 61	[redacted] / 61
ABBV-951	1941.93		SC /CONTINUOUS	[redacted] / 62	[redacted] / 62
ABBV-951		76.83	SC /ONCE	[redacted] / 63	
ABBV-951	2037.73		SC /CONTINUOUS	[redacted] / 63	[redacted] / 63
ABBV-951		76.83	SC /ONCE	[redacted] / 64	
ABBV-951	2020.31		SC /CONTINUOUS	[redacted] / 64	[redacted] / 64

ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 65	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 66	
ABBV-951	2020.31		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 67	
ABBV-951	2037.73		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 68	
ABBV-951	1759.06		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 69	
ABBV-951	1462.98		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 70	
ABBV-951	1706.81		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 71	
ABBV-951	1968.06		SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 72	
ABBV-951	1985.48		SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 73	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 74	
ABBV-951	1985.48		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 75	
ABBV-951	2029.02		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 76	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 77	
ABBV-951	2002.89		SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 78	
ABBV-951	1950.64		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 79	
ABBV-951	1941.93		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 80	
ABBV-951	2037.73		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1828.73		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	235.12		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 83	
ABBV-951	2037.73		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 84	

ABBV-951	2081.27		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 85	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 86	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 87	
ABBV-951	1436.86		SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951		230.51	SC /ONCE	[redacted]20[redacted] / 88	
ABBV-951	2029.02		SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 89	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		332.96	SC /ONCE	[redacted]20[redacted] / 90	
ABBV-951	1898.39		SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		307.35	SC /ONCE	[redacted]20[redacted] / 91	
ABBV-951	2011.60		SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 92	
ABBV-951	2020.31		SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 93	
ABBV-951	2002.89		SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 94	
ABBV-951	2089.98		SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 95	
ABBV-951	2189.35		SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	2391.69		SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 97	
ABBV-951	2388.10		SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 98	
ABBV-951	2471.60		SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 99	
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 100	
ABBV-951	2431.13		SC /CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951		256.12	SC /ONCE	[redacted]20[redacted] / 101	
ABBV-951	2465.45		SC /CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 102	
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 103	

ABBV-951	2320.49		SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 104	
ABBV-951	2538.71		SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 105	
ABBV-951	2059.24		SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		179.28	SC /ONCE	[redacted]20[redacted] / 106	
ABBV-951	2180.64		SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 107	
ABBV-951	2441.89		SC /CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951		128.06	SC /ONCE	[redacted]20[redacted] / 108	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951		230.51	SC /ONCE	[redacted]20[redacted] / 109	
ABBV-951	2484.92		SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		230.51	SC /ONCE	[redacted]20[redacted] / 110	
ABBV-951	2474.16		SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 111	
ABBV-951	2420.38		SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951		281.73	SC /ONCE	[redacted]20[redacted] / 112	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 113	
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 117	
ABBV-951	2493.63		SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951		230.51	SC /ONCE	[redacted]20[redacted] / 118	
ABBV-951	2517.19		SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 119	
ABBV-951	2371.20		SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951		307.35	SC /ONCE	[redacted]20[redacted] / 120	
ABBV-951	2560.22		SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 121	
ABBV-951	2495.68		SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 122	
ABBV-951	2549.46		SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	2506.43		SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123

ABBV-951		153.67	SC /ONCE	[redacted] / 124	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 124	[redacted] / 124
ABBV-951		128.06	SC /ONCE	[redacted] / 125	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 125	[redacted] / 125
ABBV-951		153.67	SC /ONCE	[redacted] / 126	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 126	[redacted] / 126
ABBV-951		76.83	SC /ONCE	[redacted] / 127	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 127	[redacted] / 127
ABBV-951		25.61	SC /ONCE	[redacted] / 128	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 128	[redacted] / 128
ABBV-951		128.06	SC /ONCE	[redacted] / 129	
ABBV-951	2441.89		SC /CONTINUOUS	[redacted] / 129	[redacted] / 129
ABBV-951		307.35	SC /ONCE	[redacted] / 130	
ABBV-951	2538.71		SC /CONTINUOUS	[redacted] / 130	[redacted] / 130
ABBV-951	2474.16		SC /CONTINUOUS	[redacted] / 131	[redacted] / 131
ABBV-951		102.45	SC /ONCE	[redacted] / 132	
ABBV-951	2538.71		SC /CONTINUOUS	[redacted] / 132	[redacted] / 132
ABBV-951		128.06	SC /ONCE	[redacted] / 133	
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 133	[redacted] / 133
ABBV-951		102.45	SC /ONCE	[redacted] / 134	
ABBV-951	2420.38		SC /CONTINUOUS	[redacted] / 134	[redacted] / 134
ABBV-951		51.22	SC /ONCE	[redacted] / 135	
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 135	[redacted] / 135
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 136	[redacted] / 136
ABBV-951		25.61	SC /ONCE	[redacted] / 137	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 137	[redacted] / 137
ABBV-951		25.61	SC /ONCE	[redacted] / 138	
ABBV-951	2495.68		SC /CONTINUOUS	[redacted] / 138	[redacted] / 138
ABBV-951		51.22	SC /ONCE	[redacted] / 139	
ABBV-951	2355.83		SC /CONTINUOUS	[redacted] / 139	[redacted] / 139
ABBV-951		76.83	SC /ONCE	[redacted] / 140	
ABBV-951	2517.19		SC /CONTINUOUS	[redacted] / 140	[redacted] / 140
ABBV-951		25.61	SC /ONCE	[redacted] / 141	
ABBV-951	1194.05		SC /CONTINUOUS	[redacted] / 141	[redacted] / 141
ABBV-951		102.45	SC /ONCE	[redacted] / 142	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 142	[redacted] / 142
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 143	[redacted] / 143

ABBV-951		51.22	SC /ONCE	[redacted] / 144	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 144	[redacted] / 144
ABBV-951		51.22	SC /ONCE	[redacted] / 145	
ABBV-951	2420.38		SC /CONTINUOUS	[redacted] / 145	[redacted] / 145
ABBV-951		76.83	SC /ONCE	[redacted] / 146	
ABBV-951	2538.71		SC /CONTINUOUS	[redacted] / 146	[redacted] / 146
ABBV-951		51.22	SC /ONCE	[redacted] / 147	
ABBV-951	2474.16		SC /CONTINUOUS	[redacted] / 147	[redacted] / 147
ABBV-951		51.22	SC /ONCE	[redacted] / 148	
ABBV-951	2441.89		SC /CONTINUOUS	[redacted] / 148	[redacted] / 148
ABBV-951		25.61	SC /ONCE	[redacted] / 149	
ABBV-951	2431.13		SC /CONTINUOUS	[redacted] / 149	[redacted] / 149
ABBV-951	2377.35		SC /CONTINUOUS	[redacted] / 150	[redacted] / 150
ABBV-951		76.83	SC /ONCE	[redacted] / 151	
ABBV-951	2495.68		SC /CONTINUOUS	[redacted] / 151	[redacted] / 151
ABBV-951		76.83	SC /ONCE	[redacted] / 152	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 152	[redacted] / 152
ABBV-951		128.06	SC /ONCE	[redacted] / 153	
ABBV-951	2441.89		SC /CONTINUOUS	[redacted] / 153	[redacted] / 153
ABBV-951		51.22	SC /ONCE	[redacted] / 154	
ABBV-951	2476.21		SC /CONTINUOUS	[redacted] / 154	[redacted] / 154
ABBV-951		51.22	SC /ONCE	[redacted] / 155	
ABBV-951	2325.61		SC /CONTINUOUS	[redacted] / 155	[redacted] / 155
ABBV-951		25.61	SC /ONCE	[redacted] / 156	
ABBV-951	2361.47		SC /CONTINUOUS	[redacted] / 156	[redacted] / 156
ABBV-951		25.61	SC /ONCE	[redacted] / 157	
ABBV-951	2188.84		SC /CONTINUOUS	[redacted] / 157	[redacted] / 157
ABBV-951		25.61	SC /ONCE	[redacted] / 158	
ABBV-951	2389.13		SC /CONTINUOUS	[redacted] / 158	[redacted] / 158
ABBV-951		25.61	SC /ONCE	[redacted] / 159	
ABBV-951	2448.55		SC /CONTINUOUS	[redacted] / 159	[redacted] / 159
ABBV-951		25.61	SC /ONCE	[redacted] / 160	
ABBV-951	2454.18		SC /CONTINUOUS	[redacted] / 160	[redacted] / 160
ABBV-951		25.61	SC /ONCE	[redacted] / 161	
ABBV-951	1772.38		SC /CONTINUOUS	[redacted] / 161	[redacted] / 161
ABBV-951	2439.33		SC /CONTINUOUS	[redacted] / 162	[redacted] / 162
ABBV-951		25.61	SC /ONCE	[redacted] / 163	

ABBV-951	2418.84		SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 164	
ABBV-951	2197.55		SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 165	
ABBV-951	2288.73		SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 166	
ABBV-951	2452.65		SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 167	
ABBV-951	2527.95		SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 168	
ABBV-951	2441.89		SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 169	
ABBV-951	2352.76		SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1245.79		SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 171	
ABBV-951	1866.63		SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2376.84		SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1862.54		SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	641.33		SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 179	
ABBV-951	2165.79		SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2277.46		SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted] / -125
CARBIDOPA;LEVODOPA	145.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -125
LEVODOPA	84.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -125
PRAMIPEXOLE	1.000 mg	TID	Y-M: 20[redacted]-[redacted] / -124

CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -59
GLUCOSAMINE	2000 mg	QD	Y-M: 20[redacted] / -59
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -34
BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	1 SHAKE OTHER: LIQUID SHAKE	QD	Y-M: 20[redacted] / -29

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
CALCIUM	1000 mg	QD	Y-M: 20[redacted] / -59	ONGOING
GLUCOSAMINE	2000 mg	QD	Y-M: 20[redacted] / -59	Y-M: 20[redacted] / 27
CITALOPRAM	20 mg	QD	Y-M: 20[redacted] / -34	ONGOING
BIOTIN;CARBOHYDRATES NOS;FATS NOS;MINERALS NOS;POTASSIUM;PROTEINS NOS;SODIUM;VITAMINS NOS	1 SHAKE OTHER: LIQUID SHAKE	QD	Y-M: 20[redacted] / -29	ONGOING
PROBIOTICS NOS	1 CHEWABLE OTHER: 1 CHEWABLE	QD	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 50
MIRTAZAPINE	15 mg	QD	Y-M: 20[redacted] / 27	Y-M: 20[redacted] / 37
CYAMOPSIS TETRAGONOLOBA GUM	2 TEASPOONS OTHER: POWDER	OTHER: 2 TABLESPOONS OF POWDER;3-4 8 OZ GLASSES OF WATER	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 52
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 50	Y-M: 20[redacted] / 57
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 82	Y-M: 20[redacted] / 88
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 89	Y-M: 20[redacted] / 96
SULFAMETHOXAZOLE	800/160 mg	OTHER: EVERY 12HR FOR 7 DAYS	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 98
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 137	Y-M: 20[redacted] / 143
MUPIROCIN	2%	QD	Y-M: 20[redacted] / 140	ONGOING
TRIAMCINOLONE ACETONIDE	0.5 OTHER: CC	OTHER: ONCE	Y-M: 20[redacted] / 157	Y-M: 20[redacted] / 157
PIMAVANSERIN TARTRATE	.34 mg	QD	Y-M: 20[redacted] / 161	ONGOING

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

Event Description	INFUSION SITE PAIN WITH EXTRA DOSE ONLY
Preferred Term	注入部位疼痛
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	39
Duration of AE	24 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 - Falls and Associated Injuries

Event Description	FALL- NO INJURIES
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 19
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	19
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: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT INFUSION SITE- RIGHT OF UMBILICUS
Preferred Term	注入部位紅斑
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	29
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: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	NODULES AT INFUSION SITE- RIGHT OF UMBILICUS

Preferred Term	注入部位結節
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	29
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 #5: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONAL DISORDER UNSPECIFIED
Preferred Term	妄想性障害，詳細不明
AE Onset Date / RX Day	[redacted]20[redacted] / 34
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 34): ERYTHROCYTES: 6 [NOT REPORTED - 2] UNIT NOT REPORTED; ERYTHROCYTES: 3.7 [3.9 - 5.2] 10^12/L; GLUCOSE: NEGATIVE [0 - 0] UNIT NOT REPORTED; HEMATOCRIT: 0.35 [0.34 - 0.45] FRACTION OF 1; HEMOGLOBIN: 111 [112 - 157] G/L; KETONES: 20 [NOT REPORTED - NOT REPORTED] MG/DL; LEUKOCYTES: 56 [NOT REPORTED - 2] /HPF; LEUKOCYTES: 7.2 [4 - 10.4] 10^9/L; NPTST178-LYMPH AUTO: 0.88 [1.18 - 3.74] 10^3/UL; NPTST181-MCH: 29.8 [25.6 - 32.2] PG; NPTST182-MCHC: 31.5 [32.5 - 36] G/DL; NPTST183-MCV: 94.6 [79.4 - 94.8] FL; NPTST193-MPV: 10 [9.4 - 12.3] FL; NPTST196-NEUT AUTO: 5.61 [1.56 - 6.13] 10^3/UL; NPTST249-POC AGAP: 15 [5 - 16] UNIT NOT REPORTED; NPTST250-POC BUN: 26 [7 - 23] MG/DL; NPTST251-POC CA ION: 1.13 [1.05 - 1.32] MMOL/L; NPTST252-POC CHLORIDE: 104 [98 - 109] MMOL/L; NPTST253-POC K: 3.4 [3.5 - 5.3] MMOL/L; NPTST254-POC KEYTONES: 15 [NOT REPORTED - NOT REPORTED] MG/DL; NPTST255-POC TCO2M: 26 [21 - 32] MMOL/L; NPTST256-POC URINE UROBILINOGEN: 0.2 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST257-POCI GLUCOSE: 98 [70 - 200] MG/DL; NPTST273-RDW: 12.8 [11.7 - 14.4] %; NPTST289-SQUAM EPI: 2 [NOT REPORTED - 2] HPF;

NPTST311-UROBILINOGEN: 2.0 [NOT REPORTED - NOT REPORTED] MG/DL; PLATELETS: 280 [182 - 369] 10^9/L; PROTEIN: 30 [NOT REPORTED - NOT REPORTED] MG/DL; SPECIFIC GRAVITY: 1.033 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; PH: 5.0 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 35): CT HEAD W/O CONTRAST:IMPRESSION IS NORMAL HEAD CT

AE Stopped RX Day	94
Duration of AE	61 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Event Description	BRUISE ON LEFT EYE
Preferred Term	眼挫傷
AE Onset Date / RX Day	[redacted]20[redacted] / 36
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	50
Duration of AE	15 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 Infections

Event Description	CELLULITIS AT RIGHT LOWER ABDOMEN AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 50
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	64
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS LOWER LEFT QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 82
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	101
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 #9: 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] / 94
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	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 #10: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 126
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 #11: Event of Interest - Hallucinations/Psychosis

Event Description	HEARING VOICES
Preferred Term	幻聴
AE Onset Date / RX Day	[redacted]20[redacted] / 126
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 #12: Event of Interest - Hallucinations/Psychosis

Event Description	FIGURES IN PERIPHERAL VISION- HALLUCINATIONS
Preferred Term	幻視
AE Onset Date / RX Day	[redacted]20[redacted] / 126
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 #13: 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] / 126
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 #14: 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] / 126
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 #15: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE IRRITATION-LEFT LATERAL ABDOMEN
Preferred Term	注入部位刺激感
AE Onset Date / RX Day	[redacted]20[redacted] / 133
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 #16: Event of Interest - Infusion Site Related Infections

Event Description	ABSCESS AT INFUSION SITE- LEFT LATERAL ABDOMEN
Preferred Term	注入部位膿瘍
AE Onset Date / RX Day	[redacted]20[redacted] / 137
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 #17: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	DERMATITIS AT INFUSION SITE
Preferred Term	注入部位皮膚炎
AE Onset Date / RX Day	[redacted]20[redacted] / 172
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 #18: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT MULTIPLE INFUSION SITES
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 183
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 #19: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MULTIPLE INFUSION SITE NODULES
Preferred Term	注入部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 183
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 #20: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	EDEMA AT MULTIPLE INFUSION SITES
Preferred Term	注入部位浮腫
AE Onset Date / RX Day	[redacted]20[redacted] / 183
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

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。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951 の治験で ABBV-951 が投与され，詳細不明の妄想性障害を発現した。

Event 5 の臨床経過：

関連する病歴は，不眠症，注意欠如・多動性障害，パーキンソン病，強迫行動，名前の思い出しが困難，神経原性起立性低血圧，不安，落ち着きのなさ，非喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 34 日目，被験者は詳細不明の妄想性障害を発現した。

投与 34 日目，被験者は車に乗った数人の男性に追われているという妄想のため緊急治療室を受診した。被験者は高速ででたらめに運転し救急診療部に行った。救急診療部は被験者がそこで警察官を探そうとしていたとわかった。同日，被験者は入院し観察下に置かれた。被験者は急性精神病エピソード下にあったと判断された。投与 36 日目，精神病症状の改善後，退院して被験者の配偶者による介護下に置かれた。投与 37 日目，被験者は経過観察のため受診した。精

神病エピソードはミルタザピン投与開始3日後に始まっていたことが確認された。ミルタザピンの投与は中止され，治験薬の注入速度は低下された。

The patient's past medications include:

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

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

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

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

Causality for ABBV-951 (Open Label)

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1) Delusional disorder, unspecified type (10012255) (Delusional disorder, unspecified type (10012255)) [v.21] [10012255]

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 DELUSIONAL DISORDER UNSPECIFIED

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT HEAD W/O CONTRAST:** Impression is normal head CT

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	X		
譫妄	X			
歩行障害				X
幻覚		X		X
注入部位膿瘍	X	X		X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
腰椎骨折				X
代謝性脳症		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
DIFFICULTY HEARING	19[redacted]
CONSTIPATION	19[redacted]
PARKINSONS	20[redacted]
GAIT ABNORMALITY	20[redacted]
RIGHT LEG WEAKNESS	20[redacted]
HYPERTENSION	20[redacted]
DIABETES	20[redacted]
DIFFICULTY SLEEPING	20[redacted]
DREAM ENACTMENT	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
URINARY INCONTINENCE	20[redacted]
DYSARTHRIA	20[redacted]
SOFT SLURRED SPEECH	20[redacted]

TROUBLE WITH TRAIN OF THOUGHT	20[redacted]
HALLUCINATIONS	20[redacted]
HIGH RISK FOR FALLS	20[redacted]
ONYCHOMYCOSIS	20[redacted]
WATER RENTENSION	20[redacted]
BACK TENDERNESS OVER T12-L1	20[redacted]
LEFT SHIN SCRAPE	20[redacted]
MULTIPLE BENIGN NEVI	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
BILATERAL SUBTHALAMIC NUCLEUS -DEEP BRAIN STIMULATION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	10 CIGARETTE	20	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	FORMER			

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	0.7	0	0.63	120	0.3	[redacted]20[redacted]/1
ABBV-951 CSCI	0.7	0	0.63	120	0.3	[redacted]20[redacted]/2
ABBV-951 CSCI	0.7	0	0.63	120	0.3	[redacted]20[redacted]/8
ABBV-951 CSCI	0.77	0	0.7	120	0.3	[redacted]20[redacted]/15
ABBV-951 CSCI	0.77	0	0.7	120	0.3	[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	1398.44		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		51.22	SC /ONCE	[redacted] / 2	
ABBV-951	2820.79		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951		51.22	SC /ONCE	[redacted] / 3	
ABBV-951	2820.79		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		51.22	SC /ONCE	[redacted] / 4	
ABBV-951	2844.69		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		51.22	SC /ONCE	[redacted] / 5	
ABBV-951	2796.88		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		51.22	SC /ONCE	[redacted] / 6	
ABBV-951	2844.69		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2856.64		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		102.45	SC /ONCE	[redacted] / 8	
ABBV-951	2784.93		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2856.64		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2832.74		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		51.22	SC /ONCE	[redacted] / 11	
ABBV-951	2749.07		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2844.69		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2772.98		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2844.69		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2924.77		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		51.22	SC /ONCE	[redacted] / 16	
ABBV-951	3129.16		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	3037.13		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		51.22	SC /ONCE	[redacted] / 18	
ABBV-951	3142.31		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	3142.31		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	3023.98		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	3129.16		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	3116.01		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	3142.31		SC /CONTINUOUS	[redacted] / 23	[redacted] / 23

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	1.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
RASAGILINE	1.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.000 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	780.000 mg	QID	Y-M: 20[redacted]
MINERALS NOS;VITAMINS NOS	1 TABLET OTHER: 1 TABLET	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	OTHER: 1 TAB EVERY OTHER NIGHT	Y-M: 20[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]
DILTIAZEM	240 mg	QD	Y-M: 20[redacted]
DOCUSATE SODIUM	400 MG-1 CAPSULE ON WEEKDAY ONLY mg	OTHER: 1 CAPSULE ON WEEKDAY ONLY	Y-M: 20[redacted]
LIRAGLUTIDE	0.6 SUB-Q mg	QD	Y-M: 20[redacted]
METFORMIN	500 mg	OTHER: 2 TABLETS BID	Y-M: 20[redacted]
METOPROLOL	50 mg	QD	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted]
ROPINIROLE	1.000 mg	TID	Y-M: 20[redacted] / -255
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / -206
BENAZEPRIL	5 mg	QD	Y-M: 20[redacted] / -175
PARACETAMOL	625 mg	PRN	Y-M: 20[redacted] / -84

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
MINERALS NOS;VITAMINS NOS	1 TABLET OTHER: 1 TABLET	QD	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	OTHER: 1 TAB EVERY OTHER NIGHT	Y-M: 20[redacted]	ONGOING
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]	ONGOING
DILTIAZEM	240 mg	QD	Y-M: 20[redacted]	ONGOING
DOCUSATE SODIUM	400 MG-1 CAPSULE ON WEEKDAY ONLY mg	OTHER: 1 CAPSULE ON WEEKDAY ONLY	Y-M: 20[redacted]	ONGOING
LIRAGLUTIDE	0.6 SUB-Q mg	QD	Y-M: 20[redacted]	ONGOING

METFORMIN	500 mg	OTHER: 2 TABLETS BID	Y-M: 20[redacted]	ONGOING
METOPROLOL	50 mg	QD	Y-M: 20[redacted]	ONGOING
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / -206	ONGOING
BENAZEPRIL	5 mg	QD	Y-M: 20[redacted] / -175	ONGOING
PARACETAMOL	625 mg	PRN	Y-M: 20[redacted] / -84	ONGOING
CALCITONIN, SALMON	2200 USP IN EACH NOSTRIL EVERY OTHER DAY OTHER: SPRAY	OTHER: 1 SPRAY IN EACH NOSTRIL EVERY OTHER DAY	Y-M: 20[redacted] / 11	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 23
SULFAMETHOXAZOLE;TRIMETHOPRIM	800/160 mg	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 23
CEFTRIAXONE SODIUM	2 g	QD	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 26
VANCOMYCIN	1 g	OTHER: Q12HRS	Y-M: 20[redacted] / 23	Y-M: 20[redacted] / 26
SODIUM CHLORIDE	2 L	QD	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 34
OLANZAPINE	2.5 mg	OTHER: EVERY EVENING	Y-M: 20[redacted] / 34	Y-M: 20[redacted] / 38

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

Event Description	L-1 VERTEBRAL FRACTURE
Preferred Term	腰椎骨折
AE Onset Date / RX Day	[redacted]20[redacted] / 8
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 #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	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	58 (35 DAYS AFTER LAST TREATMENT)
Duration of AE	44 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 of Interest - Infusion Site Related Infections

Event Description	ABSCESS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred Term	注入部位膿瘍
AE Onset Date / RX Day	[redacted]20[redacted] / 21
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): EKG:NORMAL SINUS RHYTHM; I & D:ABDOMINAL WALL WOUND INFECTION, CONTINUE PACKING OPEN WOUND DAILY TILL HEALED; [redacted]20[redacted] (RX DAY 34): CHEST XRAY:IMPRESSION: NO ACUTE PULMONARY PROCESS; I & D 3 CM PURULENT DISCHARGE EXPRESSED AND CULTURE PERFORMED:WOUND LEFT OPENED, DRESSED AND LEFT TO HEAL

AE Stopped RX Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	CAREGIVER HAD TO GIVE MULTIPLE STICKS OF THE CLEO NEEDLE, THIS IS THE AREA OF INFECTION. EVENTUALLY THEY WERE ABLE TO FIND AN INFUSION SITE
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 of Interest - Infusion Site Related Infections

Event Description	CELLULITIS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 21
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): EKG:NORMAL SINUS RHYTHM; I & D:ABDOMINAL WALL WOUND INFECTION, CONTINUE PACKING OPEN WOUND DAILY TILL HEALED; [redacted]20[redacted] (RX DAY 34): CHEST XRAY:IMPRESSION: NO ACUTE PULMONARY PROCESS; I & D 3 CM PURULENT DISCHARGE EXPRESSED AND CULTURE PERFORMED:WOUND LEFT OPENED, DRESSED AND LEFT TO HEAL

AE Stopped RX Day	34 (11 DAYS AFTER LAST TREATMENT)
Duration of AE	14 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	CAREGIVER DID MULTIPLE STICKS WITH THE CLEO NEEDLE UNSUCCESSFULLY, THIS IS THE AREA OF INFECTION. ULTIMATELY WAS ABLE FIND AN INFUSION SITE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Event of Interest - Polyneuropathy

Event Description	WORSENING OF GAIT
Preferred Term	歩行障害
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	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 #6: Serious Adverse Event, AE Leading to Discontinuation of Study Drug

Event Description	COGNITIVE CONFUSION
Preferred Term	錯乱状態
AE Onset Date / RX Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): EKG:NORMAL SINUS RHYTHM; I & D:ABDOMINAL WALL WOUND INFECTION, CONTINUE PACKING OPEN WOUND DAILY TILL HEALED; [redacted]20[redacted] (RX DAY 34): CHEST XRAY:IMPRESSION: NO ACUTE PULMONARY PROCESS; I & D 3 CM PURULENT DISCHARGE EXPRESSED AND CULTURE PERFORMED:WOUND LEFT OPENED, DRESSED AND LEFT TO HEAL

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 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 #7: Serious Adverse Event

Event Description	ACUTE DELIRIUM
Preferred Term	譫妄

AE Onset Date / RX Day	[redacted]20[redacted] / 23
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 23): ERYTHROCYTES: 4.6 [3.8 - 5.9] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.5] MMOL/L; HEMATOCRIT: 0.41 [0.34 - 0.51] FRACTION OF 1; HEMOGLOBIN: 143 [126 - 174] G/L; LEUKOCYTES: 7.4 [4 - 11] 10^9/L; NPTST181-MCH: 31.4 [27 - 33.5] PG; NPTST182-MCHC: 35.3 [32 - 36] G/DL; NPTST183-MCV: 88.9 [78 - 99] FL; NPTST193-MPV: 8.2 [7.2 - 11.7] FL; NPTST274-RDW-CV: 14.2 [10 - 15] %; PLATELETS: 253 [140 - 440] 10^9/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 23): EKG:NORMAL SINUS RHYTHM; I & D:ABDOMINAL WALL WOUND INFECTION, CONTINUE PACKING OPEN WOUND DAILY TILL HEALED; [redacted]20[redacted] (RX DAY 34): CHEST XRAY:IMPRESSION: NO ACUTE PULMONARY PROCESS; I & D 3 CM PURULENT DISCHARGE EXPRESSED AND CULTURE PERFORMED:WOUND LEFT OPENED, DRESSED AND LEFT TO HEAL

AE Stopped RX Day	54 (31 DAYS AFTER LAST TREATMENT)
Duration of AE	32 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	NOT RELATED TO STUDY PROCEDURES, TEMPORAL IMPLAUSIBILITY.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: 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] / 23
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	YES
SAE Criteria	NONE

Event #9: AE Leading to Discontinuation of Study Drug

Event Description	METABOLIC ENCEPHALOPATHY
Preferred Term	代謝性脳症
AE Onset Date / RX Day	[redacted]20[redacted] / 23
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

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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，右下腹部の注入部位膿瘍，右下腹部の注入部位蜂巣炎，認知的錯乱，及び急性譫妄を発現した。

Event 3，4，6，及び 7 の臨床経過：

関連する病歴は，パーキンソン病，歩行異常，高血圧，糖尿病，睡眠困難，夢の行動化，下肢静止不能症候群，両側視床下核–脳深部刺激療法，構語障害，口蓋化した不明瞭言語，一連の思考の困難，幻覚，高い転倒リスク，水分貯留，現喫煙者（紙巻きタバコ 1 日 10 本を 20 年間），元パイプタバコ喫煙者，及び元飲酒者（1 日 2 杯未満）であった。

投与 21 日目，被験者は右下腹部の注入部位膿瘍及び右下腹部の注入部位蜂巣炎を発現した。投与 23 日目，被験者は認知的錯乱及び急性譫妄を発現した。投与 34 日目，右下腹部の注入部位蜂巣炎は消失した。投与 54 日目，急性譫妄は消失した。

投与 21 日目，被験者は右下腹壁の注入部位膿瘍及び注入部位蜂巣炎を発現した。治験責任医師によると，介護者が注入部位に注入針を複数回刺していた。その後その部位は，発赤，紅斑，熱感，及び圧痛があることから明らかに感染が認められた。投与 23 日目，被験者は認知的錯乱を発現し同日入院した。代謝性脳症が認められた。入院中，被験者は注入部位の切開及びドレナージを受けた。投与 26 日目，被験者は退院し，感染症ケア及び認知的錯乱の管理が継続して必要なため，リハビリ施設に移った。

投与 34 日目，被験者は腹壁膿瘍，急性譫妄及び非重篤の脱水のため入院した。蜂巣炎は消失したが，検査で小膿瘍が認められた。膿瘍は 3 cm 切開後化膿性分泌物が圧出され，培養が行われた。創傷は開放創のままガーゼを当て包帯で巻かれた。急性譫妄のためジプレキサが投与された。臨床検査及び胸部X線検査が完了し，被験者は再びリハビリ施設に戻った（日付不明）。その後，ジプレキサの投与はリハビリ施設で中止された。

被験者の治験は中止された。

被験者にバンコマイシン，スルファメトキサゾール／トリメトプリム，セファレキシン，ロセフィン，及びジプレキサが投与された。

The patient's past medications include:

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

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

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

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

Dechallenge: No

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

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

3) Confusion (10010300) (Confusional state (10010305)) [v.23.1] [10010300]

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

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

Dechallenge: No

4) Acute delirium (10000702) (Delirium (10012218)) [v.23.1] [10000702]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ABSCESS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE

- **Investigator:** Caregiver had to give multiple sticks of the cleo needle, this is the area of infection. Eventually they were able to find an infusion site.

- **AbbVie:** Not applicable.

Event of CELLULITIS RIGHT LOWER QUADRANT OF ABDOMEN AT INFUSION SITE

- **Investigator:** Caregiver did multiple sticks with the cleo needle unsuccessfully, this is the area of infection. Ultimately was able find an infusion site.

- **AbbVie:** Not applicable.

Event of COGNITIVE CONFUSION

- **Investigator:** Not applicable.

- **AbbVie:** More likely related to a history of Parkinson's disease, hallucinations, and trouble with train of thought in a patient with advanced age.

Event of ACUTE DELIRIUM

- **Investigator:** Not related to study procedures, temporal implausibility.

- **AbbVie:** More likely related to a report of concurrent dehydration in an advanced aged patient with a history of Parkinson's disease, diabetes, smoking and hallucinations.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST XRAY:** impression: no acute pulmonary process

[redacted] **20**[redacted] **EKG:** NORMAL SINUS RHYTHM

[redacted] **20**[redacted] **GLUCOSE:** 116 mg/dL (normal 70 to 99)

[redacted] **20**[redacted] **HEMATOCRIT:** 40.6% (normal 34.0 to 51.0)

[redacted] **20**[redacted] **HEMOGLOBIN:** 14.3 G/DL (normal 12.36 to 17.4)

[redacted] **20**[redacted] **MCH:** 31.4 PG (normal 27.0 to 33.5)

[redacted] **20**[redacted] **MCHC:** 35.3 G/DL (normal 32.0 to 36.0)

[redacted] **20**[redacted] **MCV:** 88.9 FL (normal 78.0 to 99.0)

[redacted] **20**[redacted] **PLATELET COUNT:** 253 K/uL (normal 140 to 440)

[redacted] **20**[redacted] **RDW-CV:** 14.2% (normal 10.0 to 15.0)

[redacted] **20**[redacted] **RED BLOOD CELLS:** 4.56 m/UL (normal 3.8 to 5.9)

[redacted] **20**[redacted] **WHITE BLOOD CELLS:** 7.4 K/UL (normal 4.0 to 11.0)

[redacted] 20[redacted] WOUND CULTURE: Not Reported

[redacted] **20**[redacted] **MPV:** 8.2 FL (normal 7.2 to 11.7)

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
血中ナトリウム減少	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	AMERICAN INDIAN OR ALASKA NATIVE

Medical History	Onset Year
PARKINSON'S DISEASE	20[redacted]
DECREASED SODIUM LEVELS	20[redacted]
NAUSEA	20[redacted]
CONSTIPATION	20[redacted]
GERD	20[redacted]
HYPERTENSION	20[redacted]
BILATERAL MILD ANKLE EDEMA	20[redacted]
OVERACTIVE BLADDER	20[redacted]
DRY EYES	20[redacted]
DEPRESSION	20[redacted]
SLEEP PROBLEMS	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	0.25	0.21	60	0.11	[redacted]/1
ABBV-951 CSCI	0.23	0.25	0.21	60	0.11	[redacted]/2
ABBV-951 CSCI	0.24	0.25	0.23	60	0.11	[redacted]/8
ABBV-951 CSCI	0.24	0.25	0.23	60	0.11	[redacted]/14
ABBV-951 CSCI	0.24	0.25	0.23	60	0.11	[redacted]/21
ABBV-951 CSCI	0.24	0.25	0.23	60	0.11	[redacted]/29
ABBV-951 CSCI	0.25	0.26	0.24	60	0.11	[redacted]/42
ABBV-951 CSCI	0.25	0.26	0.24	60	0.11	[redacted]/94
ABBV-951 CSCI	0.26	0.27	0.24	60	0.11	[redacted]/183
ABBV-951 CSCI	0.25	0.27	0.24	60	0.11	[redacted]/274
ABBV-951 CSCI	0.27	0.26	0.24	60	0.11	[redacted]/381

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	635.19		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	983.52		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	986.93		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19

ABBV-951	963.03	SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	942.54	SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	942.54	SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	942.54	SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
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ABBV-951	950.73	SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
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ABBV-951	980.10	SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
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ABBV-951	942.54	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 92	
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ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 93	
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ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
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ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165

ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	1065.48	SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
ABBV-951	1043.45	SC /CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
ABBV-951	1032.86	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
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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
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ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 217
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239

ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	1024.5	SC /CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[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	1059.16	SC /CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	1088.01	SC /CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMIN B12 NOS	100 OTHER: MCG	QD	Y-M: 20[redacted]
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted] / -358
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted] / -274
MELATONIN	5 mg	QD	Y-M: 20[redacted] / -133
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted] / -121
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted] / -121

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	100 OTHER: MCG	QD	Y-M: 20[redacted]	ONGOING
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]	ONGOING
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]	ONGOING
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]	ONGOING
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]	ONGOING
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]	ONGOING
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309	ONGOING
MELATONIN	5 mg	QD	Y-M: 20[redacted] / -133	ONGOING
SERTRALINE HYDROCHLORIDE	50 mg	QD	Y-M: 20[redacted] / -121	ONGOING
SODIUM CHLORIDE	125 ML/HR OTHER: ML/HR	OTHER: ONCE	Y-M: 20[redacted] / 39	Y-M: 20[redacted] / 39

Event #1: Serious Adverse Event

Event Description	LOW SODIUM
Preferred Term	血中ナトリウム減少
AE Onset Date / RX Day	[redacted]20[redacted] / 38
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 37): SODIUM: 124 [136 - 145] MMOL/L

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	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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，低ナトリウムを発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，悪心，便秘，胃食道逆流症，高血圧，両側軽度足関節浮腫，過活動膀胱，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 38 日目，被験者は低ナトリウムを発現した。

投与 37 日目，本事象の発現前に，被験者は臨床検査を受けた。

投与 39 日目，被験者は臨床検査で低ナトリウムが認められ，疲労及び錯乱も認められたため入院した。治験責任医師によると，被験者には低ナトリウムの病歴があった。被験者は輸液療法を受け，塩分の摂取量を増やすよう指示された。投与 40 日目，被験者は退院した。
被験者に 0.9%塩化ナトリウムが投与された。

The patient's past medications include:

CARBIDOPA/ LEVODOPA IMMEDIATE RELEASE 25/100 for PARKINSONS DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Sodium low (10041274) (Blood sodium decreased (10005802)) [v.23.0] [10041274]

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

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

Dechallenge: Not ApplicableAlternative Etiology for ABBV-951 (Open Label)

Event of LOW SODIUM

- Investigator: Not applicable.

- AbbVie: More likely related to advanced age and concomitant use of Zoloft

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] SODIUM:** 124 MMOL/L (normal 136 to 145)

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
反射減弱				X
注入部位結節				X
注射部位紅斑				X

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

Medical History	Onset Year
INGUINAL HERNIA	19[redacted]
ALLERGIES TO MOLD	19[redacted]
HAYFEVER	19[redacted]
NEPHROLITHIASIS	20[redacted]
PARKINSON DISEASE	20[redacted]
ATRIAL FIBRILLATION	20[redacted]
ANXIETY	20[redacted]
DAYTIME SOMNOLENCE	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 REPAIR	19[redacted]
INGUINAL HERNIA REPAIR	19[redacted]
CARDIAC ABLATION WITH LOOP DEVICE	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	0.33	0	0	720	0.11	[redacted]/1
ABBV-951 CSCI	0.3	0	0	720	0.11	[redacted]/2
ABBV-951 CSCI	0.32	0	0	720	0.11	[redacted]/8
ABBV-951 CSCI	0.32	0	0	720	0.11	[redacted]/14
ABBV-951 CSCI	0.32	0	0	720	0.11	[redacted]/22
ABBV-951 CSCI	0.32	0	0	720	0.11	[redacted]/29
ABBV-951 CSCI	0.33	0.35	0.32	120	0.15	[redacted]/42
ABBV-951 CSCI	0.33	0.35	0.32	60	0.15	[redacted]/91
ABBV-951 CSCI	0.33	0.35	0.32	60	0.15	[redacted]/184
ABBV-951 CSCI	0.32	0.33	0.35	60	0.15	[redacted]/212
ABBV-951 CSCI	0.33	0.35	0.32	60	0.15	[redacted]/275
ABBV-951 CSCI	0.33	0.35	0.32	60	0.15	[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	480.83		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1311.36		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	781.35		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	448.04		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1305.89		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	901.56		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	109.28		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	5.46		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		18.78	SC /ONCE	[redacted] / 21	

ABBV-951	404.33		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1213.00		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1256.72		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	945.27		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 36	
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 38	
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 39	
ABBV-951	300.52		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	1311.36		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1289.50		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 42	
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ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 43	
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ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 219	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 220	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	1410.39		SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 222	
ABBV-951	1404.41		SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 223	
ABBV-951	1368.56		SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 224	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 225	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 226	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 227	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 228	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 229	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 230	
ABBV-951	1308.79		SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1344.65		SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]
MAGNESIUM	400 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]

CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	6 TIMES PER DAY	Y-M: 20[redacted] / -342
ARMODAFINIL	75 mg	QD	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
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]	ONGOING
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]	ONGOING
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]	ONGOING
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]	ONGOING
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	ONGOING
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted] / -272	ONGOING
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 42	ONGOING
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted] / 154	ONGOING

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

Event Description	MILD ERYTHEMA AT INJECTION SITE
Preferred Term	注射部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	22
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 - Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA AT PREVIOUS INJECTION SITE
Preferred Term	注射部位紅斑
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	184
Duration of AE	156 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] / 184
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	191
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 - Polyneuropathy

Event Description	HYPOACTIVE REFLEXES
Preferred Term	反射減弱
AE Onset Date / RX Day	[redacted]20[redacted] / 184
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	366
Duration of AE	183 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: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 191
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 191): PATIENT WAS HOSPITALIZED FOR HALLUCINATIONS:THE PATIENT WAS RELEASED WITH TREATMENT	
AE Stopped RX Day	192
Duration of AE	2 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	PD PROGRESSION VS LEVODOPA COMPLICATION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Event Description	FALL ACCIDENTAL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 235
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	235
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	NODULE RUQ AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 275
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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，幻覚を発現した。

Event 5 の臨床経過：

関連する病歴は，パーキンソン病，不安，日中の傾眠，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 191 日目，被験者は幻覚を発現した。投与 192 日目，幻覚は消失した。

投与 184 日目，本事象の発現に先立ち，被験者は非重篤の幻覚を発現した。

被験者は間欠的な幻覚を発現し，評価のため緊急治療室を受診した。投与 191 日目，被験者は治療のため精神科に入院した。投与 192 日目，被験者は退院した。

The patient's past medications include:

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

Causality for ABBV-951 (Open Label)

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1) Hallucinations (10019077) (Hallucination (10019063)) [v.23.0] [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: PD progression vs Levodopa complication

- AbbVie: More likely related to a history of Parkinson's disease and use of concomitant medication Armodafinil in an advanced aged patient.

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
脳圧排効果	X	X	X	X
転倒				X
幻覚				X
反射減弱				X
注射部位紅斑				X
注射部位結節				X
硬膜下血腫	X	X	X	X
体重減少				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
CERVICAL DISK COMPRESSION	19[redacted]
ELEVATED CHOLESTEROL	19[redacted]
HYPERTENSION	19[redacted]
ARTHRITIS JOINTS	20[redacted]
ALLERGY PENICILLIN	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
ROTATOR CUFF TEAR, BILATERAL	20[redacted]
ARTHRITIC CHANGES BILATERAL KNEES	20[redacted]
CONSTIPATION	20[redacted]
POSTMENOPAUSAL	20[redacted]
DAYTIME SOMNOLENCE	20[redacted]
OVERACTIVE BLADDER	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
NECK FUSION	19[redacted]
SURGERY BILATERAL SHOULDERS	20[redacted]
BILATERAL KNEE REPLACEMENTS	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	0.27	0	0	360	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.26	0.27	0.24	360	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.26	0.3	0.35	60	0.24	[redacted]20[redacted]/8
ABBV-951 CSCI	0.26	0.3	0.35	60	0.24	[redacted]20[redacted]/15
ABBV-951 CSCI	0.38	0.4	0.42	60	0.3	[redacted]20[redacted]/22
ABBV-951 CSCI	0.36	0.38	0.42	60	0.3	[redacted]20[redacted]/29
ABBV-951 CSCI	0.4	0.42	0.45	60	0.3	[redacted]20[redacted]/43
ABBV-951 CSCI	0.42	0.45	0.4	60	0.3	[redacted]20[redacted]/92
ABBV-951 CSCI	0.47	0.5	0.45	60	0.3	[redacted]20[redacted]/180
ABBV-951 CSCI	0.55	0.6	0.5	60	0.3	[redacted]20[redacted]/244
ABBV-951 CSCI	0.55	0.56	0.57	60	0.3	[redacted]20[redacted]/273

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	298.81		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	1374.53		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 16	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 18	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 19	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	690.85		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1388.53		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1485.86		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1492.35		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1492.35		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1524.79		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1518.30		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 29	
ABBV-951	1537.77		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1518.30		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951	1511.82		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 32	
ABBV-951	1498.84		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32

ABBV-951	1505.33		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 34	
ABBV-951	1492.35		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	1557.24		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 36	
ABBV-951	1544.26		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951	1511.82		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 38	
ABBV-951	1498.84		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1531.28		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1537.77		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	1453.42		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	1485.86		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1547.33		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1692.47		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1649.44		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1685.30		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1692.47		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1699.64		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1699.64		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1706.81		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1649.44		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1685.30		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1713.98		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1670.95		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 58	
ABBV-951	1706.81		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1706.81		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1656.61		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 61	
ABBV-951	1706.81		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61

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ABBV-951	2376.84	SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	2407.57	SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
ABBV-951	2397.33	SC /CONTINUOUS	[redacted]20[redacted] / 257	[redacted]20[redacted] / 257
ABBV-951	2335.86	SC /CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	2407.57	SC /CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	2397.33	SC /CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	2376.84	SC /CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	2428.06	SC /CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	2438.31	SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	2397.33	SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264

ABBV-951	2438.31	SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	2438.31	SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	2438.31	SC /CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	2346.10	SC /CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	2376.84	SC /CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
ABBV-951	1997.77	SC /CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 270
ABBV-951	2428.06	SC /CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
ABBV-951	2397.33	SC /CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
ABBV-951	2262.09	SC /CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	2189.86	SC /CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
ABBV-951	2170.40	SC /CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
ABBV-951	2170.40	SC /CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276
ABBV-951	2306.66	SC /CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
ABBV-951	2287.19	SC /CONTINUOUS	[redacted]20[redacted] / 278	[redacted]20[redacted] / 278
ABBV-951	2296.92	SC /CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
ABBV-951	2287.19	SC /CONTINUOUS	[redacted]20[redacted] / 280	[redacted]20[redacted] / 280
ABBV-951	2219.06	SC /CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
ABBV-951	2228.79	SC /CONTINUOUS	[redacted]20[redacted] / 282	[redacted]20[redacted] / 282
ABBV-951	2238.53	SC /CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	2160.67	SC /CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
ABBV-951	2121.73	SC /CONTINUOUS	[redacted]20[redacted] / 285	[redacted]20[redacted] / 285
ABBV-951	2296.92	SC /CONTINUOUS	[redacted]20[redacted] / 286	[redacted]20[redacted] / 286
ABBV-951	2316.39	SC /CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	2287.19	SC /CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ESTRADIOL;NORETHISTERONE	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]
METOPROLOL	50 mg	QD	Y-M: 20[redacted]-[redacted]
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
DICLOFENAC	75 mg	QD	Y-M: 20[redacted]-[redacted]
MISOPROSTOL	200 ug	BID	Y-M: 20[redacted]-[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]-[redacted]
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE HYDROCHLORIDE	137.000 mg	QD	Y-M: 20[redacted]-[redacted]
ATOMOXETINE HYDROCHLORIDE	40 mg	QD	Y-M: 20[redacted]-[redacted] / -232

CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	5 TIMES PER DAY	Y-M: 20[redacted] / -232
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -189

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
ESTRADIOL;NORETHISTERONE	1 OTHER: TABLET	QD	Y-M: 20[redacted]	ONGOING
METOPROLOL	50 mg	QD	Y-M: 20[redacted]	ONGOING
AMLODIPINE BESILATE;ATORVASTATIN CALCIUM	1 OTHER: TAB	QD	Y-M: 20[redacted]	ONGOING
DICLOFENAC	75 mg	QD	Y-M: 20[redacted]	ONGOING
MISOPROSTOL	200 ug	BID	Y-M: 20[redacted]	ONGOING
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	ONGOING
ATOMOXETINE HYDROCHLORIDE	40 mg	QD	Y-M: 20[redacted] / -232	ONGOING
MIRABEGRON	50 mg	QD	Y-M: 20[redacted] / -189	ONGOING
MUPIROCIN	SMALL AMOUNT OTHER: SMALL AMOUNT	TID	Y-M: 20[redacted] / 84	ONGOING
SULFAMETHOXAZOLE;TRIMETHOPRIM	400 - 80 mg	QD	Y-M: 20[redacted] / 84	ONGOING
PIMAVANSERIN	34 mg	QD	Y-M: 20[redacted] / 184	ONGOING
MELATONIN	3 mg	QD	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 261
MELATONIN	10 mg	QD	Y-M: 20[redacted] / 261	Y-M: 20[redacted] / 267
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted] / 267	Y-M: 20[redacted] / 273
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 273	Y-M: 20[redacted] / 286
QUETIAPINE FUMARATE	37.5 mg	QD	Y-M: 20[redacted] / 286	ONGOING
LORAZEPAM	1 mg	OTHER: Q1H	Y-M: 20[redacted] / 289	ONGOING
MORPHINE	4 mg	OTHER: Q1H	Y-M: 20[redacted] / 289	ONGOING

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

Event Description	ERYTHEMA AT INJECTION SITE
Preferred Term	注射部位紅斑
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	14
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	ERYTHEMA AT INJECTION SITE
Preferred Term	注射部位紅斑
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	180
Duration of AE	167 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 INJECTION SITE
Preferred Term	注射部位結節
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	180
Duration of AE	167 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	ERYTHEMA AT INJECTION SITE
Preferred Term	注射部位紅斑
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	273
Duration of AE	245 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	NODULE AT INJECTION SITE
Preferred Term	注射部位結節
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	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	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 90
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 - Polyneuropathy

Event Description	HYPOACTIVE REFLEX (1+ PATELLARS)
Preferred Term	反射減弱
AE Onset Date / RX Day	[redacted]20[redacted] / 180
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	273
Duration of AE	94 DAYS

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

Event #8: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / RX Day	[redacted]20[redacted] / 244
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

Event #9: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death, Event of Interest - Falls and Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	CEREBRAL MARKED MASS EFFECT
Preferred Term	脳圧排効果
AE Onset Date / RX Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 289): CT SCAN:FOUND LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA WITH MARKED MASS EFFECT; INTUBATION:THE PATIENT WAS INTUBATED AND THEN EXTUBATED WHEN IT WAS DECIDED TO NOT PURSUE CRANIOTOMY.	
AE Stopped RX Day	289
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	PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	LIFE THREATENING, RESULTS IN DEATH

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

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	289
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	NO
SAE Criteria	NONE

Event #11: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death, Event of Interest - Falls and Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA
Preferred Term	硬膜下血腫
AE Onset Date / RX Day	[redacted]20[redacted] / 289
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 289): CT SCAN:FOUND LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA WITH MARKED MASS EFFECT; INTUBATION:THE PATIENT WAS INTUBATED AND THEN EXTUBATED WHEN IT WAS DECIDED TO NOT PURSUE CRANIOTOMY.

AE Stopped RX Day	289
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	PATIENT DOES NOT HAVE GOOD MOBILITY DUE TO PARKINSON'S DISEASE AND GOT OUT OF BED WITHOUT ASSISTANCE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	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。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，死亡に至った急性広範右側脳硬膜下血腫及び顕著な脳圧排効果を発現した。

Event 9 及び 11 の臨床経過：

関連する病歴は，高血圧，関節炎のある関節，不安，うつ病，パーキンソン病，両膝の関節炎変化，両膝関節置換術，閉経後，日中の傾眠，過活動膀胱，非喫煙者，及び現飲酒者（1 日 2 杯未満）であった。

投与 289 日目，被験者は急性広範右側脳硬膜下血腫及び顕著な脳圧排効果を発現した。同日，被験者は死亡した。死因は脳出血と報告された。剖検の実施の有無は不明であった。

投与 289 日目，被験者は転倒のため入院した。入院前に，被験者は目覚めてベッドから出ようとしたが，転倒し頭部を打った。入院時，被験者は「脳出血」と診断された後，集中治療室で治療を受けた。同日，被験者は死亡した。これは被験者の介護者により報告された。治験実施施設は本事象に関する詳細な情報を待っていた。

被験者はパーキンソン病による移動能力の低下のリスク因子があった。被験者に本事象に関連する家族歴はなかった。

The patient's past medications include:

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

MELATONIN for HALLUCINATIONS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Acute subdural hematoma (10066659) (Subdural haematoma (10042361)) [v.23.1] [10066659]

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

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

Dechallenge: Not Applicable

2) Cerebral mass effect (10067086) (Intracranial mass (10077667)) [v.23.1] [10067086]

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 ACUTE LARGE RIGHT CEREBRAL SUBDURAL HEMATOMA, CEREBRAL MARKED MASS EFFECT

- Investigator: The patient does not have good mobility due to Parkinson's disease and got out of bed without assistance.

- AbbVie: More likely related to a traumatic injury from an accidental fall due to reported poor mobility and getting out of bed without assistance in an advanced aged patient with a history of Parkinson's disease and arthritis joints

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

Weight Decreased: Day 1 weight 10[redacted] pounds. Weight at time of event 9[redacted] pounds. Weight loss occurred over a period of 9 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 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
脳血管発作	X	X	X	
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位血管外漏出				X
注入部位疼痛				X
肺炎	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
ALLERGIES	NOT REPORTED
IRON DEFICIENCY ANEMIA	NOT REPORTED
PENICILLIN ALLERGY	NOT REPORTED
TONSILITIS	19[redacted]
COPD	20[redacted]
GERD	20[redacted]
CORONARY ARTERY DISEASE	20[redacted]
HEART ATTACK	20[redacted]
INTRAVENTRICULAR CONDUCTION DEFECT	20[redacted]
GENERALIZED HEADACHES	20[redacted]
HYPERLIPIDEMIA	20[redacted]
R WRIST FRACTURE	20[redacted]
PNEUMOTHORAX	20[redacted]
ABDOMINAL AORTIC ANEURYSM WITHOUT RUPTURE	20[redacted]
EMBOLISM AND THROMBOSIS IN UNSPECIFIED ARTERY OF R LEG	20[redacted]
PEPTIC ULCER	20[redacted]
ASPIRATION PNEUMONIA	20[redacted]

SILENT ASPIRATION	20[redacted]
GAIT DISTURBANCE	20[redacted]
ASPIRATION PNEUMONIA	20[redacted]
L ELBOW FRACTURE	20[redacted]
HYPOXIA, SLEEP RELATED	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
TONSILLECTOMY	19[redacted]
KNEE SURGERY	19[redacted]
CATH LAB WITH STENT PLACEMENT	20[redacted]
R WRIST FRACTURE REPAIR	20[redacted]
CHEST TUBE PLACEMENT	20[redacted]
LARYNGOSCOPY	20[redacted]
L ELBOW FRACTURE REPAIR	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	45	20[redacted]
CIGARS	FORMER			
E-CIGARETTES	FORMER	1 SESSIONS	45	20[redacted]
PIPES	FORMER			

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	0.52	0.34	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.47	0.56	0.38	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.5	0.6	0.4	60	0.11	[redacted]20[redacted]/6
ABBV-951 CSCI	0.5	0.6	0.4	60	0.11	[redacted]20[redacted]/20

ABBV-951 CSCI	0.6	0.72	0.48	60	0.11	[redacted]/29
ABBV-951 CSCI	0.53	0.64	0.42	60	0.11	[redacted]/36
ABBV-951 CSCI	0.57	0.68	0.46	60	0.11	[redacted]/41
ABBV-951 CSCI	0.57	0.68	0.46	60	0.11	[redacted]/90

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	697.51		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951		37.56	SC /ONCE	[redacted] / 2	
ABBV-951	1821.39		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1877.90		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		37.56	SC /ONCE	[redacted] / 4	
ABBV-951	1901.98		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		18.78	SC /ONCE	[redacted] / 5	
ABBV-951	1893.95		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		37.56	SC /ONCE	[redacted] / 6	
ABBV-951	1935.10		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2031.92		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2040.46		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		56.34	SC /ONCE	[redacted] / 9	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		18.78	SC /ONCE	[redacted] / 10	
ABBV-951	2040.46		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2103.64		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		37.56	SC /ONCE	[redacted] / 12	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		56.34	SC /ONCE	[redacted] / 13	
ABBV-951	2014.85		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		75.13	SC /ONCE	[redacted] / 14	
ABBV-951	2014.85		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		56.34	SC /ONCE	[redacted] / 15	
ABBV-951	1869.71		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951		75.13	SC /ONCE	[redacted] / 16	
ABBV-951	1881.66		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		18.78	SC /ONCE	[redacted] / 17	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17

ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 18	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 19	
ABBV-951	2189.01		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	2397.33		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2407.57		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	2387.08		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	2428.06		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 24	
ABBV-951	2428.06		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 25	
ABBV-951	2428.06		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	2387.08		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		93.91	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	2458.8		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	2438.31		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 29	
ABBV-951	2587.88		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 30	
ABBV-951	2407.57		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951	2335.86		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1901.47		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 33	
ABBV-951	1885.08		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1950.64		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	1950.64		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 36	
ABBV-951	1897.37		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951	2153.84		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37

ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 38	
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 39	
ABBV-951	2108.59		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	2162.89		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	2263.12		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 44	
ABBV-951	2267.73		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2219.06		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 47	
ABBV-951	2257.99		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2277.46		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 51	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 53	
ABBV-951	2267.73		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 54	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 55	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 56	
ABBV-951	2267.73		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 61	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61

ABBV-951	2306.66		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 63	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 65	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2316.39		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2296.92		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 70	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2316.39		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	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2267.73		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2238.53		SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2316.39		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 80	
ABBV-951	2277.46		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 81	
ABBV-951	2316.39		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2287.19		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 84	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 85	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 86	
ABBV-951	2017.92		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1877.22		SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1869.37		SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	1814.38		SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 90	

ABBV-951	2101.07		SC /CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	2287.19		SC /CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	2306.66		SC /CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2335.86		SC /CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		37.56	SC /ONCE	[redacted] / 96	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		37.56	SC /ONCE	[redacted] / 97	
ABBV-951	2316.39		SC /CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951		56.34	SC /ONCE	[redacted] / 99	
ABBV-951	2257.99		SC /CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	2335.86		SC /CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951		18.78	SC /ONCE	[redacted] / 101	
ABBV-951	2316.39		SC /CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951		18.78	SC /ONCE	[redacted] / 102	
ABBV-951	2228.79		SC /CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951		18.78	SC /ONCE	[redacted] / 103	
ABBV-951	2306.66		SC /CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	2306.66		SC /CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951		18.78	SC /ONCE	[redacted] / 105	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951		18.78	SC /ONCE	[redacted] / 106	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted] / 106	[redacted] / 106
ABBV-951		18.78	SC /ONCE	[redacted] / 107	
ABBV-951	2306.66		SC /CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951		37.56	SC /ONCE	[redacted] / 108	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 108	[redacted] / 108
ABBV-951		37.56	SC /ONCE	[redacted] / 109	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted] / 109	[redacted] / 109
ABBV-951		18.78	SC /ONCE	[redacted] / 110	
ABBV-951	2335.86		SC /CONTINUOUS	[redacted] / 110	[redacted] / 110
ABBV-951		37.56	SC /ONCE	[redacted] / 111	
ABBV-951	2296.92		SC /CONTINUOUS	[redacted] / 111	[redacted] / 111
ABBV-951		56.34	SC /ONCE	[redacted] / 112	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 112	[redacted] / 112

ABBV-951		37.56	SC /ONCE	[redacted] / 113	
ABBV-951	2287.19		SC /CONTINUOUS	[redacted] / 113	[redacted] / 113
ABBV-951		37.56	SC /ONCE	[redacted] / 114	
ABBV-951	2267.73		SC /CONTINUOUS	[redacted] / 114	[redacted] / 114
ABBV-951		18.78	SC /ONCE	[redacted] / 115	
ABBV-951	2326.12		SC /CONTINUOUS	[redacted] / 115	[redacted] / 115
ABBV-951		37.56	SC /ONCE	[redacted] / 116	
ABBV-951	2267.73		SC /CONTINUOUS	[redacted] / 116	[redacted] / 116

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	PRN	Y-M: 20[redacted]
CALCIUM CARBONATE	2 OTHER: TABS	PRN	Y-M: 20[redacted]
LORATADINE	10 mg	QD	Y-M: 20[redacted]
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]
PARACETAMOL	1,000 mg	TID	Y-M: 20[redacted]
TIOTROPIUM BROMIDE MONOHYDRATE	18 OTHER: MCG	QD	Y-M: 20[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 OTHER: TAB	QD	Y-M: 20[redacted]
FERROUS FUMARATE	2 OTHER: TABS	QD	Y-M: 20[redacted]
CALCIUM PHOSPHATE;COLECALCIFEROL	1 OTHER: TAB	QD	Y-M: 20[redacted]
OXYGEN	3 OTHER: L	OTHER: BEDTIME	Y-M: 20[redacted]
SALBUTAMOL	2 MG/5 ML OTHER: MG/ML	QD	Y-M: 20[redacted] / -328
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	1 OTHER: PUFF	QD	Y-M: 20[redacted] / -170
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted] / -158
APOMORPHINE HYDROCHLORIDE	6.000 mg	PRN	Y-M: 20[redacted] / -155
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted] / -155
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	QID	Y-M: 20[redacted] / -155
CYANOCOBALAMIN;FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	2 OTHER: TABLETS	BID	Y-M: 20[redacted] / -20

INFLUENZA VACCINE	1 OTHER: SHOT	OTHER: ONCE	Y-M: 20[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
PSEUDOEPHEDRINE HYDROCHLORIDE	60 mg	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
CALCIUM CARBONATE	2 OTHER: TABS	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
LORATADINE	10 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
PARACETAMOL	1,000 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
TIOTROPIUM BROMIDE MONOHYDRATE	18 OTHER: MCG	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
ATORVASTATIN CALCIUM	40 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM	1 OTHER: TAB	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
FERROUS FUMARATE	2 OTHER: TABS	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
CALCIUM PHOSPHATE;COLECALCIFEROL	1 OTHER: TAB	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
OXYGEN	3 OTHER: L	OTHER: BEDTIME	Y-M: 20[redacted]	Y-M: 20[redacted] / 117
SALBUTAMOL	2 MG/5 ML OTHER: MG/ML	QD	Y-M: 20[redacted] / -328	Y-M: 20[redacted] / 117
FLUTICASONE FUROATE;VILANTEROL TRIFENATATE	1 OTHER: PUFF	QD	Y-M: 20[redacted] / -170	Y-M: 20[redacted] / 117
CYANOCOBALAMIN; FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	2 OTHER: TABLETS	BID	Y-M: 20[redacted] / -20	Y-M: 20[redacted] / 117
INFLUENZA VACCINE	1 OTHER: SHOT	OTHER: ONCE	Y-M: 20[redacted] / -6	Y-M: 20[redacted] / -6
SODIUM CHLORIDE	3,225 mL	OTHER: ONCE	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 12
AZITHROMYCIN	500 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 14

CEFTRIAXONE	1,000 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 14
LEVOFLOXACIN	750 mg	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 21
NYSTATIN	500,000 OTHER: UNITS/5 ML	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 21
OXYGEN	2-4 L	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 61
CEFALEXIN	500 mg	QD	Y-M: 20[redacted] / 47	Y-M: 20[redacted] / 48
DOXYCYCLINE	100 mg	TID	Y-M: 20[redacted] / 49	Y-M: 20[redacted] / 59
LEVOFLOXACIN	750 mg	QD	Y-M: 20[redacted] / 94	Y-M: 20[redacted] / 101

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

Event Description	STINGING SENSATION WHEN INFUSION FIRST STARTED
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	117
Duration of AE	117 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	REDNESS (1) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY [redacted], MD ON [redacted]/[redacted]/20[redacted].
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 6
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	117
Duration of AE	112 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	BILATERAL PNEUMONIA
Preferred Term	肺炎
AE Onset Date / RX Day	[redacted]20[redacted] / 12
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 12): ALBUMIN: 43 [32 - 55] G/L; ALKALINE PHOSPHATASE: 70 [42 - 121] U/L; BILIRUBIN: 10 [3 - 17] UMOL/L; GLUCOSE: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; KETONES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST010-ALT: 5 [10 - 60] U/L; NPTST033-AST: 16 [10 - 42] U/L; NPTST035-BACTERIA, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] U/L; NPTST046-BILIRUBIN, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST050-BLOOD, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST082-CLARITY: CLEAR [NOT REPORTED - NOT REPORTED] CLARITY; NPTST089-COLOR, UA: LIGHT YELLOW [NOT REPORTED - NOT REPORTED] COLOR; NPTST144-HYALINE CAST: 0-2 [0 - 5] IPF; NPTST156-INR: 1.17

[0.85 - 1.13] RATIO; NPTST165-LACTIC ACID LEVEL: 2 [0.5 - 2] MMOL/L; NPTST172-LEUKOCYTE ESTERASE: NEGATIVE [NOT REPORTED - NOT REPORTED] LEU/UL; NPTST200-NITRITES, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST261-PROCALCITONIN: 0.22 [0 - 0.49] NG/ML; NPTST264-PROTEIN, UA: NEGATIVE [NOT REPORTED - NOT REPORTED] MG/DL; NPTST267-PT: 14.7 [11.5 - 14.5] SEC; NPTST272-RBC, UA: 0-5 [0 - 5] HPF; NPTST290-SQUAMOUS EPITHELIAL: NEGATIVE/FEW [1 - 5] HPF; NPTST312-UROBILINOGEN, UA: NORMAL [NOT REPORTED - NOT REPORTED] MG/DL; NPTST320-WBC, UA: 0-5 [0 - 5] HPF; PROTEIN: 74 [60 - 80] G/L; SPECIFIC GRAVITY: 1.010 [1.003 - 1.03] UNIT NOT REPORTED; PH: 6.5 [4.5 - 8] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 14): BASOPHILS: 30 [0 - 105] 10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0.2 - 1] %; CALCIUM: 2.25 [2.12 - 2.62] MMOL/L; CREATININE: 71 [44 - 106] UMOL/L; EOSINOPHILS: 50 [40 - 315] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.3 [0.9 - 2.9] %; ERYTHROCYTES: 3.2 [4.5 - 6] 10^12/L; GLUCOSE: 5.7 [3.9 - 5.6] MMOL/L; HEMATOCRIT: 0.3 [0.42 - 0.52] FRACTION OF 1; HEMOGLOBIN: 97 [130 - 175] G/L; LEUKOCYTES: 16.8 [4 - 10.5] 10^9/L; LYMPHOCYTES: 2480 [840 - 4830] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 14.7 [20.5 - 45] %; MONOCYTES: 1170 [240 - 1260] 10^9/L; MONOCYTES/LEUKOCYTES: 7 [5.5 - 11.7] %; NPTST014-ANION GAP: 8 [3 - 10] MMOL/L; NPTST049-BLOOD UREA NITROGEN: 18 [6 - 20] MG/DL; NPTST075-CHLORIDE: 106 [101 - 111] MMOL/L; NPTST086-CO2: 27 [21 - 31] MMOL/L; NPTST182-MCHC: 32.3 [32 - 36] G/DL; NPTST183-MCV: 93.5 [78 - 100] FL; NPTST186-MEAN CORPUSCULAR HEMOGLOBIN: 30.2 [27 - 31] PG; NPTST193-MPV: 9.7 [8 - 11.7] FL; NPTST273-RDW: 14.4 [11.5 - 14] %; NEUTROPHILS: 12930 [1720 - 6825] 10^9/L; NEUTROPHILS/LEUKOCYTES: 76.8 [43 - 65] %; PLATELETS: 328 [150 - 450] 10^9/L; POTASSIUM: 4.3 [3.6 - 5] MMOL/L; SODIUM: 141 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 12): SPUTUM FLU A BY PCR: NEGATIVE; SPUTUM FLU B BY PCR: NEGATIVE; URINE LEGIONELLA AG, URINE: NEGATIVE; SPUTUM RSV BY PCR: NEGATIVE; URINE STREP. PNEUMO. AG, URINE: NEGATIVE

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 12): XR CHEST 1 VIEW: XR CHEST 1 VIEW:ASPIRATION PNEUMONIA; [redacted]20[redacted] (RX DAY 14): XR SWALLOWING FUNCTION ESOPH VIDEO: ZR SWALLOWING FUNCTION ESOPH VIDEO:1. ASPIRATION WITH THIN CONSISTENCY BARIUM 2. LARYNGEAL PENETRATION AND EVENTUAL COATING OF THE CORDS WITH NECTAR AND HONEY CONSISTENCY, 3. THINNNING AND THICKER CONSISTENCIES APPEAR TO BE SAFE WITHOU T SIGNIFICANT LARYNGEAL PENETRATION OR EVIDENCE FOR ASPIRATION.

AE Stopped RX Day	61
Duration of AE	50 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	PT HISTORY OF ASPIRATION PNEUMONIA IN PAST AS WELL AS COPD MEDICAL CONDITION.
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	LEAKING AT SITE OF INFUSION
Preferred Term	注入部位血管外漏出
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	117
Duration of AE	92 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	REDNESS NOTED ON INFUSION SITE ASSESSMENT (1) AND (B) PERFORMED BY [redacted] ON [redacted]/[redacted]/20[redacted]
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 36
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	117

Duration of AE	82 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	REDNESS (1) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY [redacted], MD ON [redacted].
Preferred Term	注入部位紅斑
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	117
Duration of AE	77 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	CELLULITIS AT INFUSION SITE LL ABDOMEN
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 47
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	59
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 #8: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	REDNESS (2) AND (B) NOTED ON INFUSION SITE ASSESSMENT PERFORMED BY [redacted], MD ON [redacted]/[redacted]/20[redacted].
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 90
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	117

Duration of AE	28 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Serious Adverse Event

Event Description	PNEUMONIA
Preferred Term	肺炎
AE Onset Date / RX Day	[redacted]20[redacted] / 114
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 114): ALBUMIN: 47 [32 - 55] G/L; ALKALINE PHOSPHATASE: 73 [42 - 121] U/L; NPTST010-ALT: 8 [10 - 60] U/L; NPTST033-AST: 65 [10 - 42] U/L; NPTST037-BASE EXCESS, VENOUS: -2 [-2 - 2] MMOL/L; NPTST045-BILIRUBIN TOTAL: 0.5 [0.2 - 1] MG/DL; NPTST080-CK-MB ISOENZYME: 25 [0 - 7] NG/ML; NPTST137-HCO3 VENOUS: 26 [22 - 28] MMOL/L; NPTST156-INR: 1.16 [0.85 - 1.13] RATIO; NPTST165-LACTIC ACID LEVEL: 1.2 [0.5 - 2] MMOL/L; NPTST195-MYOGLOBIN: 239 [0 - 70] NG/ML; NPTST205-O2 SAT VEN: 46 [94 - 100] %; NPTST214-PCO2, VENOUS: 55 [40 - 52] MMHG; NPTST240-PH VENOUS: 7.29 [7.31 - 7.41] PH; NPTST248-PO2, VENOUS: 28 [30 - 50] MMHG; NPTST260-PRO B-TYPE NATRIURETIC PEPTIDE: 1604 [0 - 900] PG/ML; NPTST261-PROCALCITONIN: 0.22 [0 - 0.49] NG/ML; NPTST267-PT: 14.2 [11.5 - 14.5] SEC; PROTEIN: 79 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 115): BASOPHILS: 20 [0 - 105] 10^9/L; BASOPHILS/LEUKOCYTES: 0.2 [0.2 - 1] %; CALCIUM: 2.17 [2.12 - 2.62] MMOL/L; CREATININE: 62 [44 - 106] UMOL/L; EOSINOPHILS: 80 [40 - 315] 10^9/L; EOSINOPHILS/LEUKOCYTES: 0.7 [0.9 - 2.9] %; ERYTHROCYTES: 3.7 [4.5 - 6] 10^12/L; GLUCOSE: 6.4 [3.9 - 5.6] MMOL/L; HEMATOCRIT: 0.33 [0.42 - 0.52] FRACTION OF 1; HEMOGLOBIN: 106 [130 - 175] G/L; LEUKOCYTES: 11.2 [4 - 10.5] 10^9/L; LYMPHOCYTES: 880 [840 - 4830] 10^9/L; LYMPHOCYTES/LEUKOCYTES: 7.9 [20.5 - 45] %; MONOCYTES: 1100 [240 - 1260] 10^9/L; MONOCYTES/LEUKOCYTES: 9.8 [5.5 - 11.7] %; NPTST014-ANION GAP: 11 [3 - 10] MMOL/L; NPTST052-BUN: 14 [6 - 20] MG/DL; NPTST075-CHLORIDE: 100 [101 - 111] MMOL/L; NPTST086-CO2: 23 [21 - 31] MMOL/L; NPTST181-MCH: 29 [27 - 31] PG; NPTST182-MCHC: 32.6 [32 - 36] G/DL; NPTST183-MCV: 89 [78 - 100] FL; NPTST193-MPV: 9.7 [8 - 11.7] FL; NPTST204-NUCLEATED RBC ABSOLUTE: 0 [0.3 - 339] U/L; NPTST273-RDW: 17.2 [11.5 - 14] %; NPTST303-TROPONIN T: 0.02 [0 - 0.02] NG/ML; NEUTROPHILS: 9010 [1720 - 6825] 10^9/L; NEUTROPHILS/LEUKOCYTES: 80.6 [43 - 65] %; PLATELETS: 294 [150 - 450] 10^9/L; POTASSIUM: 4 [3.6 - 5] MMOL/L; SODIUM: 134 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 114): SPUTUM ADENOVIRUS (A-F): NEGATIVE; URINE BACTERIA, UA: NEGATIVE; URINE BILIRUBIN, UA: NEGATIVE; URINE BLOOD, UA: NEGATIVE; SPUTUM CHLAMYDIA PNEUMONIAE: NEGATIVE; URINE CLARITY, UA: NEGATIVE-CLEAR; URINE COLOR, UA: NEGATIVE-YELLOW; SPUTUM

CORONAVIRUS (229E, HKU1, NL63,: NEGATIVE; SPUTUM FLU A BY PCR: POSITIVE-INFLUENZA A FOUND TO BE POSITIVE; SPUTUM FLU B BY PCR: NEGATIVE; URINE GLUCOSE, UA: NEGATIVE; SPUTUM HUMAN METAPNEUMOVIRUS: NEGATIVE; SPUTUM HUMAN RHINOVIRUS/ENTEROVIRUS: NEGATIVE; URINE HYALINE CAST: NEGATIVE-0-2/LPF; SPUTUM INFLUENZA A BY PCR: NEGATIVE; SPUTUM INFLUENZA A H1: NEGATIVE; SPUTUM INFLUENZA A H1-2009: NEGATIVE; SPUTUM INFLUENZA A H3: NEGATIVE; SPUTUM INFLUENZA B BY PCR: NEGATIVE; URINE KETONES, UA: POSITIVE-TRACE MG/DL; URINE LEGIONELLA AG: NEGATIVE; URINE LEUKOCYTES ESTERASE: NEGATIVE; SPUTUM MYCOPLASMA PNEUMONIAE: NEGATIVE; URINE NITRITES, UA: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 1: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 2: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 3: NEGATIVE; SPUTUM PARAINFLUENZA VIRUS 4: NEGATIVE; URINE PH, UA: NEGATIVE-5.5; URINE PROTEIN, UA: POSITIVE-20 MG/DL; URINE RBC, UA: NEGATIVE-0-2/HPF; SPUTUM RESPIRATORY PANEL BY PCR: NEGATIVE; SPUTUM RESPIRATORY SYNCYTIAL VIRUS A: NEGATIVE; SPUTUM RESPIRATORY SYNCYTIAL VIRUS B: NEGATIVE; SPUTUM RSV BY PCR: NEGATIVE; URINE SPECIFIC GRAVITY, UA: NEGATIVE-NORMAL: 1.0036 AND 1.030; URINE SQUAMOUS EPITHELIAL: NEGATIVE-FEW/HPF; URINE STREP. PNEUMO. AG: NEGATIVE; URINE UROBILINOGEN, UA: NEGATIVE-NORMAL MG/DL; URINE WBC, UA: NEGATIVE-0-5/ HPF

SAE Supplemental Procedure

NOT REPORTED

AE Stopped RX Day	116
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	COPD, HISTORY OF ASPIRATION PNEUMONIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #10: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	CEREBRAL VASCULAR ACCIDENT
Preferred Term	脳血管発作
AE Onset Date / RX Day	[redacted]20[redacted] / 117
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED	
AE Stopped RX Day	117
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	MEDICAL HISTORY OF: CAD, INFERIOR MI [redacted]/[redacted]/20[redacted], INFRARENAL ABDOMINAL AORTIC ANEURYSM, BILATERAL LOWER LOBE CAP, EMPHYSEMA/COPD
Discontinued Study Drug Due to the Event	YES
SAE Criteria	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。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，両側肺炎を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，心臓発作，気胸，非破裂性腹部大動脈瘤，誤嚥性肺炎，不顕性誤嚥，低酸素症，睡眠関連，高脂血症，胃食道逆流症，慢性閉塞性肺疾患，右脚部位不明の動脈血栓塞栓症，冠動脈疾患，元喫煙者（紙巻きタバコ 1 日 20 本を 45 年間，パイプタバコ，及び葉巻），及び現飲酒者（1 日 2 杯未満）であった。

投与 12 日目，被験者は両側肺炎を発現した。投与 61 日目，両側肺炎は消失した。

本事象の発現に先立ち，投与の約 11 ヵ月前及び投与の約 3 ヵ月前，被験者は誤嚥性肺炎を発現していた。

投与 12 日目，被験者は発熱のため緊急治療室を受診した。被験者の妻は，聴診器で被験者の呼吸音を聴取したとき，「被験者の呼吸音がしなかった」と知らせた。救急診療部到着前の被

験者の体温は 101.4°F であった。被験者は継続中の誤嚥に起因することが強く疑われる両側市中感染性肺炎と診断された。被験者は入院し，抗生物質の静脈内投与が開始された。投与 14 日目，被験者は退院した。

本事象に関連するリスク因子には，被験者が夜間に酸素補給を必要としていたことがあった。

被験者にナイスタチン，酸素，アジスロマイシン，セフトリアキソン，レボフロキサシン，及び塩化ナトリウムが投与された。

The patient's past medications include:

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

INFLUENZA VACCINE for FLU PREVENTION ([redacted] 20[redacted] - [redacted])

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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1) Bilateral pneumonia (10058686) (Pneumonia (10035664)) [v.22.1] [10058686]

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 BILATERAL PNEUMONIA

- Investigator: Patient history of aspiration pneumonia in past as well as COPD medical condition

- AbbVie: More likely related to a history of aspiration pneumonia, chronic pulmonary obstructive disease, sleep related hypoxia, gastro-esophageal reflux disease and Parkinson's disease in a patient with advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **ALT:** <5 U/L

[redacted] **20**[redacted] **ANION GAP:** 8 MMOL/L (normal 3 to 10)

[redacted] **20**[redacted] **BILIRUBIN, UA:** Negative

[redacted] **20**[redacted] **BLOOD UREA NITROGEN:** 18 mg/dL (normal 6 to 20)

[redacted] **20**[redacted] **BLOOD, UA:** Negative

[redacted] **20**[redacted] **CALCIUM:** 9.0 mg/dL (normal 8.5 to 10.5)

[redacted] **20**[redacted] **CHEST X-RAY:** XR Chest 1 View- Aspiration Pneumonia

[redacted] **20**[redacted] **CREATININE:** 0.8 mg/dL (normal 0.5 to 1.2)

[redacted] **20**[redacted] **EOSINOPHILS %:** 0.3% (normal 0.9 to 2.9)

[redacted] **20**[redacted] **GLUCOSE:** 102 mg/dL (normal 70 to 100)

[redacted] **20**[redacted] **HEMATOCRIT:** 30% (normal 42 to 52)

[redacted] **20**[redacted] **HEMOGLOBIN:** 9.7 G/DL (normal 13 to 17.5)

[redacted] **20**[redacted] **INR:** 1.17 Ratio (normal 0.85 to 1.13)

[redacted] **20**[redacted] **LACTIC ACID LEVEL:** 2.0 MMOL/L (normal 0.5 to 2.0)

[redacted] **20**[redacted] **LYMPHOCYTES %:** 14.7% (normal 20.5 to 45.0)

[redacted] **20**[redacted] **LYMPHOCYTES ABS:** 2480 U/L (normal 840 to 4830)

[redacted] **20**[redacted] **MCHC:** 32.3 G/DL (normal 32.0 to 36.0)

[redacted] **20**[redacted] **MCV:** 93.5 FL (normal 78.0 to 100.0)

[redacted] **20**[redacted] **MEAN CORPUSCULAR HEMOGLOBIN:** 30.2 PG (normal 27.0 to 31.0)

[redacted] **20**[redacted] **MONOCYTES %:** 7.0% (normal 5.5 to 11.7)

[redacted] **20**[redacted] **MONOCYTES ABS:** 1170 U/L (normal 240 to 1260)

[redacted] **20**[redacted] **MPV:** 9.7 FL (normal 8.0 to 11.7)

[redacted] **20**[redacted] **NEUTROPHILS %:** 76.8% (normal 43.0 to 65.0)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 12930 U/L (normal 1720 to 6825)

[redacted] 20[redacted] **PLATELET COUNT:** 328 KU/L (normal 150 to 450)

[redacted] 20[redacted] **POTASSIUM:** 4.3 MMOL/L (normal 3.6 to 5.0)

[redacted] 20[redacted] **PROCALCITONIN:** 0.22 NG/ML (normal 0.00 to 0.49)

[redacted] 20[redacted] **PT:** 14.70 SEC (normal 11.50 to 14.50)

[redacted] 20[redacted] **RDW:** 14.4% (normal 11.5 to 14.0)

[redacted] 20[redacted] **RED BLOOD CELLS:** 3.21 M/uL (normal 4.50 to 6.00)

[redacted] 20[redacted] **SODIUM:** 141 MMOL/L (normal 135 to 145)

[redacted] 20[redacted] **SPUTUM CULTURE:** Flu A by PCR - Negative

[redacted] 20[redacted] **SPUTUM RSV BY PCR:** Negative

[redacted] 20[redacted] **TOTAL BILIRUBIN:** 0.6 mg/dL (normal 0.2 to 1.0)

[redacted] 20[redacted] **URINE:** Clarity- Clear

[redacted] 20[redacted] **URINE:** Color-Light Yellow

[redacted] 20[redacted] **URINE BACTERIA, UA:** Negative

[redacted] 20[redacted] **URINE GLUCOSE:** Negative

[redacted] 20[redacted] **URINE HYALINE CAST:** 0-2 IPF

[redacted] 20[redacted] **URINE KETONES:** Negative

[redacted] 20[redacted] **URINE LEGIONELLA AG:** Negative

[redacted] 20[redacted] **URINE LEUKOCYTE ESTERASE:** Negative

[redacted] 20[redacted] **URINE NITRITES:** Negative

[redacted] 20[redacted] **URINE PH:** 6.5 PH (normal 4.5 to 8)

[redacted] 20[redacted] **URINE PROTEIN:** Negative

[redacted] 20[redacted] **URINE RBC:** 0-5 (HPF)

[redacted] 20[redacted] **URINE SPECIFIC GRAVITY:** 1.010 No units (normal 1.003 to 1.030)

[redacted] 20[redacted] **URINE SQUAMOUS EPITHELIAL:** Negative/Few HPF

[redacted] **20[redacted] URINE STREP. PNEUMO. AG:** Negative

[redacted] **20[redacted] URINE UROBILINOGEN:** Normal

[redacted] **20[redacted] URINE WBC:** 0-5 (HPF)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 16.8 k/uL (normal 4.0 to 10.5)

[redacted] **20[redacted] XR SWALLOWING FUNCTION ESOPH VIDEO:** ZR SWALLOWING FUNCTION ESOPH VIDEO: 1. ASPIRATION WITH THIN CONSISTENCY BARIUM 2. LARYNGEAL PENETRATION AND EVENTUAL COATING OF THE CORDS WITH NECTAR AND HONEY CONSISTENCY, 3. THINNNING AND THICKER CONSISTENCIES APPEAR TO BE SAFE WITHOUT SIGNIFICANT LARYNGEAL PENETRATION OR EVIDENCE FOR ASPIRATION.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，死亡に至った脳血管障害及び肺炎を発現した。

Event 9 及び 10 の臨床経過：

関連する病歴は，パーキンソン病，慢性閉塞性肺疾患，胃食道逆流症，心臓発作，高脂血症，非破裂性腹部大動脈瘤，右脚部位不明の動脈血栓塞栓症，誤嚥性肺炎，低酸素症，睡眠関連，冠動脈疾患，不顕性誤嚥，鉄欠乏性貧血，冠動脈ステント留置，元喫煙者（紙巻きタバコ 1 日 20 本を 45 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 114 日目，被験者は肺炎を発現した。投与 116 日目，肺炎は消失した。投与 117 日目，被験者は脳血管障害を発現した。同日，被験者は死亡した。死因は脳血管障害であった。剖検は実施されなかった。

投与 114 日目，被験者は肺炎及び A 型インフルエンザ感染のため入院した。投与 116 日目被験者は退院し帰宅した。投与 117 日目，被験者の妻が被験者の死亡に気づいたと報告した。

主な死因は脳血管障害とした死亡証明書を入手した。副次的要因は敗血症及び肺炎であった。被験者は低酸素症及び高炭酸ガス血症を伴う急性呼吸不全を発現した。

本事象に関連するリスク因子：誤嚥，低酸素症，A 型インフルエンザ感染，及び市中感染性肺炎による重度敗血症。また，以下の病歴：冠動脈疾患，下壁心筋梗塞（20[redacted] 年 [redacted] 月 [redacted] 日），腎臓下腹部大動脈瘤，両下葉市中肺炎，肺気腫／慢性閉塞性肺疾患。

The patient's past medications include:

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

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

INFLUENZA VACCINE for FLU PREVENTION; VACCINE ([redacted] 20[redacted] - [redacted] 20[redacted])

LEVOFOXACIN for BILATERAL PNEUMONIA and COUGH ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

NYSTATIN for BILATERAL PNEUMONIA ([redacted] 20[redacted] - [redacted] 20[redacted])

OXYGEN SUPPLEMENT for BILATERAL PNEUMONIA ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Cerebrovascular accident (10008190) (Cerebrovascular accident (10008190)) [v.23.0] [10008190]

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

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

Dechallenge: Not Applicable

2) Pneumonia (10035664) (Pneumonia (10035664)) [v.23.0] [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 CEREBRAL VASCULAR ACCIDENT

- **Investigator:** Medical History of: CAD, Inferior MI [redacted]/[redacted]/20[redacted], Infrarenal abdominal aortic aneurysm, Bilateral lower lobe CAP, Emphysema/COPD

- **AbbVie:** More likely related to a history of aspiration pneumonia, silent aspiration, chronic obstructive pulmonary disease, coronary artery disease with stent placement, right leg arterial thrombosis, right leg arterial embolism and Parkinson's disease in an advanced aged patient with an increased BMI and a recent event of pneumonia.

Event of PNEUMONIA

- **Investigator:** COPD and history of aspiration pneumonia.

- **AbbVie:** More likely related to a history of aspiration pneumonia, silent aspiration, chronic obstructive pulmonary disease and Parkinson's disease in an advanced aged patient with increased BMI.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABSOLUTE NEUTROPHILS:** 9010 k/uL (normal 1720 to 6825)

[redacted] **20[redacted] ALT:** 8 UNIT/L (normal 10 to 60)

[redacted] **20[redacted] ANION GAP:** 11 MMOL/L (normal 3 to 10)

[redacted] **20[redacted] AST:** 65 UNIT/L (normal 10 to 42)

[redacted] **20[redacted] BASE EXCESS, VENOUS:** -2 mmol/L. Lower normal range: -2, Upper normal range: +2

[redacted] **20[redacted] CHLORIDE:** 100 MMOL/L (normal 101 to 111)

[redacted] **20[redacted] CK-MB:** 25 NG/ML (normal 0 to 7)

[redacted] **20[redacted] EOSINOPHILS:** 0.7% (normal 0.9 to 2.9)

[redacted] **20[redacted] GLUCOSE:** 116 mg/dL (normal 70 to 100)

[redacted] **20[redacted] HEMATOCRIT:** 32.5% (normal 42.0to 52.0)

[redacted] **20[redacted] HEMOGLOBIN:** 10.6 G/DL (normal 13.0 to 17.5)

[redacted] **20[redacted] INR:** 1.16 RATIO (normal 0.85 to 1.13)

[redacted]**20**[redacted] **LYMPHOCYTES:** 7.9% (normal 20.5 to 45.0)

[redacted]**20**[redacted] **MYOGLOBIN:** 239 NG/ML (normal 0 to 70)

[redacted]**20**[redacted] **NEUTROPHILS:** 80.6% (normal 43.0 to 65.0)

[redacted]**20**[redacted] **NEUTROPHILS ABS:** 9010 k/uL (normal 1720 to 6825)

[redacted]**20**[redacted] **NUCLEATED RBC ABSOLUTE:** 0.0 U/L (normal 0.3 to 339)

[redacted]**20**[redacted] **PCO2:** 55 mmHg (normal 40 to 52)

[redacted]**20**[redacted] **PH:** 7.29 PH (normal 7.31 to 7.41)

[redacted]**20**[redacted] **PO2:** 28 mmHg (normal 30 to 50)

[redacted]**20**[redacted] **PRO B-TYPE NATRIURETIC PEPTIDE:** 1604 PG/ML (normal 0 to 900)

[redacted]**20**[redacted] **RBC:** 3.65 M/UL (normal 4.50 to 6.00)

[redacted]**20**[redacted] **RDW:** 17.2% (normal 11.5 to 14.0)

[redacted]**20**[redacted] **SODIUM:** 134 MMOL/L (normal 135 to 145)

[redacted]**20**[redacted] **TROPONIN T:** 0.02 NG/ML (normal 0.00 to 0.02)

[redacted]**20**[redacted] **VENOUS OXYGEN SATURATION:** 46% (normal 94 to 100)

[redacted]**20**[redacted] **WBC:** 11.2 KU/L (normal 4.0 to 10.5)

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
無力症	X			
脱水	X			
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位結節				X
注入部位浮腫				X
注入部位丘疹				X
敗血症	X			
尿路感染	X			
体重減少				X
** Alkaline phosphatase elevations > 1.5 × ULN				X

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

Medical History	Onset Year
HEADACHES	NOT REPORTED
APPENDICITIS	19[redacted]
MIXED INCONTINENCE	19[redacted]
PREMENOPAUSAL MENORRHAGIA	19[redacted]
CHOLECYSTITIS	19[redacted]
ADDISON DISEASE	19[redacted]
HASHIMOTOS THYROIDITIS	19[redacted]
CELIAC -NON TROPICAL SPRUE	20[redacted]
WALKING PNEUMONIA	20[redacted]
BILATERAL CATARACTS	20[redacted]
MACULAR DEGENERATION BOTH EYES	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
LEFT BUNDLE BRANCH BLOCK	20[redacted]
EPIRETINAL MEMBRANE	20[redacted]

POLYMYALGIA RHEUMATICA	20[redacted]
OSTEOARTHRITIS	20[redacted]
CARPAL TUNNEL SYNDROME LEFT HAND	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
APPENDECTOMY	19[redacted]
CESAREAN SECTION	19[redacted]
HYSTERECTOMY	19[redacted]
CHOLECYSTECTOMY	19[redacted]
BLADDER REPAIR	19[redacted]
BILATERAL CATARACT EXTRACTION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	3 CIGARETTE	3	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	0.52	0.34	60	0.15	[redacted]20[redacted]/1
ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/2
ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/8
ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/17
ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]20[redacted]/24

ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]/32
ABBV-951 CSCI	0.28	0.34	0.23	60	0.15	[redacted]/43
ABBV-951 CSCI	0.34	0.4	0.28	60	0.15	[redacted]/92
ABBV-951 CSCI	0.38	0.46	0.3	60	0.15	[redacted]/184
ABBV-951 CSCI	0.38	0.46	0.3	60	0.15	[redacted]/269
ABBV-951 CSCI	0.38	0.46	0.3	60	0.15	[redacted]/297
ABBV-951 CSCI	0.38	0.46	0.3	60	0.15	[redacted]/303
ABBV-951 CSCI	0.4	0.48	0.32	60	0.15	[redacted]/338
ABBV-951 CSCI	0.46	0.55	0.37	60	0.15	[redacted]/352
ABBV-951 CSCI	0.57	0.68	0.46	60	0.15	[redacted]/367

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	669.34		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		25.61	SC /ONCE	[redacted] / 4	
ABBV-951	1147.44		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		76.83	SC /ONCE	[redacted] / 5	
ABBV-951	1147.44		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		51.22	SC /ONCE	[redacted] / 6	
ABBV-951	1105.77		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		25.61	SC /ONCE	[redacted] / 7	
ABBV-951	1056.77		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1393.32		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1393.32		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1393.32		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1393.32		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1393.32		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		153.67	SC /ONCE	[redacted] / 13	
ABBV-951	1234.52		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		76.83	SC /ONCE	[redacted] / 14	
ABBV-951	1066.33		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		51.22	SC /ONCE	[redacted] / 15	
ABBV-951	1055.57		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1147.44		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	1147.44		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	1147.44		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18

ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	1128.31		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		102.45	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	1111.75		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1220.17		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1393.32		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 30	
ABBV-951	1166.05		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 31	
ABBV-951	1171.00		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1036.79		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	1070.77		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	1147.44		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48

ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	1147.44	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
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ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 267	
ABBV-951	507.12		SC /CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 268	

ABBV-951	680.26	SC /CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-[redacted]
ROPINIROLE	2.000 mg	BID	Y-M: 20[redacted]-[redacted]
ROPINIROLE HYDROCHLORIDE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]-[redacted]
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted]
SOLIFENACIN	5 mg	QD	Y-M: 20[redacted]-[redacted]
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOFERSOLAN;ZINC	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]-[redacted]
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	95.000 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	150.000 mg	8 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
ENTACAPONE	200.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted]

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]-[redacted]	ONGOING
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted]	ONGOING
SOLIFENACIN	5 mg	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 288
ASCORBIC ACID;BETACAROTENE;COPPER;TOCOFERSOLAN;ZINC	1 OTHER: TABLET	QD	Y-M: 20[redacted]-[redacted]	ONGOING
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]-[redacted]	ONGOING
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted]	Y-M: 20[redacted]-[redacted] / 289
GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted]-[redacted] / 66	ONGOING
CEFTRIAXONE	1 g	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 104	Y-M: 20[redacted]-[redacted] / 104
DEXAMETHASONE	10 mg	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 104	Y-M: 20[redacted]-[redacted] / 104
FENTANYL CITRATE	25 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 104	Y-M: 20[redacted]-[redacted] / 104

SODIUM CHLORIDE	500 mL	OTHER: ONCE	Y-M: 20[redacted] / 104	Y-M: 20[redacted] / 104
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 184	Y-M: 20[redacted] / 191
CEFTRIAXONE	1 g	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
LORAZEPAM	0.5 mg	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
PARACETAMOL	650 mg	OTHER: ONCE	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 281
VANCOMYCIN	1000 mg	BID	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 288
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	3 L	QD	Y-M: 20[redacted] / 281	Y-M: 20[redacted] / 289
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 288	Y-M: 20[redacted] / 296
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted] / 289	ONGOING
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 289	ONGOING
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 289	ONGOING
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted] / 289	ONGOING
PREDNISONE	15 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 290
PREDNISONE	10 mg	QD	Y-M: 20[redacted] / 291	Y-M: 20[redacted] / 292
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 297	Y-M: 20[redacted] / 304
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 359	Y-M: 20[redacted] / 364

Event #1: 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] / 8
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	17
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 #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	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	43
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #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] / 9
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	43
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #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] / 9
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	43
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	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 #5: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
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	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: Serious Adverse Event

Event Description	WEAKNESS
Preferred Term	無力症
AE Onset Date / RX Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT

Microbiology

[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE

SAE Supplemental Procedure

NOT REPORTED

AE Stopped RX Day	107
Duration of AE	4 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 REPORTED
Other Cause of Event	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event

Event Description	DEHYDRATION
Preferred Term	脱水
AE Onset Date / RX Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT

Microbiology

[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE

SAE Supplemental Procedure

NOT REPORTED

AE Stopped RX Day	107
Duration of AE	4 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 REPORTED
Other Cause of Event	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Serious Adverse Event

Event Description	URINARY TRACT INFECTION
Preferred Term	尿路感染
AE Onset Date / RX Day	[redacted]20[redacted] / 104
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 104): NPTST309-URINALYSIS BACTERIAL: MANY [NOT REPORTED - NOT REPORTED] CELL COUNT

Microbiology

[redacted]20[redacted] (RX DAY 105): BLOOD CULTURE, BACTERIAL, BLOOD: NEGATIVE

SAE Supplemental Procedure

NOT REPORTED

AE Stopped RX Day	107
Duration of AE	4 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 REPORTED
Other Cause of Event	URINARY TRACT INFECTION (UTI) CAUSED BY BACTERIA, WITH DEHYDRATION AND WEAKNESS SECONDARY TO UTI.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #9: 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] / 181
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	188
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 #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] / 281
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 281): LEUKOCYTES: 17.9 [4.5 - 10] 10^9/L; SODIUM: 130 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 284): SODIUM: 122 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 285): NPTST180-MAGNESIUM: 1.2 [1.6 - 2.6] MEQ/L; NPTST243-PHOSPHORUS: 1.8 [2.5 - 4.6] MG/DL; POTASSIUM: 3.3 [3.6 - 5.1] MMOL/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 284): CT HEAD WO CONTRAST:1. NO ACUTE INTRACRANIAL FINDINGS. MILD SENESCENT CHANGES AND INVOLUTIONAL CHANGES. INTRACRANIAL ATHEROSCLEROTIC DISEASE. 2. SLIGHTLY ASYMMETRIC APPEARANCE OF THE LEFT POSTERIOR PARIETAL LOBE POSSIBL Y ASYMMETRIC ATROPHY.

AE Stopped RX Day	367

Duration of AE	87 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 #11: Serious Adverse Event

Event Description	SEPSIS
Preferred Term	敗血症
AE Onset Date / RX Day	[redacted]20[redacted] / 281
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 281): LEUKOCYTES: 17.9 [4.5 - 10] 10^9/L; SODIUM: 130 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 284): SODIUM: 122 [136 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 285): NPTST180-MAGNESIUM: 1.2 [1.6 - 2.6] MEQ/L; NPTST243-PHOSPHORUS: 1.8 [2.5 - 4.6] MG/DL; POTASSIUM: 3.3 [3.6 - 5.1] MMOL/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 284): CT HEAD WO CONTRAST:1. NO ACUTE INTRACRANIAL FINDINGS. MILD SENESCENT CHANGES AND INVOLUTIONAL CHANGES. INTRACRANIAL ATHEROSCLEROTIC DISEASE. 2. SLIGHTLY ASYMMETRIC APPEARANCE OF THE LEFT POSTERIOR PARIETAL LOBE POSSIBL Y ASYMMETRIC ATROPHY.

AE Stopped RX Day	289
Duration of AE	9 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 #12: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	NODULE RIGHT UPPER ABDOMEN, AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 337
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	367
Duration of AE	31 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	MODERATE ERYTHEMA AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 352
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 #14: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT PRIOR INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 359
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	367
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 #15: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PAPULE RIGHT UPPER ABDOMEN AT INFUSION SITE
Preferred Term	注入部位丘疹
AE Onset Date / RX Day	[redacted]20[redacted] / 367
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 #16: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PAPULE LEFT LOWER ABDOMEN AT INFUSION SITE
Preferred Term	注入部位丘疹
AE Onset Date / RX Day	[redacted]20[redacted] / 367
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。本被験者は米国の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，尿路感染，脱水，及び脱力感を発現した。

Event 6，7，及び 8 の臨床経過：

関連する病歴は，混合性尿失禁，膀胱修復，アジソン病，橋本病，パーキンソン病，非熱帯性セリアックスプルー，尿路感染，元喫煙者（1 日 3 本を 3 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 104 日目，被験者は尿路感染，脱水，及び脱力感を発現した。投与 107 日目，尿路感染，脱水，及び脱力感は消失した。

投与 104 日目，被験者は全身の脱力感の悪化並びに摂食量及び摂水量の減少が徐々に発現したため緊急治療室を受診した。被験者は入院し，脱水及び脱力感の原因となっている尿路感染の治療を受けた。被験者はアジソン病のクリーゼと考えられたため，デキサメタゾンの静脈内投与を一度受けたが，後に尿路感染，脱力感，及び脱水と診断された。被験者は脱水のため塩化ナトリウムが投与され，尿路感染のためセフトリアキソンが投与され回復した。投与 107 日目，被験者は退院した。

被験者に塩化ナトリウム，セフトリアキソン，塩化ナトリウム，デキサメタゾン，フェンタニルが投与された。

The patient's past medications include:

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

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

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

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

Causality for ABBV-951 (Open Label)

----------1) Urinary tract infection (10046571) (Urinary tract infection (10046571)) [v.23.0] [10046571]

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

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

Dechallenge: Not Applicable

2) Dehydration (10012174) (Dehydration (10012174)) [v.23.0] [10012174]

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

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

Dechallenge: Not Applicable

3) Weakness (10047862) (Asthenia (10003549)) [v.23.0] [10047862]

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 URINARY TRACT INFECTION, DEHYDRATION, WEAKNESS

- Investigator: Urinary tract infection (UTI) caused by bacteria, with dehydration and weakness secondary to UTI.- AbbVie: More likely related to a history of mixed incontinence, bladder repair, Addison's disease and Parkinson's disease in a patient with advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURE:** Negative

[redacted] **20[redacted] URINALYSIS:** Many cells

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者は米国の 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，注入部位蜂巣炎及び敗血症を発現した。

Event 10 及び 11 の臨床経過：

関連する病歴は，アジソン病，橋本病，パーキンソン病，元喫煙者（1 日 3 本を 3 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 281 日目，被験者は注入部位蜂巣炎及び敗血症を発現した。投与 289 日目，敗血症は消失した。投与 367 日目，注入部位蜂巣炎は消失した。

投与 281 日目の朝，注入部位がより紅斑化し硬くなった。被験者は次第に気分が悪くなり，被験者の夫が被験者を病院に連れて行った。同日，被験者は敗血症のため入院したが，これは被験者のポンプ挿入部位からの腹壁蜂巣炎に続発するものであった。徴候や症状として，精神状態の変化，発熱，脱水，並びに，注入部位周囲の紅斑及び硬結がみられた。被験者はアジソン病の病歴がありそれが脱水のリスクを高めていたが，原因は敗血症による可能性が高いと考えられた。被験者は静脈内投与による抗生物質と輸液の治療を受けた。投与 289 日目，被験者は退院した。

病院の診療記録：

被験者は，前腹部に過去の皮下ポンプ挿入部位の発赤及び硬結があり，白血球が 17.9 と増加し，プロカルシトニン値が 6.95 と上昇したが，乳酸値は正常であった。超音波で膿瘍は認められなかった。被験者は最初にバンコマイシン及びセファゾリンの抗生物質による治療を受けた。後にバンコマイシンの投与は中止された。MRSA について，鼻のスクリーニングは陰性で，血液培養でも認められなかった。被験者は慢性副腎機能不全があり，ナトリウム値は 130 であったが，その後投与 285 日目には 117 と減少傾向がみられた。被験者は等張液とステロイドによる治療を受けた。また被験者は，副腎機能障害／低ナトリウム血症の悪化，脱水，及び入院関連譫妄に起因して間をあけて悪化した敗血症による急性代謝性脳症を発現した。

敗血症は消失し白血球数は正常化したため，投与 288 日目，抗生物質による治療はケフレックスに移行した。被験者の精神状態は著しく改善し，退院時のナトリウム値も 135 と安定した。

皮膚科医の診療記録：

投与 313 日目，被験者は腹部の注入部位発疹の評価のため，皮膚科医を受診した。検査により，以前のポンプ挿入位置に多数の赤青色 1-2 cm で硬結性の皮膚／皮下局面が認められた。非挿入部や関与する他の範囲には病変が認められなかった。投与から約 10 ヵ月目の上旬，直近に被験者はセファレキシンを投与されていたが，改善がみられなかった。この来院時に右中間腹部の穿刺生検が行われた。

投与 319 日目，被験者は経過観察のため皮膚科医を受診した。診察で，右中腹部の穿刺部位に，良好に治癒したピンク色の斑が認められた。生検の結果は被験者に共有された。皮膚科医は，腹部の発疹は注射部位反応に一致しているようであり，おそらく薬物の刺激効果が組織壊死及び漿液腫形成を引き起こしたと示唆した。

被験者にロラゼパム，乳酸リンゲル液，セフトリアキソン，タイレノール，ケフレックス，及びバンコマイシンが投与された。

The patient's past medications include:

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

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

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

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

ENTACAPONE for PARKINSON'S DISEASE ([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.23.1] [10065455]

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Event of SEPSIS

- Investigator: Not applicable.

- AbbVie: Not applicable.

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

Weight Decreased: Day 1 weight 4[redacted] kg. Weight at time of event 4[redacted] kg. 4[redacted] kg at Week 26 visit. Weight loss occurred over a period of 10 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced temporal cognitive decline, temporal and previous episodes of dyskinesia worsening since treatment began, temporal and previous episodes of malnutrition, temporal episode of infection, and previous episode of anosmia.

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
急性心筋梗塞	X			
心停止	X			
冠動脈疾患	X			
低ナトリウム血症	X			
注入部位蜂巣炎				X
注入部位不快感				X

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

Medical History	Onset Year
HERNIA	19[redacted]
TONSILLITIS	19[redacted]
TYPE 1 DIABETES	19[redacted]
CHRONIC BACK PAIN	19[redacted]
HERPES SIMPLEX VIRUS	19[redacted]
MIXED HYPERLIPIDEMIA	20[redacted]
INTERMITTENT VERTIGO	20[redacted]
SLEEP APNEA	20[redacted]
SCOLIOSIS	20[redacted]
SPONDYLOLISTHESIS	20[redacted]
CAROTID STENOSIS	20[redacted]
CEREBROVASCULAR ACCIDENT	20[redacted]
HYPERTENSION	20[redacted]
ERECTILE DYSFUNCTION	20[redacted]
GENERALIZED ANXIETY DISORDER	20[redacted]
DEPRESSION	20[redacted]

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

ONSET OF MOTOR FLUCTUATION	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
HERNIA REPAIR	19[redacted]
TONSILLECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	4 CIGARETTE	4	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	FORMER			

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	0.17	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.21	0.24	0.18	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.2	0.24	0.18	60	0.11	[redacted]20[redacted]/8
ABBV-951 CSCI	0.2	0.24	0.18	60	0.11	[redacted]20[redacted]/15
ABBV-951 CSCI	0.2	0.23	0.18	60	0.11	[redacted]20[redacted]/22
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/29
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/44
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/85
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/183
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/273
ABBV-951 CSCI	0.21	0.23	0.19	60	0.11	[redacted]20[redacted]/363

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	375.65		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		37.56	SC /ONCE	[redacted]20[redacted] / 6	
ABBV-951	815.16		SC /CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 7	
ABBV-951	912.82		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	983.52		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	946.63		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		75.13	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	889.26		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	849.65		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	848.96		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	950.05		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	846.23		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	935.36		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	934.85		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	749.59		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	901.56		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32

ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	914.19		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	877.65		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
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ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
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ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
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ABBV-951	894.73		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		75.13	SC /ONCE	[redacted]20[redacted] / 84	
ABBV-951	901.56		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
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ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
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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
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951	860.58	SC /CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
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] / 322	[redacted] / 322
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 323	[redacted] / 323
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 324	[redacted] / 324
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 325	[redacted] / 325
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 326	[redacted] / 326
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 327	[redacted] / 327
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 328	[redacted] / 328
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 329	[redacted] / 329
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 330	[redacted] / 330
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 331	[redacted] / 331
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 332	[redacted] / 332
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 333	[redacted] / 333
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 334	[redacted] / 334
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 335	[redacted] / 335
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 336	[redacted] / 336
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 337	[redacted] / 337
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 338	[redacted] / 338
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 339	[redacted] / 339
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 340	[redacted] / 340
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 341	[redacted] / 341
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 342	[redacted] / 342
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 343	[redacted] / 343
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 344	[redacted] / 344
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 345	[redacted] / 345
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 346	[redacted] / 346
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 347	[redacted] / 347
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 348	[redacted] / 348
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 349	[redacted] / 349
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 350	[redacted] / 350
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 351	[redacted] / 351
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 352	[redacted] / 352
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 353	[redacted] / 353
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 354	[redacted] / 354
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 355	[redacted] / 355
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 356	[redacted] / 356
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 357	[redacted] / 357
ABBV-951	860.58	SC /CONTINUOUS	[redacted] / 358	[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		56.34	SC /ONCE	[redacted]20[redacted] / 361	
ABBV-951	860.58		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		112.69	SC /ONCE	[redacted]20[redacted] / 362	
ABBV-951	860.58		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
INSULIN ASPART	33-55 OTHER: UNITS, VIA INSULIN PUMP	OTHER: INSULIN PUMP	Y-M: 19[redacted]
ROPINIROLE	1.000 mg	TID	Y-M: 20[redacted]-[redacted]
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted]-[redacted]
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
GLUTATHIONE	100%	QD	Y-M: 20[redacted]-[redacted]
UBIDECARENONE	1 OTHER: TAB	QD	Y-M: 20[redacted]-[redacted]
DICLOFENAC	1%	BID	Y-M: 20[redacted]-[redacted] / -265
HYDROCHLOROTHIAZIDE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / -265
LOSARTAN	25 mg	QD	Y-M: 20[redacted]-[redacted] / -150
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted]-[redacted] / -150
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted]-[redacted] / -126
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -113
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted]-[redacted] / -35
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted]-[redacted] / -35
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted]-[redacted] / -35
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]-[redacted] / -35
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted]-[redacted] / -35
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted]-[redacted] / -35
TRAMADOL	50 mg	PRN	Y-M: 20[redacted]-[redacted] / -35

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INSULIN ASPART	33-55 OTHER: UNITS, VIA INSULIN PUMP	OTHER: INSULIN PUMP	Y-M: 19[redacted]	ONGOING
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]	ONGOING
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]	ONGOING
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 327
LOSARTAN	25 mg	QD	Y-M: 20[redacted] / -150	ONGOING
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted] / -150	ONGOING
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / -126	Y-M: 20[redacted] / 330
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / -113	ONGOING
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted] / -35	ONGOING
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted] / -35	ONGOING
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted] / -35	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / -35	ONGOING
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted] / -35	ONGOING
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted] / -35	ONGOING
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / -35	ONGOING
CLINDAMYCIN	300 mg	QID	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 30
ROSUVASTATIN	5 mg	QD	Y-M: 20[redacted] / 291	Y-M: 20[redacted] / 330
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 326	Y-M: 20[redacted] / 326
SODIUM CHLORIDE	1 L	QD	Y-M: 20[redacted] / 326	Y-M: 20[redacted] / 326
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted] / 327	ONGOING
CALCIUM CHLORIDE DIHYDRATE;GLUCOSE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1 L	QD	Y-M: 20[redacted] / 328	Y-M: 20[redacted] / 328
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted] / 331	ONGOING
LISINOPRIL	15 mg	BID	Y-M: 20[redacted] / 331	ONGOING
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 331	ONGOING
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 331	ONGOING
OMEPRAZOLE	20 mg	BID	Y-M: 20[redacted] / 331	Y-M: 20[redacted] / 348

SALBUTAMOL	4 OTHER: PUFFS	PRN	Y-M: 20[redacted] / 336	Y-M: 20[redacted] / 345
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 337	Y-M: 20[redacted] / 338
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted] / 338	ONGOING
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 339	ONGOING
FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345	ONGOING
SALBUTAMOL	1-2 OTHER: PUFFS	PRN	Y-M: 20[redacted] / 345	Y-M: 20[redacted] / 355
CETIRIZINE	10 mg	QD	Y-M: 20[redacted] / 346	Y-M: 20[redacted] / 355
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352	ONGOING
FUROSEMIDE	20 mg	BID	Y-M: 20[redacted] / 355	Y-M: 20[redacted] / 356

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

Event Description	DISCOMFORT AT THE INFUSION SITE
Preferred Term	注入部位不快感
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	6
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 #2: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF ABDOMEN AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
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	44
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 #3: Serious Adverse Event

Event Description	NSTEMI
Preferred Term	急性心筋梗塞
AE Onset Date / RX Day	[redacted]20[redacted] / 326
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 326): NPTST096-CREATININE KINASE: 445 [25 - 300] IU/L; NPTST207-OCCULT BLOOD, GASTRIC: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; SODIUM: 117 [135 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 327): NPTST300-TROPONIN: 3.79 [0 - 0.03] NG/ML; [redacted]20[redacted] (RX DAY 330): SODIUM: 127 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 328): CARDIAC CATHETERIZATION:1. DIFFUSELY DISEASED DIABETIC APPEARING

LEFT ANTERIOR DESCENDING ARTERY WITH HIGH-GRADE STENOSIS IN THE MIDPORTION AS WELL AS DIFFUSE DISEASE. THIS APPEARS TO BE AFFECTING MULTIPLE SMAL L DIAGONAL VESSELS. 2. HIGH-GRADE STENOSIS IN THE PROXIMAL CIRCUMFLEX AND 1ST OBTUSE MARGINAL VESSEL. 3. HIGH-GRADE STENOSIS IN THE POSTERIOR DESCENDING ARTERY AND POSTEROLATERAL VESSEL. 4. DIABETIC APPEARANCE TO THE CORONARY ARTERY DISEASE. 5. NORMAL RESTING END-DIASTOLIC PRESSURE OF THE LEFT VENTRICLE WITHOUT AORTIC VALVE GRADIENT ON PULLBACK.

AE Stopped RX Day	326
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	LIKELY UNDERLYING CORONARY ARTERY DISEASE (FOR NSTEMI). HYPONATREMIA DUE TO DEHYDRATION AND POOR PO INTAKE (WHICH COULD BE DUE TO NSTEMI). RHABDOMYOLYSIS IS DUE TO STATIN THERAPY (DISCONTINUED)
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #4: Serious Adverse Event

Event Description	HYPONATREMIA
Preferred Term	低ナトリウム血症
AE Onset Date / RX Day	[redacted]20[redacted] / 326
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 326): NPTST096-CREATININE KINASE: 445 [25 - 300] IU/L; NPTST207-OCCULT BLOOD, GASTRIC: POSITIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; SODIUM: 117 [135 - 144] MMOL/L; [redacted]20[redacted] (RX DAY 327): NPTST300-TROPONIN: 3.79 [0 - 0.03] NG/ML; [redacted]20[redacted] (RX DAY 330): SODIUM: 127 [136 - 145] MMOL/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 328): CARDIAC CATHETERIZATION:1. DIFFUSELY DISEASED DIABETIC APPEARING LEFT ANTERIOR DESCENDING ARTERY WITH HIGH-GRADE STENOSIS IN THE MIDPORTION AS WELL AS DIFFUSE DISEASE. THIS APPEARS TO BE AFFECTING MULTIPLE SMAL L DIAGONAL VESSELS. 2. HIGH-GRADE STENOSIS IN THE PROXIMAL CIRCUMFLEX AND 1ST OBTUSE MARGINAL VESSEL. 3.

HIGH-GRADE STENOSIS IN THE POSTERIOR DESCENDING ARTERY AND POSTEROLATERAL VESSEL. 4. DIABETIC APPEARANCE TO THE CORONARY ARTERY DISEASE. 5. NORMAL RESTING END-DIASTOLIC PRESSURE OF THE LEFT VENTRICLE WITHOUT AORTIC VALVE GRADIENT ON PULLBACK.

AE Stopped RX Day	335
Duration of AE	10 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	HYPONATREMIA DUE TO DEHYDRATION AND POOR PO INTAKE (WHICH COULD BE DUE TO NSTEMI).
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #5: Serious Adverse Event

Event Description	CORONARY ARTERY DISEASE
Preferred Term	冠動脈疾患
AE Onset Date / RX Day	[redacted]20[redacted] / 328
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 336): HEMOGLOBIN: 69 [136 - 180] G/L; LEUKOCYTES: 20.3 [4 - 10] 10^9/L; NPTST162-LACTATE: 6.4 [0.5 - 2] MMOL/L; PH: 7.28 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 337): POTASSIUM: 3.3 [3.6 - 5] MMOL/L; PH: 7.48 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 342): HEMOGLOBIN: 92 [136 - 180] G/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 336): CABG X3:CORONARY REVASCULARIZATION X3, TRANSESOPHAGEAL ECHOCARDIOGRAM, LEFT INTERNAL MAMMARY TAKEDOWN, ENDOSCOPIC LEFT SAPHENOUS VEIN HARVEST; TRANSESOPHAGEAL ECHOCARDIOGRAM:SUCCESSFUL

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	PATIENT HAD AN NSTEMI RECENTLY (SEE SEPARATE SAE REPORT PREVIOUSLY ENTERED) AND WAS FOUND TO HAVE DIFFUSE DISEASE FROM HIS DM1. RECOMMENDED TO HAVE CABG WHICH WAS COMPLETED [redacted]20[redacted]
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

Event #6: Serious Adverse Event

Event Description	CARDIAC ARREST
Preferred Term	心停止
AE Onset Date / RX Day	[redacted]20[redacted] / 336
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 336): HEMOGLOBIN: 69 [136 - 180] G/L; LEUKOCYTES: 20.3 [4 - 10] 10^9/L; NPTST162-LACTATE: 6.4 [0.5 - 2] MMOL/L; PH: 7.28 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 337): POTASSIUM: 3.3 [3.6 - 5] MMOL/L; PH: 7.48 [7.35 - 7.45] UNIT NOT REPORTED; [redacted]20[redacted] (RX DAY 342): HEMOGLOBIN: 92 [136 - 180] G/L

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 336): CABG X3:CORONARY REVASCULARIZATION X3, TRANSESOPHAGEAL ECHOCARDIOGRAM, LEFT INTERNAL MAMMARY TAKEDOWN, ENDOSCOPIC LEFT SAPHENOUS VEIN HARVEST; TRANSESOPHAGEAL ECHOCARDIOGRAM:SUCCESSFUL

AE Stopped RX Day	336
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	POST-SURGICAL VASOVAGAL REACTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION, OTHER

MEDICALLY IMPORTANT SERIOUS EVENT, LIFE THREATENING

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。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，非 ST 上昇型心筋梗塞，冠動脈疾患，心停止，及び低ナトリウム血症を発現した。

Event 3，4，5，及び 6 の臨床経過：

関連する病歴は，1 型糖尿病，混合型脂質異常症，頚動脈狭窄症，脳血管障害，高血圧，パーキンソン病，全般性不安障害，父親の糖尿病歴，父親の高血圧歴，父親の冠動脈疾患歴，母親の脳卒中歴，元喫煙者（1 日 4 本を 4 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 326 日目，被験者は非 ST 上昇型心筋梗塞及び低ナトリウム血症を発現した。投与 328 日目，被験者は冠動脈疾患を発現した。投与 335 日目，低ナトリウム血症は消失した。投与 336 日目，被験者は心停止を発現した。同日，心停止は消失した。

投与 326 日目，被験者は浮動性めまい，悪心，及び嘔吐を訴え救急診療部を受診した。被験者はこれらの症状は約 1 週間続いており，おおむね 2 つの新しい薬剤（ロスバスタチン及びヒドロクロロチアジド）を開始していた期間だと述べた。被験者はヒドロクロロチアジドを断続的に使用してきたと述べた。被験者は数回嘔吐し，嘔吐物は「古い血液」のように見えると言われたと報告した。被験者は最近の旅行や病人との接触を否定した。被験者は妻と 2 階建の家に住み，大きな困難もなく階段を使用していた。被験者は経口摂取の低下も述べた。被験者はインスリンポンプを使用し自分でグルコース値の管理をしていた。被験者は，SINEMET 用ポンプも所有し，これまで治験に参加していた。被験者は低ナトリウム血症及び脱水のため入院した。また，非重篤の横紋筋融解症も診断された。更に，頚部痛及び嘔吐症状も認められた。初期のトロポニン検査は陰性であったが，後にトロポニン値が上昇した（非 ST 上昇型心筋梗塞）。

被験者は別の病院に移送され，低ナトリウム血症，非 ST 上昇型心筋梗塞，及び上部消化管出血の可能性のため集中治療室に収容された。被験者に脱力感，便秘，悪心，嘔吐，及び不安が認められた。被験者は発熱，悪寒，咳嗽，息切れ，及び下痢を否定した。投与 327 日目遅くまで

トロポニン値は上昇した。投与 328 日目，被験者は心臓カテーテル手術を受け，びまん性，糖尿病型心疾患が認められた。投与 335 日目，非重篤の横紋筋融解症は消失した。投与 336 日目，被験者は 3 ヵ所冠動脈バイパス手術を受けた。その夜，被験者は血管迷走神経反射から心停止を起こした。被験者は心肺蘇生を受け自発循環を取り戻し再挿管されたが，最終的に抜管された。最初にラシックスの投与が必要とされた。両側に胸腔チューブが挿入され，後に抜去された。血圧は集中治療室にいる間ずっと不安定であった。利尿から数日安静後，フロセミドの静脈注射に移行し，その後経口に移行した。被験者への酸素補給は徐々に離脱された。体重は手術前約 12[redacted] ポンドで，退院時は 14[redacted] ポンドであった。被験者は室内気酸素飽和度 97%，経口ラシックス 20 mg を 1 日 2 回 7 日間及びカリウム値 4.3 の高値を維持するための塩化カリウム 10 mEq 連日投与にて退院した。クレアチニン値は安定しており，術後の最高値は 1.19 であった。

被験者にラシックス，リシノプリル，メトプロロール酒石酸塩，5%ブドウ糖加乳酸リンゲル液，生理食塩水，及び塩化カリウムが投与された。

The patient's past medications include:

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

Causality for ABBV-951 (Open Label)

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1) Non ST segment elevation myocardial infarction (10064347) (Acute myocardial infarction (10000891)) [v.23.1] [10064347]

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

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

Dechallenge: Not Applicable

2) Coronary artery disease (10011078) (Coronary artery disease (10011078)) [v.23.1] [10011078]

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

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

Dechallenge: No

3) Cardiac arrest (10007515) (Cardiac arrest (10007515)) [v.23.1] [10007515]

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) Hyponatremia (10021038) (Hyponatraemia (10021036)) [v.23.1] [10021038]

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 NSTEMI

- Investigator: Likely underlying coronary artery disease (for NSTEMI). Hypernatremia due to dehydration and poor oral intake (which could be due to NSTEMI). Rhabdomyolysis (non-serious) is due to statin therapy (discontinued).

- AbbVie: More likely related to a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, diabetes and Parkinson's disease in a 6[redacted] year old patient with family history of coronary arterial disease.

Event of CORONARY ARTERY DISEASE

- Investigator: Patient had an NSTEMI recently and was found to have diffuse disease from his DM1. Recommended to have CABG which was completed [redacted] 20[redacted].

- AbbVie: More likely related to a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, diabetes and Parkinson's disease in a 6[redacted] year old patient with family history of coronary arterial disease.

Event of CARDIAC ARREST

- Investigator: .Post-surgical vasovagal reaction

- AbbVie: More likely related to a complication of concurrent bypass surgery in a 6[redacted] year old patient with a history of hypertension, mixed hyperlipidemia, cerebrovascular accident, sleep apnea diabetes and

Parkinson's disease

Event of HYPONATREMIA

- Investigator: Hyponatremia due to dehydration and poor oral intake (which could be due to NSTEMI).

- AbbVie: More likely related to reported nausea, vomiting, poor oral intake, rhabdomyolysis and dehydration in an advanced aged patient with a history of type 1 diabetes.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD PH:** 7.28 no unit (normal 7.35 to 7.45)

[redacted] **20[redacted] BLOOD PH:** 7.48 no unit (normal 7.35 to 7.45)

[redacted] **20[redacted] BODY WEIGHT:** 14[redacted] Pounds

[redacted] **20[redacted] CARDIAC CATHETERIZATION:** 1. Diffusely diseased diabetic appearing left anterior descending artery with high-grade stenosis in the midportion as well as diffuse disease. This appears to be affecting multiple small diagonal vessels. 2. High-grade stenosis in the proximal circumflex and 1st obtuse marginal vessel. 3. High-grade stenosis in the posterior descending artery and posterolateral vessel. 4. Diabetic appearance to the coronary artery disease. 5. Normal resting end-diastolic pressure of the left ventricle without aortic valve gradient on pullback

[redacted] **20[redacted] CREATININE:** 1.19 no units

[redacted] **20[redacted] CREATININE KINASE:** 445 IU/L (normal 25 to 300)

[redacted] **20[redacted] HEMOGLOBIN:** 6.9 G/DL (normal 13.6 to 18.0)

[redacted] **20[redacted] HEMOGLOBIN:** 13.6 G/DL (normal 13.6 to 18.0)

[redacted] **20[redacted] LACTATE:** 6.4 MMOL/L (normal 0.5 to 2.0)

[redacted] **20[redacted] OCCULT BLOOD, GASTRIC:** specimen: emesis - positive

[redacted] **20[redacted] POTASSIUM:** 3.3 MMOL/L (normal 3.8 to 5.0)

[redacted] **20[redacted] POTASSIUM:** 4.3 MMOL/L (normal 3.8 to 5.0)

[redacted] **20[redacted] SODIUM:** 117 MMOL/L (normal 135 to 144)

[redacted] **20[redacted] SODIUM:** 127 MMOL/L (normal 135 to 144)

[redacted] **20[redacted] TRANSESOPHAGEAL ECHOCARDIOGRAM:** Successful

[redacted] **20[redacted] TROPONIN:** 3.79 NG/ML (normal 0 to 0.03)

[redacted] **20[redacted] WBC:** 20.27 X10**3/MCL (normal 4 to 10)

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
注入部位蜂巣炎				X
注入部位紅斑				X
注入部位血管外漏出				X
注入部位硬結				X
注入部位浮腫				X
注入部位丘疹				X
注入部位反応				X
靭帯捻挫				X
変形性関節症	X			
皮膚裂傷				X
体重減少				X

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

Medical History	Onset Year
ASTHMA	19[redacted]
FOOD ALLERGIES	19[redacted]
SEASONAL ALLERGIES	19[redacted]
ESOPHAGEAL WEBS	19[redacted]
CHRONIC SHOULDER PAIN	19[redacted]
SHOULDER NUMBNESS	19[redacted]
SHOULDER TINGLING	19[redacted]
CATARACT RIGHT EYE	20[redacted]
PINCHED NERVE NECK	20[redacted]
CONSTIPATION	20[redacted]
SCOLIOSIS	20[redacted]
INTERMITTENT INSOMNIA	20[redacted]
SHOULDER ARTHRITIS BOTH	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
NECK SURGERY	20[redacted]
BACK 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	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	0.67	0.8	0.54	75	0.19	[redacted]20[redacted]/1
ABBV-951 CSCI	0.67	0.8	0.54	75	0.19	[redacted]20[redacted]/2
ABBV-951 CSCI	0.8	0.96	0.64	120	0.19	[redacted]20[redacted]/9
ABBV-951 CSCI	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/16
ABBV-951 CSCI	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/21
ABBV-951 CSCI	0.67	0.8	0.54	180	0.19	[redacted]20[redacted]/23
ABBV-951 CSCI	0.8	0.96	0.64	180	0.24	[redacted]20[redacted]/30
ABBV-951 CSCI	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/44
ABBV-951 CSCI	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/93
ABBV-951 CSCI	0.8	0.96	0.64	180	0.19	[redacted]20[redacted]/183
ABBV-951 CSCI	0.96	1.14	0.8	180	0.19	[redacted]20[redacted]/259
ABBV-951 CSCI	0.96	1.14	0.8	180	0.19	[redacted]20[redacted]/274
ABBV-951 CSCI	0.96	1.04	0.83	180	0	[redacted]20[redacted]/357
ABBV-951 CSCI	0.96	1.04	0.83	0	0	[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	1601.63		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2471.09		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	274.56		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	3123.01		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	3696.39		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	3934.08		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	3934.08		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1426.10		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	458.97		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	1828.39		SC /CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2745.66		SC /CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2745.66		SC /CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2745.66		SC /CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	1029.62		SC /CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	1681.71		SC /CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	1304.18		SC /CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	3109.69		SC /CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	3278.4		SC /CONTINUOUS	[redacted] / 39	[redacted] / 39

ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	3223.76	SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2923.24	SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	3073.5	SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76

ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
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ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 287	[redacted]20[redacted] / 287
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
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
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
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
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
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
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
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
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	3278.4	SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	3360.36	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
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 19[redacted]
PRAMIPEXOLE	0.500 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]-[redacted]
SENNA ALEXANDRINA	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted]

SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]
CANNABIDIOL	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted] / -148
CYANOCOBALAMIN	100 OTHER: MCG	QD	Y-M: 20[redacted] / -21
PYRIDOXINE HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / -21

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: 19[redacted]	ONGOING
SENNA ALEXANDRINA	1 OTHER: CAPSULE	PRN	Y-M: 20[redacted]	ONGOING
CYANOCOBALAMIN	100 OTHER: MCG	QD	Y-M: 20[redacted] / -21	ONGOING
PYRIDOXINE HYDROCHLORIDE	5 mg	QD	Y-M: 20[redacted] / -21	ONGOING
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 28
LACTOBACILLUS NOS	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 21	Y-M: 20[redacted] / 28
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 42
LACTOBACILLUS NOS	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 35	Y-M: 20[redacted] / 42
BUPIVACAINE	5 mL	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
DEXAMETHASONE	4 mg	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
METHYLPREDNISOLONE	40 mg	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
TRANEXAMIC ACID	1 g	QD	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 224
CEFAZOLIN SODIUM	2 g	BID	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 225
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / 224	Y-M: 20[redacted] / 254
DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID	0.5 mL	OTHER: ONCE	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 258
HYDROCODONE BITARTRATE;PARACETAMOL	5-325 mg	OTHER: ONCE	Y-M: 20[redacted] / 258	Y-M: 20[redacted] / 258

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

Event Description	INFUSION SITE ERYTHEMA

Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	14
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 - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE PAPULE
Preferred Term	注入部位丘疹
AE Onset Date / RX Day	[redacted]20[redacted] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	14
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 #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] / 1
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	14
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: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 4

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	30
Duration of AE	27 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	INFUSION SITE PAPULE
Preferred Term	注入部位丘疹
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	30
Duration of AE	27 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	SLIGHT GLAZED APPEARANCE INFUSION SITE
Preferred Term	注入部位反応
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	30
Duration of AE	27 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	POOLING OF STUDY DRUG UNDER INFUSION SITE
Preferred Term	注入部位血管外漏出
AE Onset Date / RX Day	[redacted]20[redacted] / 11
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	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 #8: Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE CELLULITIS
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 20
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	30
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	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 #9: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / RX Day	[redacted]20[redacted] / 44
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 #10: Event of Interest - Falls and Associated Injuries

Event Description	LEFT FOOT SPRAIN
Preferred Term	靭帯捻挫
AE Onset Date / RX Day	[redacted]20[redacted] / 132
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	135
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 #11: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE INDURATION
Preferred Term	注入部位硬結
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	365
Duration of AE	183 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	INFUSION SITE REACTION
Preferred Term	注入部位反応
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	365
Duration of AE	183 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	INFUSION SITE GLAZING
Preferred Term	注入部位反応
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	365
Duration of AE	183 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: Serious Adverse Event

Event Description	WORSENING RIGHT SHOULDER DEGENERATIVE JOINT DISEASE
Preferred Term	変形性関節症
AE Onset Date / RX Day	[redacted]20[redacted] / 224
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	

[redacted]20[redacted] (RX DAY 224): RIGHT SHOULDER X-RAY:EXPECTED FINDINGS OF A RECENT RIGHT SHOULDER ARTHROPLASTY; RIGHT TOTAL SHOULDER ARTHROPLASTY:PATIENT UNDERWENT A RIGHT TOTAL SHOULDER ARTHROPLASTY ON [redacted]/[redacted]/20[redacted]. HE TOLERATED THE PROCEDURE WELL. HE WAS ADMITTED TO THE ORTHOPEDIC FLOOR WITH POST-OP ORDERS. HE IS SITTING UP IN BED THIS MORNING. PAIN IS CONTROLLED. NO COMPLAINTS. HE WOULD LIKE TO BE DISCHARGED HOME.

AE Stopped RX Day	224
Duration of AE	1 DAY
Severity	SEVERE
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 REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	PATIENT HAS SEVERE DJD AND THUS REQUIRED TOTAL SHOULDER ARTHROPLASTY AFTER SEVERAL NON-SURGICAL OPTIONS FAILED.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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] / 258
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	258
Duration of AE	1 DAY
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 #16: Event of Interest - Falls and Associated Injuries

Event Description	LEFT HAND LACERATION
Preferred Term	皮膚裂傷

AE Onset Date / RX Day	[redacted]20[redacted] / 258
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	271
Duration of AE	14 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 #17: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 259
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
Duration of AE	107 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 #18: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 274
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
Duration of AE	92 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	INFUSION SITE MARKED GLAZING
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 274
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
Duration of AE	92 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	INFUSION SITE REACTION
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 274
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
Duration of AE	92 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

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

Event #21: 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] / 356
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	364
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 #22: 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] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
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 #23: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	INFUSION SITE SLIGHT GLAZED APPEARANCE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
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 #24: 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] / 357
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
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 #25: 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] / 363
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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，右肩変形性関節疾患の悪化を発現した。

Event 14 の臨床経過：

関連する病歴は，慢性肩痛，肩のしびれ，肩のひりひり感，頚部の圧迫神経痛，頚部手術，圧迫神経痛，パーキンソン病，脊柱側彎，脊柱側彎手術，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 224 日目，被験者は右肩変形性関節疾患の悪化を発現した。同日，右肩変形性関節疾患の悪化は消失した。

投与 224 日目，被験者は過去数年間にわたる右肩痛の悪化のため入院した。治験責任医師によると，被験者は長年両肩に進行した一次性関節炎があり，疼痛は関節炎によるものであった。過去，被験者は長期間保存療法を受けていたが，結局疼痛及び機能障害の緩和にならなかった。同日，被験者は計画された右肩関節全置換術を無事に受けた。

診療記録によると，被験者は良好な状態で退院した。

被験者にオキシコドンが投与された。

The patient's past medications include:

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

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

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

Causality for ABBV-951 (Open Label)

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1) Osteoarthritis aggravated (10031162) (Osteoarthritis (10031161)) [v.23.1] [10031162]

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 RIGHT SHOULDER DEGENERATIVE JOINT DISEASE

- Investigator: Patient had severe DJD and thus required total shoulder arthroplasty after several non-surgical options failed.

- AbbVie: More likely related to a history of chronic shoulder pain, shoulder numbness, shoulder tingling, pinched nerve neck, scoliosis and Parkinson's disease in an advanced aged patient

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] X-RAY SHOULDER:** From medical records: The orthopedic component appears well positioned and intact. Air is seen within the surrounding tissues. IMPRESSION: Expected findings of a recent right shoulder arthroplasty.

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. 7[redacted] kg at Week 52 visit. Weight loss occurred over a period of 11 months. No change in diet or mobility level with pump/infusion therapy. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced temporal activity increase/more active since treatment began, temporal and previous episodes of dysphagia, and temporal episode of 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
心房細動	X			
冠動脈疾患	X			
注入部位紅斑				X
注入部位感染				X
注入部位浮腫				X
肺塞栓症	X			
穿刺部位紅斑				X
尿路感染	X			

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

Medical History	Onset Year
ANXIETY	NOT REPORTED
HYPERCHOLESTEROLEMIA	19[redacted]
ERECTILE DYSFUNCTION	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
HEADACHE	20[redacted]
DEPRESSION	20[redacted]
BILATERAL KNEE PAIN	20[redacted]
OSTEOARTHRITIS	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
PERIPHERAL NEUROPATHY	20[redacted]
HEARTBURN	20[redacted]
OVERACTIVE BLADDER	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
VITAMIN B 12 DEFICIENCY	20[redacted]
VITAMIN B 6 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
NISSEN FUNDOPLICATION	19[redacted]
DEEP BRAIN STIMULATOR	20[redacted]
RIGHT TOTAL KNEE ARTHROPLASTY	20[redacted]
RIGHT SHOULDER ARTHROPLASTY	20[redacted]
LEFT TOTAL KNEE ARTHROPLASTY	20[redacted]
LEFT SHOULDER ARTHROPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	10	19[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	0.63	0	0	0	0	[redacted]20[redacted]/1
ABBV-951 CSCI	0.63	0	0	0	0	[redacted]20[redacted]/2
ABBV-951 CSCI	0.64	0	0	0	0	[redacted]20[redacted]/8
ABBV-951 CSCI	0.65	0	0	0	0	[redacted]20[redacted]/9
ABBV-951 CSCI	0.65	0	0	0	0	[redacted]20[redacted]/12
ABBV-951 CSCI	0.64	0	0	0	0	[redacted]20[redacted]/15
ABBV-951 CSCI	0.67	0	0	60	0.11	[redacted]20[redacted]/22
ABBV-951 CSCI	0.68	0	0.66	0	0	[redacted]20[redacted]/29
ABBV-951 CSCI	0.68	0	0.66	0	0	[redacted]20[redacted]/37
ABBV-951 CSCI	0.7	0	0.66	0	0	[redacted]20[redacted]/43

ABBV-951 CSCI	0.7	0	0	0	0	[redacted]/51
ABBV-951 CSCI	0.7	0	0.66	0	0	[redacted]/53
ABBV-951 CSCI	0.7	0	0.66	0	0	[redacted]/57
ABBV-951 CSCI	0.7	0	0.66	0	0	[redacted]/64
ABBV-951 CSCI	0.7	0	0	0	0	[redacted]/78
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/92
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/96
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/106
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/134
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/162
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/177
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/183
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/212
ABBV-951 CSCI	0.7	0.71	0	0	0	[redacted]/226
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/240
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/254
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/270
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/282
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/297
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/316
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/330
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/344
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[redacted]/358
ABBV-951 CSCI	0.7	0.71	0.68	0	0	[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	1506.01		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	2560.22		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		0	SC /ONCE	[redacted] / 7	
ABBV-951	2506.43		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8

ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	2581.74		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	2559.03		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	2597.10		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2663.7		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		0	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	2591.98		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	2627.15		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2688.45		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2699.89		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2745.66		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951		0	SC /ONCE	[redacted]20[redacted] / 34	
ABBV-951	2693.23		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2685.89		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2704.68		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2704.68		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2704.68		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2704.68		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2704.68		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2705.02		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2688.28		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42

ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
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ABBV-951	2780.15	SC /CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	2716.97	SC /CONTINUOUS	[redacted] / 364	[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SILDENAFIL	20 mg	TID	Y-M: 20[redacted]
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]

MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	63.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]-[redacted]
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]
AMANTADINE	137.000 mg	QD	Y-M: 20[redacted] / -335
VITAMIN B12 NOS	1000 OTHER: UG	OTHER: QIW	Y-M: 20[redacted]-[redacted] / -101
PYRIDOXINE HYDROCHLORIDE	25 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted] / -70
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	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
SILDENAFIL	20 mg	TID	Y-M: 20[redacted]-[redacted]	ONGOING
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]	ONGOING
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	ONGOING
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]	ONGOING
MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]	ONGOING
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]	ONGOING
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]-[redacted]	ONGOING
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]	ONGOING
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]-[redacted]	ONGOING
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]	ONGOING
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted]-[redacted] / -40	Y-M: 20[redacted]-[redacted] / 305
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted]-[redacted] / 29	Y-M: 20[redacted]-[redacted] / 38
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG BID mg	BID	Y-M: 20[redacted]-[redacted] / 49	Y-M: 20[redacted]-[redacted] / 59
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted]-[redacted] / 112	Y-M: 20[redacted]-[redacted] / 122
DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted]-[redacted] / 114	Y-M: 20[redacted]-[redacted] / 125
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted]-[redacted] / 131	Y-M: 20[redacted]-[redacted] / 141

SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 131	Y-M: 20[redacted] / 141
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 147	Y-M: 20[redacted] / 157
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 178	Y-M: 20[redacted] / 189
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted] / 191	ONGOING
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 191	Y-M: 20[redacted] / 297
METOPROLOL	25 mg	QD	Y-M: 20[redacted] / 191	Y-M: 20[redacted] / 297
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 221	Y-M: 20[redacted] / 231
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 248	Y-M: 20[redacted] / 258
AMIODARONE	200 mg	QD	Y-M: 20[redacted] / 263	ONGOING
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 263	Y-M: 20[redacted] / 297
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 267	Y-M: 20[redacted] / 277
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 279
CEFDINIR	300 mg	BID	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 294
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 284	Y-M: 20[redacted] / 294
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 323	Y-M: 20[redacted] / 333
DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted] / 341	Y-M: 20[redacted] / 344
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 341	Y-M: 20[redacted] / 344
CEFTRIAXONE	250 mg	OTHER: ONCE	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 344
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 354

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

Event Description	MILD ERYTHEMA TO LEFT LOWER QUADRANT OLD INSERTION SITE
Preferred Term	穿刺部位紅斑
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	39
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 #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA TO LEFT LOWER QUADERATANT OLD INSERTION SITE
Preferred Term	穿刺部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 49
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	62
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 #3: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	RIGHT UPPER ABDOMINAL QUADRANT SUBCUTANEOUS EDEMA AROUND INFUSION SITE
Preferred Term	注入部位浮腫
AE Onset Date / RX Day	[redacted]20[redacted] / 67
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	67
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	GRADE 1 ERYTHEMA TO INFUSION SITE LEFT LOWER QUADERANT
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 112
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	

AE Stopped RX Day	129
Duration of AE	18 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	GRADE 1 ERYTHEMA TO RIGHT LOWER QUADRANT ABDOMEN INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 127
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	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 #6: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	GRADE 1 ERYTHEMA TO RIGHT UPPER QUADRANT INSERTION SITE
Preferred Term	穿刺部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 131
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	141
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 #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	GRADE 1 ERYTHEMA MILD TO RIGHT UPPER QUADRANT ABDOMINAL INSERTION SITE.
Preferred Term	穿刺部位紅斑
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	155
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 #8: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	LEFT LOWER ABDOMINAL QUADRANT INFUSION SITE ERYTHEMA
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 177
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	186
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 #9: Serious Adverse Event

Event Description	CORONARY ARTERY DISEASE
Preferred Term	冠動脈疾患
AE Onset Date / RX Day	[redacted]20[redacted] / 191
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 191): EKG:NOT CLINICAL SIGNIFICANT; [redacted]20[redacted] (RX DAY 192): LHC/PCI CORONARY STENT PLACEMENT X2:SUCCESSFUL STENT PLACEMENT; [redacted]20[redacted] (RX DAY 194): EKG:NOT CLINICALLY SIGNIFICANT; [redacted]20[redacted] (RX DAY 197): EKG:NOT CLINICALLY SIGNIFICANT	
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	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	RISK FACTORS, FAMILY HISTORY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #10: Serious Adverse Event

Event Description	ATRIAL FIBRILLATION
Preferred Term	心房細動
AE Onset Date / RX Day	[redacted]20[redacted] / 195
Age at AE Onset	7[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	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
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	RISK FACTOR, NEW DIAGNOSIS OF CORONARY ARTERY DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #11: Serious Adverse Event

Event Description	URINARY TRACT INFECTION
Preferred Term	尿路感染
AE Onset Date / RX Day	[redacted]20[redacted] / 195
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped RX Day	199
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 RELATED
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	RISK FACTOR, URINARY RETENTION DUE TO PARKINSON'S DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

Event Description	ERYTHEMA TO LEFT LOWER ABDOMINAL QUADRANT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 221
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	225
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 #13: Serious Adverse Event

Event Description	PULMONARY EMBOLI
Preferred Term	肺塞栓症
AE Onset Date / RX Day	[redacted]20[redacted] / 333
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 333): CT SCAN OF THE CHEST:PULMONARY EMBOLI	

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	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	SUBJECT HAS A HISTORY OF ATRIAL FIBRILLATION, PER LAST AE, NEW SINCE SIGNING CONSENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #14: Event of Interest - Infusion Site Related Infections

Event Description	INFUSION SITE INFECTION
Preferred Term	注入部位感染
AE Onset Date / RX Day	[redacted]20[redacted] / 341
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365
Duration of AE	25 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

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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，冠動脈疾患，尿路感染，及び心房細動を発現した。

Event 9，10，及び 11 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，うつ病，過活動膀胱，起立性低血圧，不安，元喫煙者（1 日 10 本を 10 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 191 日目，被験者は冠動脈疾患を発現した。投与 195 日目，被験者は尿路感染，及び心房細動を発現した。投与 199 日目，尿路感染は消失した。

投与 191 日目，被験者は胸部圧迫感及び心窩部痛のため緊急治療室を受診した。投与 192 日目，被験者は心臓カテーテル手術を受け，2 本のステントが留置された。投与 195 日目，被験者は尿路感染を発現し入院延長となった。被験者に錯乱及び尿閉の症状が認められた。入院中，被験者に心房細動も認められた。被験者は入院中の心臓モニタリング時に無症候性の心房細動が認められた。投与 199 日目，被験者は退院した。

治験責任医師は，被験者に心疾患の家族歴があったことを指摘した。

被験者にアミオダロン，メトプロロール，プラビックス，アスピリン，及び BACTRIM が投与された。

The patient's past medications include:

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

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

Causality for ABBV-951 (Open Label)

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1) Coronary artery disease (10011078) (Coronary artery disease (10011078)) [v.23.1] [10011078]

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

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

Dechallenge: Not Applicable

2) 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

3) Atrial fibrillation (10003658) (Atrial fibrillation (10003658)) [v.23.1] [10003658]

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 CORONARY ARTERY DISEASE

- Investigator: Risk factor: Family history

- AbbVie: More likely related to a history of hypercholesterolemia and Parkinson's disease in an advanced aged patient

Event of URINARY TRACT INFECTION

- Investigator: Risk factor, urinary retention due to Parkinson's disease

- AbbVie: More likely related to a history of overactive bladder and Parkinson's disease in an advanced aged patient

Event of ATRIAL FIBRILLATION

- Investigator: Risk factor, new diagnosis of coronary artery disease

- AbbVie: More likely related to a history of hypercholesterolemia and Parkinson's disease in an advanced aged patient with concurrent event of coronary artery disease with a report of recent stent placement.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] EKG:** Not clinically significant

[redacted] **20[redacted] EKG:** Not clinically significant

[redacted] **20[redacted] EKG:** Not clinically significant

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

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

Event 13 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，うつ病，不安，元喫煙者（1 日 10 本を 10 年間），及び元飲酒者（1 日 2 杯未満）であった。

投与 333 日目，被験者は肺塞栓症を発現した。

本事象の発現前，被験者は投与から約 6 ヵ月後に発現した尿路感染のため入院延長となっていた。投与から約 6 ヵ月後の入院中，被験者に心房細動（間欠性）とみなされる心拍リズム異常が認められた。

投与から約 10 ヵ月後，被験者は胸痛及び最近発現した心房細動のため入院した。被験者は胸部 CT 検査後に肺塞栓症と診断された。大静脈フィルターが留置され，心臓専門医により抗凝固薬は使用しないと判断された。投与 334 日目，被験者は退院した。

治験責任医師によると，被験者には心房細動のリスク因子があった。

The patient's past medications include:

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

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

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

VITAMIN B12 for VITAMIN B 12 DEFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

VITAMIN B 6 for VITAMIN B DEFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

CEFDINAR for GRADE 1 MILD ERYTHEMA TO INSERTION/INFUSION SITE ([redacted] 20[redacted] - [redacted] 20[redacted])

METOPROLOL for CORONARY ARTERY DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

PLAVIX for PREVENTATIVE BLOOD THINNER, CORONARY ARTERY DISEASE and PREVENTATIVE BLOOD THINNER, CORONARY ARTERY DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])

ELIQUIS for ATRIAL FIBRILLATION ([redacted] 20[redacted] - [redacted] 20[redacted])

OMNICEF for ERYTHEMA TO INFUSION SITE GRADE 2 ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Pulmonary embolism (10037377) (Pulmonary embolism (10037377)) [v.23.1] [10037377]

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 PULMONARY EMBOLI

- Investigator: Subject has a history of atrial fibrillation, per last AE, new since signing consent.

- AbbVie: More likely related to reported atrial fibrillation, elevated hsCRP, and recent hospitalization in a 7[redacted] year old subject with Parkinson's disorder

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD PRESSURE:** 101/57mmHg

[redacted] **20[redacted] BLOOD PRESSURE - SCREENING:** 128/88mmHg

[redacted] **20[redacted] CT CHEST:** PULMONARY EMBOLI

[redacted] **20[redacted] PULSE:** 67 bpm

[redacted] **20[redacted] PULSE - SCREENING:** 69 bpm

[redacted] **20[redacted] WEIGHT:** 16[redacted] Pounds

[redacted] **20[redacted] WEIGHT - SCREENING:** 8[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
注入部位膿瘍				X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
注射部位紅斑				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	19[redacted]
ANXIETY	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
ANAL FISSURE	20[redacted]
PERIPHERAL EDEMA BILATERAL	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
TONSILLECTOMY ADENOIDECTOMY	19[redacted]
CHOLECYSTECTOMY	20[redacted]
DEEP BRAIN STIMULATION IMPLANT	20[redacted]
HERNIA REPAIR INGUINAL (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	0.7	0	0	0	0	[redacted]/1
ABBV-951 CSCI	0.7	0	0	0	0	[redacted]/2
ABBV-951 CSCI	0.7	0	0	60	0.15	[redacted]/8
ABBV-951 CSCI	0.55	0	0.53	60	0.11	[redacted]/15
ABBV-951 CSCI	0.55	0	0.53	0	0	[redacted]/22
ABBV-951 CSCI	0.55	0	0.53	0	0	[redacted]/29
ABBV-951 CSCI	0.55	0.57	0.53	0	0	[redacted]/45
ABBV-951 CSCI	0.55	0.57	0.53	0	0	[redacted]/53
ABBV-951 CSCI	0.55	0	0	0	0	[redacted]/68
ABBV-951 CSCI	0.55	0.57	0.53	0	0	[redacted]/80
ABBV-951 CSCI	0.55	0.57	0.53	0	0	[redacted]/87
ABBV-951 CSCI	0.55	0.57	0.53	0	0	[redacted]/101
ABBV-951 CSCI	0.56	0.57	0.55	0	0	[redacted]/116

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	1517.96		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1255.01		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	1278.91		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7

ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2868.6		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		102.45	SC /ONCE	[redacted] / 12	
ABBV-951	1434.3		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		25.61	SC /ONCE	[redacted] / 13	
ABBV-951	2450.26		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	1410.39		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	1315.62		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	2196.18		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951	2195.84		SC /CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951	2209.50		SC /CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 31	[redacted] / 31
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 32	[redacted] / 32
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 33	[redacted] / 33
ABBV-951	2172.79		SC /CONTINUOUS	[redacted] / 34	[redacted] / 34
ABBV-951	2166.81		SC /CONTINUOUS	[redacted] / 35	[redacted] / 35
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 36	[redacted] / 36
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 37	[redacted] / 37
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 38	[redacted] / 38
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 39	[redacted] / 39
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 40	[redacted] / 40
ABBV-951	2198.23		SC /CONTINUOUS	[redacted] / 41	[redacted] / 41
ABBV-951	2185.42		SC /CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 46	[redacted] / 46
ABBV-951	2171.94		SC /CONTINUOUS	[redacted] / 47	[redacted] / 47

ABBV-951	2207.79	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2263.29	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2234.09	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	2253.9	SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84

ABBV-951	2284.63	SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	2274.39	SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BUPROPION	100 mg	BID	Y-M: 20[redacted]
AMANTADINE	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	OTHER: QHS	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted]
DOCUSATE SODIUM	50 mg	PRN	Y-M: 20[redacted]
MACROGOL 3350	1 OTHER: CAPFUL	QD	Y-M: 20[redacted]
MELATONIN	10 mg	OTHER: QHS	Y-M: 20[redacted]
UBIDECARENONE	100 mg	QD	Y-M: 20[redacted]
AMANTADINE	500.000 mg	BID	Y-M: 20[redacted]
BUSPIRONE HYDROCHLORIDE	7.5 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
BUPROPION	100 mg	BID	Y-M: 20[redacted]	ONGOING
CLONAZEPAM	0.5 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
DOCUSATE SODIUM	50 mg	PRN	Y-M: 20[redacted]	ONGOING
MACROGOL 3350	1 OTHER: CAPFUL	QD	Y-M: 20[redacted]	ONGOING
MELATONIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
UBIDECARENONE	100 mg	QD	Y-M: 20[redacted]	ONGOING
BUSPIRONE HYDROCHLORIDE	7.5 mg	TID	Y-M: 20[redacted]	ONGOING
CEFALEXIN	500 mg	TID	Y-M: 20[redacted]-[redacted] / 51	Y-M: 20[redacted]-[redacted] / 53
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted]-[redacted] / 53	Y-M: 20[redacted]-[redacted] / 57
VANCOMYCIN	1250 mg	OTHER: EVERY 8 HOURS	Y-M: 20[redacted]-[redacted] / 57	Y-M: 20[redacted]-[redacted] / 59
CEFDINIR	300 mg	OTHER: EVERY 12 HOURS	Y-M: 20[redacted]-[redacted] / 60	Y-M: 20[redacted]-[redacted] / 70
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted]-[redacted] / 60	Y-M: 20[redacted]-[redacted] / 70

SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 120	Y-M: 20[redacted] / 130
DOXYCYCLINE	100 MG mg	BID	Y-M: 20[redacted] / 122	Y-M: 20[redacted] / 132
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 124	ONGOING

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

Event Description	MINIMAL ERYTHEMA AREA TO RIGHT UPPER QUADRANT ABDOMEN, INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 11
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	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 #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	LEFT UPPER AND LOWER QUADRANT GRADE 2 MODERATE ERYTHEMA AT INJECTION SITE
Preferred Term	注射部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 50
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	54
Duration of AE	5 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 - Infusion Site Related Infections

Event Description	CELLULITIS TO LEFT UPPER/LOWER ABDOMINAL QUADERANT AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 56
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 57): CT ABDOMEN AND PELVIS:MULTIFOCAL ABDOMINAL WALL CELLULITIS AND DERMATITIS CHANGES; INCISION AND DRAINAGE OF LEFT ABDOMINAL WALL ABSCESSESX2:SUBJECT TOLERATED THE PROCEDURE WELL WITH NO COMPLICATIONS AND DRESSING CHANGE 3X WEEK ORDERED

AE Stopped RX Day	100
Duration of AE	45 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	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	LEFT ABDOMINAL WALL ABSCESS X 2 AT INFUSION SITE
Preferred Term	注入部位膿瘍
AE Onset Date / RX Day	[redacted]20[redacted] / 57
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	100
Duration of AE	44 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	RIGHT UPPER ABDOMINAL QUADRANT ERYTHEMA TO INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 120
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 #6: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MODERATE ERYTHEMA TO THE RIGHT MIDDLE ABDOMINAL QUADRANT AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 121
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	124
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

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

Event #7: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO RIGHT MIDDLE QUADRANT ABDOMEN AT THE INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 124
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。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左上下腹部の注入部位蜂巣炎を発現した。

Event 3 の臨床経過：

関連する病歴は，うつ病，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 10 日目から投与 17 日目まで，被験者は非盲検下プレドニゾロン漸減療法を受け，投与 18 日目，盲検下プレドニゾロン漸減療法を開始した。

投与 56 日目，被験者は左上下腹部の注入部位蜂巣炎を発現した。投与 100 日目，左上下腹部の注入部位蜂巣炎は消失した。

本事象の発現前，投与 11 日目，被験者は右上腹部注入部位に非重篤の軽微な紅斑を発現した。投与 50 日目，被験者はまた左上下挿入部位に非重篤でグレード 2 の紅斑を発現した。投与 56 日目，被験者は抗生物質経口投与中に多少症状の進行がみられ，左腹壁挿入部の膿瘍及び蜂巣炎の可能性があるため入院した。

退院時サマリ：

入院前，被験者は非重篤の事象のため外来にてケフレックス投与後，3 日間 BACTRIM 投与による治療を受けていたが，持続的に悪化していた。

被験者は腹壁紅斑，軽度発熱，及び注入部位に「触れると熱い」を発現したため，緊急治療室を受診した。膿瘍及び蜂巣炎の可能性が懸念された。腹部骨盤の CT 検査が実施され，腹壁蜂巣炎及び皮膚炎，並びに左中腹部に限局性の液貯留が認められた。被験者は救急診療部でバンコマイシンの投与を開始し，一般外科を受診した。治験薬の投与は外科的治療のため中断された。被験者は左腹壁の 2 か所の感染膿瘍の切開及びドレナージを無事に完了した。術後の経過は特記なし。被験者は反対側の腹壁で注入を継続するよう指導された。被験者は蜂巣炎の良好な改善がみられ，投与 59 日目，自宅で抗生物質治療をすることとし退院帰宅した。

被験者にバンコマイシン，OMNICEF，及びドキシサイクリンが投与された。

The patient's past medications include:

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

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

STALEVO 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.22.1] [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 TO LEFT UPPER/LOWER ABDOMINAL QUADRANT AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT ABDOMEN PELVIS:** MULTIFOCAL ABDOMINAL WALL CELLULITIS AND DERMATITIS CHANGES AND FOCAL FLUID COLLECTION OVER THE LEFT MID ABDOMEN, ALSO SOME RETAINED STOOL IN THE COLON

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
顔面骨骨折				X
転倒				X
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位浮腫				X
注入部位反応				X
穿刺部位紅斑				X
鼻痛				X
皮膚裂傷				X

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

Medical History	Onset Year
ALLERGIES (SEASONAL)	19[redacted]
CONSTIPATION	19[redacted]
DEPRESSION	19[redacted]
MUSCULOSKELETAL PAIN	20[redacted]
HYPERTENSION	20[redacted]
SLEEP DISORDER	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
HYPOTHYROIDISM	20[redacted]
FALL	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
IRRITABILITY	20[redacted]
GLAUCOMA	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
SEPTOPLASTY	19[redacted]
ANGIOPLASTY AND STENT PLACEMENT	20[redacted]
CATARACT SURGERY (RIGHT)	20[redacted]
CATARACT SURGERY (LEFT)	20[redacted]
CYSTOURETHROSCOPY WITH RIGHT RETROGRADE URETERAL PYOLOGRAMS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	2	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	0.68	0	0	0	0	[redacted]20[redacted]/1
ABBV-951 CSCI	0.63	0	0	0	0	[redacted]20[redacted]/2
ABBV-951 CSCI	0.65	0	0	0	0	[redacted]20[redacted]/8
ABBV-951 CSCI	0.65	0	0	0	0	[redacted]20[redacted]/15
ABBV-951 CSCI	0.66	0	0	0	0	[redacted]20[redacted]/22
ABBV-951 CSCI	0.66	0	0	0	0	[redacted]20[redacted]/29
ABBV-951 CSCI	0.66	0	0	0	0	[redacted]20[redacted]/43
ABBV-951 CSCI	0.66	0	0	0	0	[redacted]20[redacted]/61
ABBV-951 CSCI	0.65	0	0	0	0	[redacted]20[redacted]/64
ABBV-951 CSCI	0.67	0	0	0	0	[redacted]20[redacted]/75
ABBV-951 CSCI	0.67	0	0	0	0	[redacted]20[redacted]/92
ABBV-951 CSCI	0.67	0	0	0	0	[redacted]20[redacted]/107
ABBV-951 CSCI	0.68	0	0	0	0	[redacted]20[redacted]/122
ABBV-951 CSCI	0.68	0	0	0	0	[redacted]20[redacted]/124
ABBV-951 CSCI	0.68	0.69	0	0	0	[redacted]20[redacted]/142

ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/145
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/152
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/155
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/180
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/197
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/206
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/220
ABBV-951 CSCI	0.68	0.7	0.67	0	0	[redacted]/234
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/248
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/262
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/270
ABBV-951 CSCI	0.68	0.69	0	0	0	[redacted]/276
ABBV-951 CSCI	0.68	0.69	0.67	0	0	[redacted]/290
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/304
ABBV-951 CSCI	0.68	0.7	0	0	0	[redacted]/318
ABBV-951 CSCI	0.66	0.68	0	0	0	[redacted]/332
ABBV-951 CSCI	0.66	0.68	0	0	0	[redacted]/346
ABBV-951 CSCI	0.66	0.68	0	0	0	[redacted]/358
ABBV-951 CSCI	0.67	0.68	0	0	0	[redacted]/374

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	1602.31		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	2786.64		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	2786.64		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	2786.64		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	2786.64		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	1395.71		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	2527.95		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2581.74		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2563.81		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2619.30		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14

ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	2552.71	SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2608.20	SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2663.7	SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	2612.98	SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	2670.87	SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	2659.60	SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2670.87	SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51

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ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
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ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
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ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
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ABBV-951	2704.68	SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
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ABBV-951	2677.01	SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
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ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
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ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
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ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
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ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	2745.66	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
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ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 164	[redacted] / 164
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 165	[redacted] / 165
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 166	[redacted] / 166
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 167	[redacted] / 167
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 168	[redacted] / 168
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 169	[redacted] / 169
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 170	[redacted] / 170
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 171	[redacted] / 171
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 172	[redacted] / 172
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 173	[redacted] / 173
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 174	[redacted] / 174
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 175	[redacted] / 175
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 176	[redacted] / 176
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 177	[redacted] / 177
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 178	[redacted] / 178
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 179	[redacted] / 179
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 180	[redacted] / 180
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 181	[redacted] / 181
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 182	[redacted] / 182
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 183	[redacted] / 183
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 184	[redacted] / 184
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 185	[redacted] / 185
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 186	[redacted] / 186
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 187	[redacted] / 187
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 188	[redacted] / 188
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 189	[redacted] / 189
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 190	[redacted] / 190
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 191	[redacted] / 191
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 192	[redacted] / 192
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 193	[redacted] / 193
ABBV-951	2745.66	SC /CONTINUOUS	[redacted] / 194	[redacted] / 194
ABBV-951	2700.75	SC /CONTINUOUS	[redacted] / 195	[redacted] / 195
ABBV-951	2716.97	SC /CONTINUOUS	[redacted] / 196	[redacted] / 196
ABBV-951	2786.64	SC /CONTINUOUS	[redacted] / 197	[redacted] / 197
ABBV-951	2786.64	SC /CONTINUOUS	[redacted] / 198	[redacted] / 198
ABBV-951	2786.64	SC /CONTINUOUS	[redacted] / 199	[redacted] / 199

ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
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ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 206	[redacted]20[redacted] / 206
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 207	[redacted]20[redacted] / 207
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
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ABBV-951	2786.64	SC /CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
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ABBV-951	2670.87	SC /CONTINUOUS	[redacted]20[redacted] / 373	[redacted]20[redacted] / 373

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
FEXOFENADINE HYDROCHLORIDE	180 mg	PRN	Y-M: 19[redacted]
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]
CITALOPRAM	40 mg	QD	Y-M: 20[redacted]
ATORVASTATIN	40 mg	OTHER: QHS	Y-M: 20[redacted]
LEVOTHYROXINE	50 ug	OTHER: QAM	Y-M: 20[redacted]
VITAMIN D NOS	4000 IU	QD	Y-M: 20[redacted]

SENNA ALEXANDRINA	6-8 mg	PRN	Y-M: 20[redacted]
DRONABINOL	1000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	400.000 mg	QD	Y-M: 20[redacted]
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	980.000 mg	BID	Y-M: 20[redacted] / -286
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted] / -237
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted] / -105
METOPROLOL	50 mg	BID	Y-M: 20[redacted] / -58

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
FEXOFENADINE HYDROCHLORIDE	180 mg	PRN	Y-M: 19[redacted]	ONGOING
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]	ONGOING
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	ONGOING
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	ONGOING
CITALOPRAM	40 mg	QD	Y-M: 20[redacted]	ONGOING
LEVOTHYROXINE	50 ug	OTHER: QAM	Y-M: 20[redacted]	ONGOING
VITAMIN D NOS	4000 IU	QD	Y-M: 20[redacted]	ONGOING
ATORVASTATIN	40 mg	OTHER: QHS	Y-M: 20[redacted]	Y-M: 20[redacted] / 346
SENNA ALEXANDRINA	6-8 mg	PRN	Y-M: 20[redacted]	ONGOING
DRONABINOL	1000 mg	QD	Y-M: 20[redacted]	ONGOING
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]	ONGOING
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]	ONGOING
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted] / -237	ONGOING
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted] / -105	ONGOING
METOPROLOL	50 mg	BID	Y-M: 20[redacted] / -58	Y-M: 20[redacted] / 61
NIFEDIPINE	30 mg	QD	Y-M: 20[redacted] / 20	ONGOING
CEFALEXIN	500 mg	TID	Y-M: 20[redacted] / 24	Y-M: 20[redacted] / 31
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 41
HYDROCHLOROTHI	25 mg	QD	Y-M: 20[redacted] / 62	Y-M: 20[redacted] / 276

AZIDE				
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 122	Y-M: 20[redacted] / 130
LATANOPROST	0.005% 1 DROP EACH EYE gtt	QD	Y-M: 20[redacted] / 157	ONGOING
CEFDINIR	300 MG mg	BID	Y-M: 20[redacted] / 197	Y-M: 20[redacted] / 207
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 232	Y-M: 20[redacted] / 241
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 MG mg	BID	Y-M: 20[redacted] / 266	Y-M: 20[redacted] / 269
SULFAMETHOXAZOLE;TRIMETHOPRIM	800 mg	BID	Y-M: 20[redacted] / 266	Y-M: 20[redacted] / 276
CEFDINIR	300 mg	BID	Y-M: 20[redacted] / 268	Y-M: 20[redacted] / 269
CEFEPIME	2 GM g	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 271
VANCOMYCIN	1500 MG mg	BID	Y-M: 20[redacted] / 269	Y-M: 20[redacted] / 271

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

Event Description	ACUTE LEFT NASAL BONE FRACTURE
Preferred Term	顔面骨骨折
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	49
Duration of AE	34 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 #2: Event of Interest - Falls and Associated Injuries

Event Description	FRACTURE NASAL SEPTUM
Preferred Term	顔面骨骨折
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	49
Duration of AE	34 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 #3: Event of Interest - Falls and Associated Injuries

Event Description	FALL, ACCIDENTAL
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	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 of Interest - Falls and Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	1/2 INCH WHITE RING AROUND UPPER LEFT ABDOMINAL QUADRANT INFUSION SITE
Preferred Term	注入部位反応
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	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

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

Event Description	NASAL PAIN
Preferred Term	鼻痛
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	49
Duration of AE	34 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CUT TO RIGHT HAND MEDIAL ASPECT POSTERIOR
Preferred Term	皮膚裂傷
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	49
Duration of AE	34 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	GRADE 2 MODERATE ERYTHEMA AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 24
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	20 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	MILD EDEMA TO RIGHT LOWER QUADRANT INSERTION SITE, INFUSION
Preferred Term	注入部位浮腫
AE Onset Date / RX Day	[redacted]20[redacted] / 24
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	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Infusion Site Related Infections

Event Description	PHLEGMON RIGHT LATERAL ABDOMEN INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 30
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	14 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 Non Infection Reactions

Event Description	ERYTHEMA MODERATE TO LOWER ABDOMEN AT INSERTION SITE
Preferred Term	穿刺部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 115
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	122
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 #11: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	GRADE 1 ERYTHEMA TO RIGHT UPPER QUADRANT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 197
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	210
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 #12: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	ERYTHEMA TO RIGHT LOWER ABDOMINAL QUADRANT 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	248
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	ERYTHEMA TO MID-LOWER ABDOMINAL AREA INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 266
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	270
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 #14: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO MID-LOWER ABDOMINAL AREA INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 268
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	269
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 #15: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS TO MID-LOWER ABDOMINAL INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 269
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 269): NPTST048-BLOOD CULTURES: NEGATIVE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
[redacted]20[redacted] (RX DAY 269): ULTRASOUND OF THE ABDOMEN:NO ABSCESS NOTED, INDURATION ONLY	
AE Stopped RX Day	271

Duration of AE	3 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	UNLIKELY
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	UNLIKELY
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted] 20[redacted]: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。本被験者は米国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，中下腹部の注入部位蜂巣炎を発現した。

Event 15 の臨床経過：

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

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

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

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

を発現し，2 番目の抗生物質の投与を開始した。被験者は抗生物質の静脈内投与のため，緊急治療室を受診するよう指示された。

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

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

The patient's past medications include:

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS TO MID-LOWER ABDOMINAL INFUSIONSITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

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

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

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

Reason for Narrative

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

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

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

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

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

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

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

Study Drug Prescription

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

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

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1408.68		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	725.68		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	1408.68		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	2014.85		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951	2023.38		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951	2006.31		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951	2049		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248

ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 258	[redacted]20[redacted] / 258
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 260	[redacted]20[redacted] / 260
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 261	[redacted]20[redacted] / 261
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 262	[redacted]20[redacted] / 262
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 263	[redacted]20[redacted] / 263
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 264	[redacted]20[redacted] / 264
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 265	[redacted]20[redacted] / 265
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 266	[redacted]20[redacted] / 266
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 277	[redacted]20[redacted] / 277
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 279	[redacted]20[redacted] / 279
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 281	[redacted]20[redacted] / 281
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ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
ABBV-951	819.6	SC /CONTINUOUS	[redacted]20[redacted] / 284	[redacted]20[redacted] / 284
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ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 288	[redacted] / 288
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ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 291	[redacted] / 291
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ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 296	[redacted] / 296
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ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 310	[redacted] / 310
ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 311	[redacted] / 311
ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 312	[redacted] / 312
ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 313	[redacted] / 313
ABBV-951	901.56	SC /CONTINUOUS	[redacted] / 314	[redacted] / 314
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ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
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ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
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ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
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ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
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ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	901.56	SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353

Previous Therapy - Prior to baseline/enrollment

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

SERTRALINE	150 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	195.000 mg	5 TIMES PER DAY	Y-M: 20[redacted]
ROTIGOTINE	8.000 mg	QD	Y-M: 20[redacted] / -322

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

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

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

Event Description	CELLULITIS OF RIGHT ABDOMINAL WALL INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 24
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	45
Duration of AE	22 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

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

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 168
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	169
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	COVID
Preferred Term	COVID-19
AE Onset Date / RX Day	[redacted]20[redacted] / 346
Age at AE Onset	7[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 347): CHEST XRAY:NORMAL

AE Stopped RX Day	358 (5 DAYS AFTER LAST TREATMENT)
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	VOID 19 VIRUS

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

Event 4 の臨床経過：

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

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

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

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

被験者には本事象発現に関するリスク因子がなかった。

The patient's past medications include:

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

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of COVID

- Investigator: Covid-9 Virus

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

Relevant Laboratory & Other Diagnostic Tests

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

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

Reason for Narrative

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

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

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

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

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

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

Alcohol Use	Status	Number/Day

ALCOHOL	NEVER

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.44	0	0	0	0	[redacted]/1
ABBV-951 CSCI	0.44	0	0	0	0	[redacted]/2
ABBV-951 CSCI	0.45	0	0	0	0	[redacted]/9
ABBV-951 CSCI	0.46	0	0	0	0	[redacted]/12
ABBV-951 CSCI	0.48	0	0	0	0	[redacted]/15
ABBV-951 CSCI	0.49	0	0	0	0	[redacted]/16
ABBV-951 CSCI	0.49	0	0	0	0	[redacted]/22
ABBV-951 CSCI	0.52	0	0	0	0	[redacted]/29
ABBV-951 CSCI	0.54	0	0	0	0	[redacted]/36
ABBV-951 CSCI	0.55	0	0	0	0	[redacted]/44
ABBV-951 CSCI	0.57	0	0	0	0	[redacted]/50
ABBV-951 CSCI	0.58	0	0	0	0	[redacted]/64
ABBV-951 CSCI	0.58	0	0	0	0	[redacted]/82
ABBV-951 CSCI	0.59	0	0	0	0	[redacted]/92
ABBV-951 CSCI	0.59	0	0	0	0	[redacted]/106
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/120
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/134
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/148
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/162
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/176
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/192
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/193
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/204
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/218
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/232
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/262
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/276
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/304
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/320
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/333
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/348
ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]/361

ABBV-951 CSCI	0.6	0.61	0.59	0	0	[redacted]20[redacted]/367

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	1036.79		SC /CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
ABBV-951	1788.09		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	1788.09		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	1841.02		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	1925.37		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	1967.04		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1967.04		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1967.04		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1967.04		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951	1972.33		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	2008.02		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1982.91		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1957.81		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	2008.02	SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	2154.18	SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	2194.47	SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2212.92	SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69

ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 70	[redacted] / 70
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 71	[redacted] / 71
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 72	[redacted] / 72
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 73	[redacted] / 73
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 74	[redacted] / 74
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 75	[redacted] / 75
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 76	[redacted] / 76
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 77	[redacted] / 77
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 78	[redacted] / 78
ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 79	[redacted] / 79
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ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 81	[redacted] / 81
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ABBV-951	2212.92	SC /CONTINUOUS	[redacted] / 83	[redacted] / 83
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ABBV-951	2069.14	SC /CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951	2366.93	SC /CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951	2376.84	SC /CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951	2384.52	SC /CONTINUOUS	[redacted] / 104	[redacted] / 104
ABBV-951	2397.67	SC /CONTINUOUS	[redacted] / 105	[redacted] / 105
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 106	[redacted] / 106

ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 107	[redacted] / 107
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 108	[redacted] / 108
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 109	[redacted] / 109
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 110	[redacted] / 110
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 111	[redacted] / 111
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 112	[redacted] / 112
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 113	[redacted] / 113
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 114	[redacted] / 114
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 115	[redacted] / 115
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 116	[redacted] / 116
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 117	[redacted] / 117
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 118	[redacted] / 118
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 119	[redacted] / 119
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 120	[redacted] / 120
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 121	[redacted] / 121
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 122	[redacted] / 122
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 123	[redacted] / 123
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 124	[redacted] / 124
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 125	[redacted] / 125
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 126	[redacted] / 126
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 127	[redacted] / 127
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 128	[redacted] / 128
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 129	[redacted] / 129
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 130	[redacted] / 130
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 131	[redacted] / 131
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 132	[redacted] / 132
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 133	[redacted] / 133
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 134	[redacted] / 134
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 135	[redacted] / 135
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 136	[redacted] / 136
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 137	[redacted] / 137
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 138	[redacted] / 138
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 139	[redacted] / 139
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 140	[redacted] / 140
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ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 142	[redacted] / 142
ABBV-951	2417.82	SC /CONTINUOUS	[redacted] / 143	[redacted] / 143

ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
ABBV-951	2417.82	SC /CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180

ABBV-951	2417.82	SC /CONTINUOUS	[redacted]	[redacted]

ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 218	[redacted]20[redacted] / 218
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 219	[redacted]20[redacted] / 219
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 233	[redacted]20[redacted] / 233
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 234	[redacted]20[redacted] / 234
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 235	[redacted]20[redacted] / 235
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 239	[redacted]20[redacted] / 239
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 240	[redacted]20[redacted] / 240
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 241	[redacted]20[redacted] / 241
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 244	[redacted]20[redacted] / 244
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ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 246	[redacted]20[redacted] / 246
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 247	[redacted]20[redacted] / 247
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 248	[redacted]20[redacted] / 248
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 249	[redacted]20[redacted] / 249
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 251	[redacted]20[redacted] / 251
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 252	[redacted]20[redacted] / 252
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 253	[redacted]20[redacted] / 253
ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254

ABBV-951	2499.78	SC /CONTINUOUS	[redacted]20[redacted] / 255	[redacted]20[redacted] / 255
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ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
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ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
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ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	2458.8	SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	2465.97	SC /CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	0.250 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	7 TIMES PER DAY	Y-M: 20[redacted]
MELATONIN	5 mg	QD	Y-M: 20[redacted]
BUSPIRONE	50 MG mg	BID	Y-M: 20[redacted]
TRAZODONE	100 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
MELATONIN	5 mg	QD	Y-M: 20[redacted]	ONGOING
BUSPIRONE	50 MG mg	BID	Y-M: 20[redacted]	ONGOING
TRAZODONE	100 mg	QD	Y-M: 20[redacted]	ONGOING
SERTRALINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 248	ONGOING

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

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

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

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

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

Generated: [redacted]20[redacted]: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。本被験者は米国の 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，左大腿部大血腫を発現した。

Event 2 の臨床経過：

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

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

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

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

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

The patient's past medications include:

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

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of LARGE LEFT THIGH HEMATOMA

- Investigator: Fall

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

Relevant Laboratory & Other Diagnostic Tests

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

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

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

Reason for Narrative

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

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

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

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

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

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

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

Study Drug Prescription

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

Daily Dose (mg LD) by Molecular Weight

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

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

ABBV-951	3153.41		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	3222.56		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 30	
ABBV-951	3098.08		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	3236.39		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 32	
ABBV-951	3305.54		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	3291.71		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1120.29		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	648.85		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 39	
ABBV-951	1989.23		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1885.25		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	1558.26		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	1840.17		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 44	
ABBV-951	1914.10		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 45	
ABBV-951	2199.60		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 46	
ABBV-951	2327.32		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2337.22		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2287.70		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	1118.41		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 51	
ABBV-951	1972.16		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 53	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	700.07		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	1519.67		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 56	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 57	

ABBV-951	2049		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 58	
ABBV-951	2014.85		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 59	
ABBV-951	2031.92		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 60	
ABBV-951	1963.62		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 61	
ABBV-951	2173.30		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	1564.75		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 63	
ABBV-951	2238.19		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 64	
ABBV-951	2115.08		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 65	
ABBV-951	1847.17		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 66	
ABBV-951	2151.45		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 67	
ABBV-951	2201.30		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 68	
ABBV-951	1967.38		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 69	
ABBV-951	2053.78		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	991.03		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1856.56		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 80	
ABBV-951	2357.37		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 81	
ABBV-951	1894.98		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 82	
ABBV-951	1972.16		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 83	
ABBV-951	2007.33		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 84	
ABBV-951	2067.27		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 85	

ABBV-951	1831.46		SC /CONTINUOUS	[redacted] / 85	[redacted] / 85
ABBV-951		97.32	SC /ONCE	[redacted] / 86	
ABBV-951	2006.31		SC /CONTINUOUS	[redacted] / 86	[redacted] / 86
ABBV-951		32.44	SC /ONCE	[redacted] / 87	
ABBV-951	2050.70		SC /CONTINUOUS	[redacted] / 87	[redacted] / 87
ABBV-951		64.88	SC /ONCE	[redacted] / 88	
ABBV-951	1938.01		SC /CONTINUOUS	[redacted] / 88	[redacted] / 88
ABBV-951		97.32	SC /ONCE	[redacted] / 89	
ABBV-951	1614.44		SC /CONTINUOUS	[redacted] / 89	[redacted] / 89
ABBV-951		97.32	SC /ONCE	[redacted] / 90	
ABBV-951	2057.87		SC /CONTINUOUS	[redacted] / 90	[redacted] / 90
ABBV-951		129.77	SC /ONCE	[redacted] / 91	
ABBV-951	2357.03		SC /CONTINUOUS	[redacted] / 91	[redacted] / 91
ABBV-951		97.32	SC /ONCE	[redacted] / 92	
ABBV-951	2376.84		SC /CONTINUOUS	[redacted] / 92	[redacted] / 92
ABBV-951		129.77	SC /ONCE	[redacted] / 93	
ABBV-951	2376.84		SC /CONTINUOUS	[redacted] / 93	[redacted] / 93
ABBV-951		32.44	SC /ONCE	[redacted] / 94	
ABBV-951	2331.07		SC /CONTINUOUS	[redacted] / 94	[redacted] / 94
ABBV-951		32.44	SC /ONCE	[redacted] / 95	
ABBV-951	2329.71		SC /CONTINUOUS	[redacted] / 95	[redacted] / 95
ABBV-951		64.88	SC /ONCE	[redacted] / 96	
ABBV-951	2257.99		SC /CONTINUOUS	[redacted] / 96	[redacted] / 96
ABBV-951		32.44	SC /ONCE	[redacted] / 97	
ABBV-951	2376.84		SC /CONTINUOUS	[redacted] / 97	[redacted] / 97
ABBV-951	2376.84		SC /CONTINUOUS	[redacted] / 98	[redacted] / 98
ABBV-951		64.88	SC /ONCE	[redacted] / 99	
ABBV-951	2327.32		SC /CONTINUOUS	[redacted] / 99	[redacted] / 99
ABBV-951		97.32	SC /ONCE	[redacted] / 100	
ABBV-951	2411.33		SC /CONTINUOUS	[redacted] / 100	[redacted] / 100
ABBV-951		97.32	SC /ONCE	[redacted] / 101	
ABBV-951	2356.17		SC /CONTINUOUS	[redacted] / 101	[redacted] / 101
ABBV-951		97.32	SC /ONCE	[redacted] / 102	
ABBV-951	2177.40		SC /CONTINUOUS	[redacted] / 102	[redacted] / 102
ABBV-951		97.32	SC /ONCE	[redacted] / 103	
ABBV-951	2319.80		SC /CONTINUOUS	[redacted] / 103	[redacted] / 103
ABBV-951		64.88	SC /ONCE	[redacted] / 104	

ABBV-951	2270.63		SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 105	
ABBV-951	2093.73		SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 106	
ABBV-951	2425.67		SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 107	
ABBV-951	2339.27		SC /CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	2639.79		SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 109	
ABBV-951	2808.83		SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 110	
ABBV-951	2812.93		SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	2772.98		SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 112	
ABBV-951	2800.98		SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 113	
ABBV-951	2856.98		SC /CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 114	
ABBV-951	2808.83		SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 115	
ABBV-951	2737.12		SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	2839.57		SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 117	
ABBV-951	2715.26		SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 118	
ABBV-951	3077.25		SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	2976.51		SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	3006.90		SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	2832.74		SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	2832.74		SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	2766.15		SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	2945.09		SC /CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129

ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 131	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 133	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 134	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 135	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 141	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 142	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 143	
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	3196.44		SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
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ABBV-951	2660.28		SC /CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
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ABBV-951	2868.6	SC /CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
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ABBV-951	2868.6	SC /CONTINUOUS	[redacted]20[redacted] / 242	[redacted]20[redacted] / 242
ABBV-951	2868.6	SC /CONTINUOUS	[redacted]20[redacted] / 243	[redacted]20[redacted] / 243
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ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 274	
ABBV-951	2296.92		SC /CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
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ABBV-951	2387.08		SC /CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 276

Previous Therapy - Prior to baseline/enrollment

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

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

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

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

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

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

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

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

Event Description	INFUSION SITE DISCOMFORT
Preferred Term	注入部位不快感
AE Onset Date / RX Day	[redacted]20[redacted] / 3
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	4
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 3
Age at AE Onset	5[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	22
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

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

Event Description	TINGLING AT INFUSION SITE
Preferred Term	注入部位異常感覚
AE Onset Date / RX Day	[redacted]20[redacted] / 3
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	3
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CANNULA DISCOMFORT (SLIGHT) AT INFUSION SITE
Preferred Term	注入部位不快感
AE Onset Date / RX Day	[redacted]20[redacted] / 8
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	

AE Stopped RX Day	8
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

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

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

Event Description	NODULE AT INFUSION SITE
Preferred Term	注射部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 15
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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	MEDICATION POOLING UNDER SKIN, AT INFUSION SITE
Preferred Term	注入部位血管外漏出
AE Onset Date / RX Day	[redacted]20[redacted] / 22
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	22
Duration of AE	1 DAY

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

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

Event Description	DRUG DRIPPED FROM THE SKIN FOR 30 MINUTES. AT INFUSION SITE
Preferred Term	注入部位血管外漏出
AE Onset Date / RX Day	[redacted]20[redacted] / 22
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	22
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL ILLUSIONS
Preferred Term	幻視
AE Onset Date / RX Day	[redacted]20[redacted] / 31
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	43
Duration of AE	13 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	A CONE SHAPED POOLING OF MEDICATION UNDER THE SKIN
Preferred Term	投与部位漏出
AE Onset Date / RX Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	107
Duration of AE	74 DAYS

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

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

Event Description	ABDOMEN REDNESS AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	107
Duration of AE	74 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ABDOMEN INFUSION SITE INFECTION

Preferred Term	注入部位感染
AE Onset Date / RX Day	[redacted]20[redacted] / 34
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	107
Duration of AE	74 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CONE-SHAPED AREA POOLING OF MEDICATION AT INFUSION SITE
Preferred Term	注入部位血管外漏出
AE Onset Date / RX Day	[redacted]20[redacted] / 36
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	47
Duration of AE	12 DAYS
Severity	MODERATE

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

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

Event Description	FALL- TRIPPED
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 40
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	40
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	REDNESS AT THE INFUSION SITE
Preferred Term	注入部位紅斑

AE Onset Date / RX Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	70
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	REDNESS AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 49
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	107
Duration of AE	59 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	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 #18: Event of Interest - Infusion Site Related Non Infection Reactions

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

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

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

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

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

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

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

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	70
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	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 #21: Event of Interest - Infusion Site Related Non Infection Reactions

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

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

Event Description	REDNESS AROUND INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

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

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

Event Description	CONE SHAPED 10 CM SIZE NODULE AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	78
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

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

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

Event Description	WARM TO TOUCH AROUND THE SITE AT INFUSION SITE
Preferred Term	注入部位熱感
AE Onset Date / RX Day	[redacted]20[redacted] / 68
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	78
Duration of AE	11 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #25: Event of Interest - Hallucinations/Psychosis

Event Description	RARE VISUAL ILLUSIONS
Preferred Term	幻視
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	296
Duration of AE	205 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	MODERATE ERYTHEMA, READILY VISIBLE; OR MINIMAL AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	113
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	EDEMA AT THE INFUSION SITE
Preferred Term	注入部位浮腫
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	113
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	SLIGHT GLAZED APPEARANCE AT THE INFUSION SITE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	113
Duration of AE	22 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	RAKE HIT; RIGHT FOREHEAD BRUISE
Preferred Term	挫傷
AE Onset Date / RX Day	[redacted]20[redacted] / 107
Age at AE Onset	5[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	114
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CUT RIGHT FINGER
Preferred Term	皮膚裂傷
AE Onset Date / RX Day	[redacted]20[redacted] / 107
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	114
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #31: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	346
Duration of AE	163 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	2 CM BRUISE LEFT ABDOMEN AT INFUSION SITE
Preferred Term	注入部位内出血
AE Onset Date / RX Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	211
Duration of AE	28 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

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

Event #34: Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOSIS
Preferred Term	精神病性障害
AE Onset Date / RX Day	[redacted]20[redacted] / 184
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	

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

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

Event Description	TINGLING SENSATION AT INFUSION SITE UPON INSERTION OF [redacted]
Preferred Term	注入部位異常感覚
AE Onset Date / RX Day	[redacted]20[redacted] / 233
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	233
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #36: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / RX Day	[redacted]20[redacted] / 240
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #37: Event of Interest - Polyneuropathy

Event Description	FACE NUMB
Preferred Term	感覚鈍麻
AE Onset Date / RX Day	[redacted]20[redacted] / 265
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	266

Duration of AE	2 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

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

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

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

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

Event Description	CELLULITIS INFECTION LEFT THIGH AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 326
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	40 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	SKIN REDNESS AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 326
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365 (12 DAYS AFTER LAST TREATMENT)

Duration of AE	40 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

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

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

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

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

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	

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

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

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

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

Event Description	SKIN PEELING AT THE INFUSION SITE
Preferred Term	注入部位皮膚剥脱
AE Onset Date / RX Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	GLAZING AT INFUSION SITE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 346
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	365 (12 DAYS AFTER LAST TREATMENT)
Duration of AE	20 DAYS

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

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

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

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

Event Description	SKIN GLAZING CRACKING AT INFUSION SITE

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

Generated: [redacted]20[redacted]: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。本被験者は米国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，精神病を発現した。

Event 38 の臨床経過：

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

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

投与 294 日目，被験者は精神病を発現した。

投与 294 日目，被験者はストーキングされていると信じていたが，夫と姉妹に信用されなかったため口論となった。被験者は車に乗り道に迷うまで運転した。その後，被験者が他人のドアをノックしたため，救急隊が呼ばれ被験者は病院に運ばれた。同日，被験者は入院した。検査は問題がなかったが，被験者は非重篤の低体温を発現した。投与 296 日目，被験者は退院した。
被験者に幻覚及び精神病の病歴のリスク因子があった。
被験者にセロクエルが投与された。

The patient's past medications include:

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of PSYCHOSIS

- Investigator: Not applicable

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

Relevant Laboratory & Other Diagnostic Tests

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

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

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

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

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

Reason for Narrative

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

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

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

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

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

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

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

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

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

Daily Dose (mg LD) by Molecular Weight

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

ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	1666.00		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	1670.95		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 23	
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 24	
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 25	
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	1721.16		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 27	
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ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 296	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 297	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
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ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 301	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 302	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 303	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 304	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 305	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 306	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 307	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
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ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 314	
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ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
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ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 319	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
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ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 321	
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ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 329	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 330	
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ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 334	
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ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 335	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 336	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 337	
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ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 352	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 353	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 354	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
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ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 357	
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ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 361	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 362	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 363	
ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
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ABBV-951	1803.12		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 365	
ABBV-951	1853.66		SC /CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 366	
ABBV-951	1934.25		SC /CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366

Previous Therapy - Prior to baseline/enrollment

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

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

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

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

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

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

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

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

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

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	INFECTION LOWER ABDOMEN AT THE INFUSION SITE
Preferred Term	注入部位感染
AE Onset Date / RX Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	DEFINITE EDEMA AT INFUSION SITE
Preferred Term	注入部位浮腫
AE Onset Date / RX Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	SLIGHT GLAZED IN APPEARANCE AT INFUSION SITE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 14
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	

NOT APPLICABLE

AE Stopped RX Day	22
Duration of AE	9 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	65
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

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

Event Description	SLIGHTLY GLAZED APPEARANCE AT INFUSION SITE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	65
Duration of AE	35 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #8: Event of Interest - Polyneuropathy

Event Description	TINGLING IN FINGER TIPS
Preferred Term	錯感覚
AE Onset Date / RX Day	[redacted]20[redacted] / 31
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	

AE Stopped RX Day	31
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Hallucinations/Psychosis

Event Description	VISUAL ILLUSIONS
Preferred Term	幻視
AE Onset Date / RX Day	[redacted]20[redacted] / 43
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	52
Duration of AE	10 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 46
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	65
Duration of AE	20 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ERYTHEMA AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	106
Duration of AE	15 DAYS

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

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

Event Description	SMALL NODULES AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	106
Duration of AE	15 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	PAPULES AT INFUSION SITE

Preferred Term	注入部位丘疹
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	106
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	MARKED GLAZING AT INFUSION SITE
Preferred Term	注入部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 92
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	106
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY

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

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

Event Description	INTRACEREBRAL HEMORRHAGE
Preferred Term	脳出血
AE Onset Date / RX Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #16: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	RIGHT FACE TRAUMA
Preferred Term	顔面損傷

AE Onset Date / RX Day [redacted]20[redacted] / 108

Age at AE Onset 7[redacted]

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM 04/18/2019. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

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

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

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

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A

SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM 04/18/2019. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

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

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

Event Description	ACTIVE FACIAL BLEEDING RELATED TO AE 12302011
Preferred Term	出血
AE Onset Date / RX Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

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

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM 04/18/2019. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

AE Stopped RX Day	120
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	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	GAIT DISORDER
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

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

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

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV

CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM [redacted]/[redacted]/20[redacted]. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

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

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

Event Description	PAIN SURROUNDING EYE RELATED TO AE 12302011
Preferred Term	眼窩周囲痛
AE Onset Date / RX Day	[redacted]20[redacted] / 108
Age at AE Onset	7[redacted]

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM [redacted]/[redacted]/20[redacted]. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

AE Stopped RX Day	120
Duration of AE	13 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

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

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

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

Laboratory Testing

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

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 108): CT ABD/PELVIS W/ IV DUAL /TRIPLE PHASE, CT CHEST W/ IV CONTRAST:NO ACUTE TRAUMATIC FINDINGS IN THE CHEST. 2.6 X 2.9 X 4.4 CM HYPODENSE LESION ARISING FROM THE RIGHT LOBE OF THE THYROID, WHICH MAY REPRESENT GOITER. RECOMMEND NON-EMERGENT FOLLOWUP THYROID ULTRASOUND FOR FURTHER EVALUATION. CARDIOMEGALY. 2.3 X 2.4 CM INTERMEDIATE DENSITY LESION ARISING FROM THE RIGHT KIDNEY, RECOMMEND F/U NON-EMERGENT RENAL ULTRASOUND. MIXED SCLEROTIC AND LUCENT MULTIOCULAR LEFT ISCHIAL LESION AS DIESCRIBED ABOVE WITH FEATURES SUGGESTING BENIGN ETIOLOGY.. SCLEROTIC LESION WITHIN L5 VERTEBRAL BODY, WHICH MAY RESPRESENT A BONE ISLAND. IN THE SETTING OF ENLARGED PROSTATE.; CT CERVICAL SPINE:NO DEFINITE EVIDENCE OF A RECENT FRACTURE INVOLVING THE CERVICAL VERTEBRAE. NO SIGNIFICANT CENTRAL CANAL COMPROMISE AT ANY LEVEL OF THE CERVICAL SPINE. GRADE 1 ANTEROLISTHESIS AT THE C4-C5 LEVEL, LIKE LY DEGENERATIVE IN NATURE.; CT HEAD W/O IV CONTRAST:SUGGESTIVE OF ISCHEMIC CHANGE INVOLVING THE R PERIETO-OCCIPITAL REGION, OF UNCERTAIN AGE, MAYBE SUBACUTE.THERE IS NOTE OF ADJACENT CURVICLINEAR HYPERATTENUATION, WHICH MAY REPRESENT GYRAL PETECHIAL HEMORRHAGE, A SMALL AMOUNT OF SUBARACHNOID HEMORRHAGE WOULD BE DIFFICULT TO EXCLUDE, THESE ARE NOT SEEN ON PRIOR STUDY. NO SIGNIFICANT INTTRACRANIAL MASS EFFECT.NO DEFINITE EVIDENCE OF CALVARIAL FRACTURE. EXTENSIVE SOFT TISSUE EDEMA OVERLYING THE R FRONTAL REGION THE RIGHT MASTICATOR SPACE, INVOLVING THE R PRESEPTAL SOFT TISSUES, W/ NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE R LATERAL ORBITAL WALL; CT HEAD W/O IV CONTRAST- CONTINUATION:AGE RELATED VOLUME LOSS OF FINDINGS SUGGESTIVE OF MILD TO MODERATE SMALL VESSEL DISEASE.; CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:THERE IS A MINIMALLY DISPLACED FRACTURE INVOLVING THE POSTEROLATERAL WALL OF THE RIGHT MAXILLARY SINUS. QUESTIONABLE NON-DISPLACED FRACTURE INVOLVING THE RIGHT POSTERIOR

ORBITAL FLOOR. EXTENSIVE RIGHT -SIDED FACIAL SOFT TISSUE EDEMA AS DISCUSSED ABOVE WITH NOTE OF MORE DISCRETE HEMATOMA OVERLYING THE RIGHT LATERAL ORBITAL WALL; CTA NECK:CALCIFIED PLAQUES CAUSE MILD NARROWING AT THE ORIGINS OF BOTH VERTEBRAL ARTERIES. NO DEFINITE EVIDENCE OF SIGNIFICANT STENOSIS INVOLVING THE CERVICAL CAROTID ARTERIES. NO DEFINITE EVIDENCE OF A DISSECTION OF THE CERVICAL CAROTID OR VERTEBRAL ARTERIES. THERE IS NOTE OF AN ASYMMETRICALLY ENLARGED RIGHT THYROID LOBE WITH A COMPONENT WHICH EXTENDS INTO THE SUPERIOR MEDIASTINUM. THIS WAS ONLY PARTIALL Y INCLUDED IN THE FIELD OF VIEW ON THE PRIOR STUDY.; [redacted]20[redacted] (RX DAY 109): MRI BRAIN/ HEAD WITHOUT CONTRAST:NO ACUTE INFARCTION; ABNORMALITY SEEN ON RECENT HEAD CT LIKELY CORRESPONDS TO A SUBACUTE INFARCTION, THOUGH NEW FROM [redacted]/[redacted]/20[redacted]. RIGHT FRONTOPARIETAL SCALP CONTUSION AND THIN RIGHT FRONTOPARIETAL SUBD URAL HEMATOMA. NO SIGNIFICANT MASS EFFECT. WHITE MATTER CHANGES OF ADVANCED CHRONIC MICROVASCULAR DISEASE.

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

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

Event Description	MINIMAL ERYTHEMA, BARELY PERCEPTIBLE AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 185
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	204
Duration of AE	20 DAYS
Severity	MILD

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

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

Event Description	REDNESS AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #24: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN PEELING AT THE INFUSION SITE
Preferred Term	注入部位皮膚剥脱

AE Onset Date / RX Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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	RAISED NODULE AT INFUSION SITE
Preferred Term	注射部位結節
AE Onset Date / RX Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #26: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN GLAZING AT INFUSION SITE
Preferred Term	注射部位反応
AE Onset Date / RX Day	[redacted]20[redacted] / 358
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #27: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION AT INFUSION SITE
Preferred Term	注射部位感染
AE Onset Date / RX Day	[redacted]20[redacted] / 360
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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。本被験者は米国の 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，転倒（偶発的），意識消失，右顔面外傷，右眼窩周囲腫脹及び眼周囲痛，並びに活動性顔面出血を発現した。

Event 16，17，18，19，20，及び 21 の臨床経過：

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

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

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

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

治験責任医師によると，被験者は過去にも転倒していたが入院はしていなかった。

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

The patient's past medications include:

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

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

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

- Investigator: Gait disorder Parkinson Disease

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

Event of PAIN SURROUNDING EYE, ACTIVE FACIAL BLEEDING

- Investigator: Gait disorder

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

Relevant Laboratory & Other Diagnostic Tests

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

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

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

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

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

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

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

[redacted] **20[redacted] CT MAXILLOFACIAL AREA/ SINUS W/O CONTRAST IV:** There is a minimally displaced fracture involving the posterolateral wall of the right maxillary sinus. Questionable non-displaced

fracture involving the Right Posterior orbital floor. Extensive right-sided facial soft tissue edema as discussed above with note of more discrete hematoma overlying the right lateral orbital wall

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

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

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

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

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

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

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

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

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

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

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

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

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

Reason for Narrative

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

Disc = Discontinued.

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

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

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

Prior Procedures	Procedure Year
HYSTERECTOMY	20[redacted]

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

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

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.17	0.2	0	60	0.11	[redacted]/1
ABBV-951 CSCI	0.17	0.2	0	60	0.11	[redacted]/2
ABBV-951 CSCI	0.17	0.18	0	660	0.11	[redacted]/8
ABBV-951 CSCI	0.2	0.22	0.18	60	0.11	[redacted]/17
ABBV-951 CSCI	0.23	0.24	0.22	60	0.11	[redacted]/22
ABBV-951 CSCI	0.27	0.28	0.26	60	0.11	[redacted]/29
ABBV-951 CSCI	0.3	0.31	0.28	60	0.11	[redacted]/43
ABBV-951 CSCI	0.3	0.31	0.24	60	0.11	[redacted]/99

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	87.08		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	690.85		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	690.85		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951	690.85		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951	701.09		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		18.78	SC /ONCE	[redacted] / 9	
ABBV-951	690.85		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		37.56	SC /ONCE	[redacted] / 10	
ABBV-951	690.85		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	720.22		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		37.56	SC /ONCE	[redacted] / 12	
ABBV-951	734.56		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12

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

ABBV-951	1137.87		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 35	
ABBV-951	1113.97		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1137.87		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 37	
ABBV-951	1099.63		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1081.53		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1074.18		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1101.84		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1101.84		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	1092.62		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 44	
ABBV-951	1194.73		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 45	
ABBV-951	1254.50		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 46	
ABBV-951	1265.08		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	1152.73		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 48	
ABBV-951	1188.24		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 49	
ABBV-951	1142.65		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	1051.82		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 51	
ABBV-951	1188.93		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	1206.51		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 53	
ABBV-951	1193.88		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	1261.15		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 55	
ABBV-951	1205.83		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 56	
ABBV-951	1248.86		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56

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

ABBV-951	1196.95		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1137.87		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1137.87		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 84	
ABBV-951	1051.82		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1047.03		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	1197.29		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 87	
ABBV-951	1249.20		SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 88	
ABBV-951	1259.79		SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 89	
ABBV-951	1259.79		SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 90	
ABBV-951	1249.20		SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1259.79		SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1259.79		SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 93	
ABBV-951	1249.20		SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		37.56	SC /ONCE	[redacted]20[redacted] / 94	
ABBV-951	1233.32		SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 95	
ABBV-951	1243.91		SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951		75.13	SC /ONCE	[redacted]20[redacted] / 96	
ABBV-951	1238.62		SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		56.34	SC /ONCE	[redacted]20[redacted] / 97	
ABBV-951	1254.50		SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 98	
ABBV-951	1259.79		SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 99	
ABBV-951	1243.91		SC /CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1230.93		SC /CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1214.03		SC /CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	1203.78		SC /CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1208.91		SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1219.15		SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1224.27		SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105

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

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

Previous Therapy - Prior to baseline/enrollment

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

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

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

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

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

Event Description	CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 81
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

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

Event #3: Serious Adverse Event

Event Description	SEPSIS
Preferred Term	敗血症
AE Onset Date / RX Day	[redacted]20[redacted] / 81
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

NOT REPORTED

AE Stopped RX Day	101
Duration of AE	21 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to	CAUSAL RELATIONSHIP

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

Event 1，2，及び 3 の臨床経過：

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

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

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

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

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

The patient's past medications include:

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

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

PENICILLIN for UNKNOWN INDICATION

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

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

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

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

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of SEPSIS

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

Event of CELLULITIS AT INFUSION SITE, ABSCESS AT INFUSION SITE

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

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

Reason for Narrative

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

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

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

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

Prior Procedures	Procedure Year

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

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

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

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.27	0.3	0.22	60	0.11	[redacted]20[redacted]/1
ABBV-951 CSCI	0.19	0.22	0.16	60	0.11	[redacted]20[redacted]/2
ABBV-951 CSCI	0.27	0.31	0.22	60	0.11	[redacted]20[redacted]/8
ABBV-951 CSCI	0.31	0.36	0.26	60	0.11	[redacted]20[redacted]/16
ABBV-951 CSCI	0.31	0.36	0.26	60	0.11	[redacted]20[redacted]/19
ABBV-951 CSCI	0.31	0.36	0.26	60	0.11	[redacted]20[redacted]/29
ABBV-951 CSCI	0.36	0.41	0.3	60	0.15	[redacted]20[redacted]/40
ABBV-951 CSCI	0.4	0.45	0.32	60	0.15	[redacted]20[redacted]/96
ABBV-951 CSCI	0.43	0.46	0.34	60	0.11	[redacted]20[redacted]/183
ABBV-951 CSCI	0.46	0.5	0.37	60	0.11	[redacted]20[redacted]/200
ABBV-951 CSCI	0.46	0.5	0.37	60	0.15	[redacted]20[redacted]/215
ABBV-951 CSCI	0.47	0.5	0.4	60	0.15	[redacted]20[redacted]/274
ABBV-951 CSCI	0.5	0.52	0.42	60	0.19	[redacted]20[redacted]/341
ABBV-951 CSCI	0.52	0.57	0.46	60	0.19	[redacted]20[redacted]/354
ABBV-951 CSCI	0.52	0.57	0.46	60	0.19	[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	901.56		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		56.34	SC /ONCE	[redacted] / 6	
ABBV-951	518.39		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		93.91	SC /ONCE	[redacted] / 7	
ABBV-951	882.77		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		18.78	SC /ONCE	[redacted] / 8	
ABBV-951	1128.14		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		18.78	SC /ONCE	[redacted] / 14	
ABBV-951	1231.61		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		18.78	SC /ONCE	[redacted] / 15	
ABBV-951	1249.20		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15
ABBV-951	1270.38		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		18.78	SC /ONCE	[redacted] / 17	
ABBV-951	1238.62		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		18.78	SC /ONCE	[redacted] / 18	
ABBV-951	1366.17		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951	1475.28		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951	1475.28		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951	1475.28		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 228
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 229	[redacted]20[redacted] / 229
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
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ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 237	[redacted]20[redacted] / 237
ABBV-951	1311.36	SC /CONTINUOUS	[redacted]20[redacted] / 238	[redacted]20[redacted] / 238
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ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 272	
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ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 273	
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ABBV-951	1516.26	SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
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ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
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ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
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ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
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ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
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ABBV-951		194.65	SC /ONCE	[redacted]20[redacted] / 363	

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

Previous Therapy - Prior to baseline/enrollment

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

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

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

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

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

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

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

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

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

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

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

Event #3: Event of Interest - Weight Loss

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

Event #4: Event of Interest - Weight Loss

Event Description	PT LOST 9 POUNDS IN 3 MONTHS
Preferred Term	体重減少
AE Onset Date / RX Day	[redacted]20[redacted] / 96
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	274
Duration of AE	179 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	CELLULITIS AT OLD INFUSION SITE (RIGHT SIDE OF ABDOMEN)
Preferred Term	注入部位蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 279
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	284
Duration of AE	6 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE

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

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

Event Description	SUBCUTANEOUS HEMATOMA AT OLD INFUSION SITE SITE
Preferred Term	注入部位血腫
AE Onset Date / RX Day	[redacted]20[redacted] / 281
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	284
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Serious Adverse Event

Event Description	CHEST PAIN OF UNDETERMINED ETIOLOGY
Preferred Term	胸痛
AE Onset Date / RX Day	[redacted]20[redacted] / 304
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 318): HEMOGLOBIN: 122 [117 - 161] G/L; NPTST131-GLOMERULAR FILTRATION RATE: 89 ML/MIN [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST300-TROPONIN: LESS THAN 2 MG PER L [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 318): ECG:ECG ABNORMAL OF UNCERTAIN SIGNIFICANCE: ST DEPRESSION IN LATERAL; [redacted]20[redacted] (RX DAY 320): CORONAROGRAPHY:NORMAL

AE Stopped RX Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
Other Cause of Event	HOSPITAL PHYSICIAN ORDERED A CONSULTATION IN GASTROENTEROLOGY, SO GASTRIC ORIGIN SUSPECTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Generated: [redacted]20[redacted]: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。本被験者はカナダの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，原因不明の胸痛を発現した。

Event 7 の臨床経過：

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

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

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

投与304日目，被験者は原因不明の胸痛を発現した。

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

被験者にNITRO DURが投与された。

The patient's past medications include:

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

RASAGILINE for PARKINSON'S DISEASE ([redacted])

AMANTADINE for PARKINSON'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of CHEST PAIN OF UNDETERMINED ETIOLOGY

- Investigator:

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

Relevant Laboratory & Other Diagnostic Tests

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

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

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

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

Reason for Narrative

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

Disc = Discontinued.

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

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

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

Prior Procedures	Procedure Year
NOT REPORTED	

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

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

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

Daily Dose (mg LD) by Molecular Weight

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

ABBV-951	1219.15		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 9	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951		194.65	SC /ONCE	[redacted]20[redacted] / 14	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951		227.09	SC /ONCE	[redacted]20[redacted] / 15	
ABBV-951	1359.17		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951		97.32	SC /ONCE	[redacted]20[redacted] / 16	
ABBV-951	1493.20		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	1689.91		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	1762.14		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	1915.81		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	1951.16		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 21	
ABBV-951	1782.80		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 22	
ABBV-951	1329.11		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	1346.87		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	1461.44		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951	1638.17		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951	1516.26		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	1626.73		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1500.03		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1347.38		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1002.30		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	928.88		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	911.80		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37

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ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	785.45		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	816.18		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	839.74		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 72	
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 73	

ABBV-951	1024.5		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 86	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 89	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 92	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 93	
ABBV-951	1101.84		SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 94	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 96	
ABBV-951	1288.30		SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 97	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 98	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 99	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 100	

ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 102	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 103	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 106	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 107	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 110	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 113	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 114	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1351.31		SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 116	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 117	
ABBV-951	1288.82		SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 120	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951		76.83	SC /ONCE	[redacted]20[redacted] / 121	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 124	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124

ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 128	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 130	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 131	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 134	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 135	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 138	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 141	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 142	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 144	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 145	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 148	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 149	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149

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ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 151	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 152	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 156	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 158	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 159	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 162	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 163	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
REBAMIPIDE	100 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]
MAGNESIUM OXIDE	330 mg	TID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted]
DROXIDOPA	200.000 mg	TID	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	40.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
MIDODRINE	4 mg	BID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA	50.000 mg	BID	Y-M: 20[redacted]-[redacted] / -335

MONOHYDRATE;ENTACAPONE;LEVODOPA			
CYANOCOBALAMIN	2 OTHER: TAB	QD	Y-M: 20[redacted] / -26

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

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

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

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

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

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

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

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSION
Preferred Term	妄想
AE Onset Date / RX Day	[redacted]20[redacted] / 30
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	83
Duration of AE	54 DAYS

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

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

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

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

Event Description	ABRASION WOUND(UPPER LIP,RIGHT CHEEK,UNDER THE NOSE)
Preferred Term	皮膚損傷
AE Onset Date / RX Day	[redacted]20[redacted] / 32
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	36
Duration of AE	5 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	FALL(SLIPPED.)
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 51
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	51

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

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

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

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

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 146
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	146
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]: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] 歳女性であり，アッヴィ社の ABBV-951 の治験で ABBV-951 が投与され，幻覚を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。
投与 18 日目，被験者は幻覚を発現した。投与 83 日目，幻覚は消失した。

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

The patient's past medications include:

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATION

- Investigator: Not applicable.

- AbbVie: Not applicable.

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

Reason for Narrative

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

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

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

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

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

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

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

Study Drug Prescription

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

Daily Dose (mg LD) by Molecular Weight

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

ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	1898.74		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 28	
ABBV-951	1851.44		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	1869.20		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951	1926.06		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	1953.55		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951		122.94	SC /ONCE	[redacted]20[redacted] / 42	
ABBV-951	1862.54		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 43	
ABBV-951	2125.83		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
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ABBV-951	2294.88		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
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ABBV-951	2004.26		SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		81.96	SC /ONCE	[redacted]20[redacted] / 91	
ABBV-951	1819.17		SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951		40.98	SC /ONCE	[redacted]20[redacted] / 92	

ABBV-951	2165.79	SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
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ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
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ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
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ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
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ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128

ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	2294.88	SC /CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
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ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340

ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951	1393.32	SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951	1647.73	SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951	1607.26	SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]
ROPINIROLE	2.000 mg	TID	Y-M: 20[redacted]-[redacted]
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	9.000 mg	QD	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	40.000 mg	QD	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	4.500 mg	QD	Y-M: 20[redacted]-[redacted]

ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	BID	Y-M: 20[redacted]
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT	2.5 g	QD	Y-M: 20[redacted]
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted]
ZONISAMIDE	50.000 mg	QD	Y-M: 20[redacted]
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted]
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
SILODOSIN	4 mg	BID	Y-M: 20[redacted]
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]
DIMETICONE	40 mg	TID	Y-M: 20[redacted]
BENSERAZIDE	100.000 mg	QD	Y-M: 20[redacted]

HYDROCHLORIDE;LEVODOPA			
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	200.000 mg	TID	Y-M: 20[redacted]
BENSERAZIDE HYDROCHLORIDE;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted]
RASAGILINE MESYLATE	0.500 mg	QD	Y-M: 20[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted] / -344
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331
ISTRADEFYLLINE	20.000 mg	QD	Y-M: 20[redacted] / -325
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / -321
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]	ONGOING
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]	ONGOING
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]	ONGOING
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]	ONGOING
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]	ONGOING
ATRACTYLODES LANCEA RHIZOME;CITRUS AURANTIUM PEEL;GLYCYRRHIZA SPP. ROOT;PANAX GINSENG ROOT;PINELLIA TERNATA TUBER;PORIA COCOS	2.5 g	QD	Y-M: 20[redacted]	ONGOING

SCLEROTIUM;ZINGIBER OFFICINALE RHIZOME;ZIZIPHUS JUJUBA FRUIT				
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]	ONGOING
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]	ONGOING
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]	ONGOING
SILODOSIN	4 mg	BID	Y-M: 20[redacted]	ONGOING
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]	ONGOING
DIMETICONE	40 mg	TID	Y-M: 20[redacted]	ONGOING
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	TID	Y-M: 20[redacted]	ONGOING
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331	ONGOING
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / -321	Y-M: 20[redacted] / 23
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191	ONGOING
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153	ONGOING
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65	ONGOING
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 12	Y-M: 20[redacted] / 43
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 44	ONGOING
CAMPHOR;ENOXOLONE;LEVOMENTHOL;METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	ONGOING
CLOBETASONE BUTYRATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	Y-M: 20[redacted] / 92

DIFLUPREDNATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 79	Y-M: 20[redacted] / 92
CLOBETASOL PROPIONATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	BID	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
DIFLUPREDNATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	BID	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
EFINACONAZOLE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 92	Y-M: 20[redacted] / 135
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135	ONGOING
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136	ONGOING
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190	ONGOING
CEFAZOLIN SODIUM	1 g	BID	Y-M: 20[redacted] / 202	Y-M: 20[redacted] / 212
PROCAINE HYDROCHLORIDE	5 mL	OTHER: ONCE	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 203
BACITRACIN;NEOMYCIN SULFATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 205
SODIUM CHLORIDE	20 mL	QD	Y-M: 20[redacted] / 203	Y-M: 20[redacted] / 212
GENTAMICIN SULFATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	QD	Y-M: 20[redacted] / 205	Y-M: 20[redacted] / 212

Event #1: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MILD ERYTHEMA(INFUSION SITE)
Preferred Term	注入部位紅斑
AE Onset Date / RX Day	[redacted]20[redacted] / 6
Age at AE Onset	7[redacted]
Laboratory Testing	

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	273
Duration of AE	268 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	RASH(ABDOMEN,INFUSION SITE)
Preferred Term	注入部位発疹
AE Onset Date / RX Day	[redacted]20[redacted] / 51
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	135
Duration of AE	85 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event

Event Description	CELLULITIS(LEFT LOWER LIMB)
Preferred Term	蜂巣炎
AE Onset Date / RX Day	[redacted]20[redacted] / 199
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 202): NPTST056-C-REACTIVE PROTEIN: 2.51 [0 - 0.3] MG/DL; [redacted]20[redacted] (RX DAY 204): NPTST056-C-REACTIVE PROTEIN: 1.78 [0 - 0.3] MG/DL; [redacted]20[redacted] (RX DAY 208): NPTST056-C-REACTIVE PROTEIN: 1.12 [0 - 0.14] MG/DL; [redacted]20[redacted] (RX DAY 212): NPTST056-C-REACTIVE PROTEIN: 0.33 [0 - 0.14] MG/DL

Microbiology

NOT REPORTED

SAE Supplemental Procedure

[redacted]20[redacted] (RX DAY 203): HAMATOMA REMOVAL(MEDIAL SIDE OF LEFT KNEE):HEMATOMA WAS ABSENT AND IMPROVED.

AE Stopped RX Day	219
Duration of AE	21 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	INFECTION.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #4: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 288
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	288
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Falls and Associated Injuries

Event Description	RIGHT RIB FRACTURE
Preferred Term	肋骨骨折
AE Onset Date / RX Day	[redacted]20[redacted] / 289
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

SAE Supplemental Procedure

NOT APPLICABLE

AE Stopped RX Day	364
Duration of AE	76 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]: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 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，蜂巣炎（左下肢）を発現した。

Event 3 の臨床経過：

関連する病歴は，脳梗塞，心房細動，高血圧，パーキンソン病，元喫煙者（1 日 1 本を 37 年間）及び現飲酒者（1 日 2 杯未満）であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 199 日目，被験者は蜂巣炎（左下肢）を発現した。

投与 219 日目，蜂巣炎（左下肢）は消失した。

入院前の投与 199 日目，被験者は自宅で転倒し，左膝を打った。その後，腫脹，発赤，及び疼痛が発現した。投与 200 日目，被験者は発赤及び腫脹のため近医を受診した。左膝の内側に局所的な血液の蓄積（血腫）があったため，左膝を部分的に切開した。

投与 202 日目，被験者は「強い腫脹」，発赤及び持続する疼痛があった。また，熱感とともに下肢に腫脹及び発赤が広がっていた。被験者は別の医療機関の皮膚科医を受診した。被験者は膝の周りに「強い皮下出血」があり，炎症が増したため，蜂巣炎と診断された。発熱はなかった。被験者は直ちに治療のため，他の病院に入院した。投与 203 日目，1 日 2 回の注射用セファゾリンの投与が開始された。左膝の周りにいくつかの血腫がみつかり，除去のために部分的な切開を行った。投与 205 日目，血腫の除去後，血腫又は血液の蓄積は観察されなかったが，治験薬の管理が困難であったため，被験者は治験実施医療機関に転院した。左膝に対しゲンタシンによる治療が追加され，弾性包帯で覆われた。投与 212 日目，セファゾリンの投与は中止された。

腫脹，疼痛及び膝の周りの炎症は改善し，ゲンタシンによる治療は中止された。投与 219 日目，被験者の蜂巣炎は消失したことが確認され，被験者は退院した。
　被験者にセファゾリンナトリウム，生理食塩液，バラマイシン及びゲンタシンが投与された。

The patient's past medications include:

ROPINIROLE for ALZHEIMER'S DISEASE ([redacted])

ROPOLE for PARKINSON’S DISEASE ([redacted])

SELEGILINE for PARKINSON’S DISEASE ([redacted])

MENESIT for PARKINSON’S DISEASE ([redacted])

ROTIGOTINE for PARKINSON’S DISEASE ([redacted])

ISTRADEFYLINE for PARKINSON’S DISEASE ([redacted])

ZONISAMIDE for PARKINSON’S DISEASE ([redacted])

ENTACAPONE for PARKINSON’S DISEASE ([redacted])

STALEVO for PARKINSON’S DISEASE ([redacted])

LEVODOPA BENSERAZIDE HYDROCHLORIDE for ALZHEIMER'S DISEASE ([redacted])

Causality for ABBV-951 (Open Label)

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1)　Cellulitis of leg (10007912)　(Cellulitis (10007882))　[v.23.1]　[10007912]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS (LEFT LOWER LIMB)

- Investigator: Infection

- AbbVie: More likely related to reported skin injury due to the fall in an advanced age patient.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CRP:** 2.51 mg/dL (normal <0.30)

[redacted] **20[redacted] CRP:** 1.78 mg/dL (normal <0.30)

[redacted] **20[redacted] CRP:** 1.12 mg/dL (normal 0.00 to 0.14)

[redacted] **20[redacted] CRP:** 0.33 mg/dL (normal 0.00 to 0.14)

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注射部位腫脹				X
嫉妬妄想				X
パーキンソン病	X			

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	ASIAN

Medical History	Onset Year
KINDNEY STONE	19[redacted]
MENOPAUSE	19[redacted]
UTERINE FIBROID	20[redacted]
CONSTIPATION DUE TO PD	20[redacted]
ANXIETY DUE TO PD	20[redacted]
CHRONIC GASTRITIS	20[redacted]
BACK PAIN	20[redacted]
SPINAL CANAL STENOSIS	20[redacted]
RIBFRACTURE(RIGHT 9TH RIB)	20[redacted]
OSTEOPOROSIS	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
KINDNEY STONE LITHOTRIPSY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.2	0.24	0.17	60	0.11	[redacted]/1
ABBV-951 CSCI	0.2	0.24	0.17	60	0.11	[redacted]/2
ABBV-951 CSCI	0.2	0.22	0.17	60	0.11	[redacted]/8
ABBV-951 CSCI	0.2	0.22	0.17	60	0.11	[redacted]/14
ABBV-951 CSCI	0.2	0.22	0.17	60	0.15	[redacted]/21
ABBV-951 CSCI	0.17	0.2	0	300	0.15	[redacted]/23
ABBV-951 CSCI	0.2	0.22	0.18	300	0.15	[redacted]/28
ABBV-951 CSCI	0.2	0.22	0.18	300	0.15	[redacted]/31
ABBV-951 CSCI	0.2	0.22	0.18	300	0.15	[redacted]/42
ABBV-951 CSCI	0.23	0.28	0.18	300	0.15	[redacted]/85
ABBV-951 CSCI	0.27	0.3	0.22	300	0.15	[redacted]/92
ABBV-951 CSCI	0.27	0.3	0.22	300	0.15	[redacted]/182
ABBV-951 CSCI	0.27	0.3	0.22	180	0.15	[redacted]/245
ABBV-951 CSCI	0.27	0.3	0.22	180	0.15	[redacted]/273
ABBV-951 CSCI	0.3	0.31	0.22	180	0.15	[redacted]/364

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951	467.85		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	819.6		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	819.6		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951	819.6		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951	819.6		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951	799.11		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6

ABBV-951	795.69		SC /CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
ABBV-951	437.12		SC /CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 12	
ABBV-951	351.74		SC /CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 13	
ABBV-951	809.35		SC /CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
ABBV-951	805.94		SC /CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
ABBV-951		18.78	SC /ONCE	[redacted]20[redacted] / 20	
ABBV-951	802.52		SC /CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 26	
ABBV-951	750.44		SC /CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 27	
ABBV-951	685.04		SC /CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
ABBV-951	715.61		SC /CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 40	
ABBV-951	728.41		SC /CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40

ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 41	
ABBV-951	728.41		SC /CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
ABBV-951	737.64		SC /CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
ABBV-951	770.76		SC /CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76

ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
ABBV-951	819.6		SC /CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
ABBV-951	870.82		SC /CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
ABBV-951	916.92		SC /CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
ABBV-951	942.54		SC /CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 90	
ABBV-951	911.12		SC /CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
ABBV-951		25.61	SC /ONCE	[redacted]20[redacted] / 91	
ABBV-951	1044.99		SC /CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
ABBV-951	1129.85		SC /CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
ABBV-951	1106.46		SC /CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111

ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 124	[redacted]20[redacted] / 124
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 132	[redacted]20[redacted] / 132
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 133	[redacted]20[redacted] / 133
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 134	[redacted]20[redacted] / 134
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 142
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 143	[redacted]20[redacted] / 143
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 144	[redacted]20[redacted] / 144
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 145	[redacted]20[redacted] / 145
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 146	[redacted]20[redacted] / 146
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 147
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148

ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 150	[redacted]20[redacted] / 150
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 157
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 158	[redacted]20[redacted] / 158
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
ABBV-951	1106.46	SC /CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177

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ABBV-951	1208.91		SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 364	
ABBV-951	1229.4		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PRAMIPEXOLE	3.000 mg	QD	Y-M: 20[redacted]-[redacted]
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	50.000 mg	TID	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	20.000 mg	QD	Y-M: 20[redacted]-[redacted]
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]-[redacted]
REBAMIPIDE	100 mg	QD	Y-M: 20[redacted]-[redacted]
FLURBIPROFEN	40 mg	BID	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted]
PREGABALIN	50 mg	BID	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;ENTACAPONE;LEVODOPA	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
TIZANIDINE	1 mg	BID	Y-M: 20[redacted]-[redacted]
RISEDRONATE SODIUM	17.5 mg	OTHER: EVERY WEEK	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]-[redacted]
VONOPRAZAN FUMARATE	10 mg	QD	Y-M: 20[redacted]-[redacted]
ZONISAMIDE	25.000 mg	BID	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.125 mg	QD	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA;LEVODOPA	100.000 mg	QD	Y-M: 20[redacted]-[redacted]
RASAGILINE MESYLATE	0.500 mg	QD	Y-M: 20[redacted]-[redacted] / -279

PRAMIPEXOLE	0.375 mg	QD	Y-M: 20[redacted] / -278
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted] / -271
PARACETAMOL	600 mg	BID	Y-M: 20[redacted] / -237
PRAMIPEXOLE	0.750 mg	QD	Y-M: 20[redacted] / -229
CYANOCOBALAMIN	2 OTHER: TAB	QD	Y-M: 20[redacted] / -75
MECOBALAMIN	1000 ug	TID	Y-M: 20[redacted] / -28

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 91
LOXOPROFEN	60 mg	QD	Y-M: 20[redacted]	ONGOING
REBAMIPIDE	100 mg	QD	Y-M: 20[redacted]	ONGOING
FLURBIPROFEN	40 mg	BID	Y-M: 20[redacted]	ONGOING
PREGABALIN	50 mg	BID	Y-M: 20[redacted]	ONGOING
TIZANIDINE	1 mg	BID	Y-M: 20[redacted]	ONGOING
RISEDRONATE SODIUM	17.5 mg	OTHER: EVERY WEEK	Y-M: 20[redacted]	ONGOING
VONOPRAZAN FUMARATE	10 mg	QD	Y-M: 20[redacted]	ONGOING
PARACETAMOL	600 mg	BID	Y-M: 20[redacted] / -237	ONGOING
MECOBALAMIN	1000 ug	TID	Y-M: 20[redacted] / -28	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 31	Y-M: 20[redacted] / 42
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 42	Y-M: 20[redacted] / 210
DIFLUCORTOLONE VALERATE;LIDOCAINE	1.45 g	QD	Y-M: 20[redacted] / 76	Y-M: 20[redacted] / 364
INDOMETACIN	70 mg	QD	Y-M: 20[redacted] / 84	Y-M: 20[redacted] / 364
GENTAMICIN	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 205	Y-M: 20[redacted] / 273
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 210	ONGOING
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 245
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 245	ONGOING

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	JEALOUSY DELUSION
Preferred Term	嫉妬妄想

AE Onset Date / RX Day	[redacted]20[redacted] / 22
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	245
Duration of AE	224 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	WORSENING OF PARKINSON'S DISEASE
Preferred Term	パーキンソン病
AE Onset Date / RX Day	[redacted]20[redacted] / 70
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped RX Day	94
Duration of AE	25 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	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	DUE TO THE SPREAD OF COVID-19 INFECTION, THE USUAL REHABILITATION COULD NOT BE PERFORMED, AND THE PATIENT WAS HOSPITALIZED FOR IMPROVEMENT OF MOTOR SYMPTOMS.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #3: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SWELLING AT THE INJECTION SITE(UPPER RIGHT ABDOMEN)
Preferred Term	注射部位腫脹
AE Onset Date / RX Day	[redacted]20[redacted] / 195
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	273
Duration of AE	79 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]: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 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 が投与され，パーキンソン病の悪化を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，パーキンソン病による不安，パーキンソン病の悪化であった。

投与 1 日目から投与 4 週時まで，本被験者は本試験の最適化期にて最適な臨床反応を達成するため治験薬の調整を必要とした。投与 5 週時，本被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 70 日目，被験者はパーキンソン病の悪化を発現した。投与 94 日目，パーキンソン病の悪化は消失した。被験者は別の病院でリハビリテーションを受けていた。COVID-19 感染の蔓延により，他の施設で定期的に行われていたリハビリテーションができなくなり，パーキンソン病の運動症状が悪化した。徴候及び症状には，すくみ足が含まれていた。投与 70 日目，被験者は定期的な検査で診察を受けた。投与 83 日目，被験者は運動症状を改善する目的で入院した。投与 95 日目，被験者は退院した。

治験責任医師によると，被験者は投与 5 年前，投与 4 年前，投与 3 年前，投与 2 年前，及び投与 1 年前にパーキンソン病の悪化を発現した。

被験者にインドメタシンが投与された。

The patient's past medications include:

QUETIAPINE for JEALOUSY DELUSION ([redacted] 20[redacted] - [redacted] 20[redacted], Started [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease aggravated (10034006) (Parkinson's disease (10061536)) [v.23.1] [10034006]

Causality as per reporter (Drug/Vaccine): No reasonable possibility

Causality as per Mfr. (Drug/Vaccine): No reasonable possibility

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF PARKINSON’S DISEASE

- Investigator: Due to the spread of covid-19 infection, the usual rehabilitation could not be performed, and the patient was hospitalized for improvement of motor symptoms.

- AbbVie: More likely related to history of Parkinson's disease and reported the usual rehabilitation could not be performed.

被験者番号 [redacted] (Investigator [redacted])

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
妄想	X			X
転倒				X
幻覚	X			X
注入部位蜂巣炎				X
注入部位皮膚炎				X
注入部位紅斑				X
靭帯捻挫				X
筋肉痛				X
肋骨骨折				X

Treatment Group	Age at Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	ASIAN

Medical History	Onset Year
RIGHT CATARACT	20[redacted]
HYPER URICEMIA	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
REM SLEEP BEHAVIOR DISORDER	20[redacted]
FREQUENCY URINARY	20[redacted]
CRASH SYNDROME	20[redacted]
FILMY VISION	20[redacted]
HEADACHES	20[redacted]
ANTI-HCV POSITIVE	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	NEVER			
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	Less than 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951 CSCI	0.27	0.31	0.23	120	0.19	[redacted]/1
ABBV-951 CSCI	0.27	0.31	0.23	120	0.19	[redacted]/2
ABBV-951 CSCI	0.29	0.31	0.25	120	0.24	[redacted]/7
ABBV-951 CSCI	0.29	0.31	0.25	120	0.24	[redacted]/14
ABBV-951 CSCI	0.31	0.33	0.27	120	0.24	[redacted]/21
ABBV-951 CSCI	0.33	0.35	0.29	120	0.24	[redacted]/22
ABBV-951 CSCI	0.35	0.37	0.31	120	0.24	[redacted]/23
ABBV-951 CSCI	0.37	0.39	0.3	120	0.24	[redacted]/27
ABBV-951 CSCI	0.34	0.37	0.27	120	0.24	[redacted]/28
ABBV-951 CSCI	0.3	0.32	0.24	120	0.24	[redacted]/29
ABBV-951 CSCI	0.25	0.3	0.2	120	0.19	[redacted]/42
ABBV-951 CSCI	0.26	0.31	0.21	120	0.19	[redacted]/49
ABBV-951 CSCI	0.27	0.32	0.22	120	0.19	[redacted]/57
ABBV-951 CSCI	0.28	0.33	0.23	120	0.19	[redacted]/63
ABBV-951 CSCI	0.29	0.34	0.24	120	0.19	[redacted]/70
ABBV-951 CSCI	0.27	0.32	0.22	120	0.19	[redacted]/76
ABBV-951 CSCI	0.29	0.34	0.24	120	0.19	[redacted]/82
ABBV-951 CSCI	0.3	0.36	0.24	120	0.19	[redacted]/89
ABBV-951 CSCI	0.32	0.38	0.25	120	0.19	[redacted]/99
ABBV-951 CSCI	0.33	0.4	0.26	120	0.19	[redacted]/104
ABBV-951 CSCI	0.37	0.44	0.3	120	0.19	[redacted]/111

ABBV-951 CSCI	0.4	0.48	0.32	120	0.3	[redacted]/135
ABBV-951 CSCI	0.4	0.48	0.32	60	0.3	[redacted]/153
ABBV-951 CSCI	0.43	0.52	0.34	60	0.3	[redacted]/182
ABBV-951 CSCI	0.52	0.56	0.34	60	0.3	[redacted]/275
ABBV-951 CSCI	0.52	0.56	0.34	60	0.3	[redacted]/365

Daily Dose (mg LD) by Molecular Weight

Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
ABBV-951		32.44	SC /ONCE	[redacted] / 1	
ABBV-951	548.61		SC /CONTINUOUS	[redacted] / 1	[redacted] / 1
ABBV-951	1106.46		SC /CONTINUOUS	[redacted] / 2	[redacted] / 2
ABBV-951	1106.46		SC /CONTINUOUS	[redacted] / 3	[redacted] / 3
ABBV-951		32.44	SC /ONCE	[redacted] / 4	
ABBV-951	1106.46		SC /CONTINUOUS	[redacted] / 4	[redacted] / 4
ABBV-951		64.88	SC /ONCE	[redacted] / 5	
ABBV-951	1097.23		SC /CONTINUOUS	[redacted] / 5	[redacted] / 5
ABBV-951		97.32	SC /ONCE	[redacted] / 6	
ABBV-951	1064.96		SC /CONTINUOUS	[redacted] / 6	[redacted] / 6
ABBV-951		81.96	SC /ONCE	[redacted] / 7	
ABBV-951	1075.04		SC /CONTINUOUS	[redacted] / 7	[redacted] / 7
ABBV-951		122.94	SC /ONCE	[redacted] / 8	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 8	[redacted] / 8
ABBV-951		163.92	SC /ONCE	[redacted] / 9	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 9	[redacted] / 9
ABBV-951		204.9	SC /ONCE	[redacted] / 10	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 10	[redacted] / 10
ABBV-951		163.92	SC /ONCE	[redacted] / 11	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 11	[redacted] / 11
ABBV-951		40.98	SC /ONCE	[redacted] / 12	
ABBV-951	1178.51		SC /CONTINUOUS	[redacted] / 12	[redacted] / 12
ABBV-951		81.96	SC /ONCE	[redacted] / 13	
ABBV-951	1138.90		SC /CONTINUOUS	[redacted] / 13	[redacted] / 13
ABBV-951		122.94	SC /ONCE	[redacted] / 14	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 14	[redacted] / 14
ABBV-951		40.98	SC /ONCE	[redacted] / 15	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 15	[redacted] / 15

ABBV-951		163.92	SC /ONCE	[redacted] / 16	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951		122.94	SC /ONCE	[redacted] / 17	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 17	[redacted] / 17
ABBV-951		40.98	SC /ONCE	[redacted] / 18	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 18	[redacted] / 18
ABBV-951		122.94	SC /ONCE	[redacted] / 19	
ABBV-951	1183.46		SC /CONTINUOUS	[redacted] / 19	[redacted] / 19
ABBV-951		122.94	SC /ONCE	[redacted] / 20	
ABBV-951	1178.51		SC /CONTINUOUS	[redacted] / 20	[redacted] / 20
ABBV-951		122.94	SC /ONCE	[redacted] / 21	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 21	[redacted] / 21
ABBV-951		122.94	SC /ONCE	[redacted] / 22	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 22	[redacted] / 22
ABBV-951		122.94	SC /ONCE	[redacted] / 23	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 23	[redacted] / 23
ABBV-951		81.96	SC /ONCE	[redacted] / 24	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 24	[redacted] / 24
ABBV-951		81.96	SC /ONCE	[redacted] / 25	
ABBV-951	1188.42		SC /CONTINUOUS	[redacted] / 25	[redacted] / 25
ABBV-951	1171.68		SC /CONTINUOUS	[redacted] / 26	[redacted] / 26
ABBV-951		81.96	SC /ONCE	[redacted] / 27	
ABBV-951	1323.48		SC /CONTINUOUS	[redacted] / 27	[redacted] / 27
ABBV-951		40.98	SC /ONCE	[redacted] / 28	
ABBV-951	1269.86		SC /CONTINUOUS	[redacted] / 28	[redacted] / 28
ABBV-951		81.96	SC /ONCE	[redacted] / 29	
ABBV-951	1115.68		SC /CONTINUOUS	[redacted] / 29	[redacted] / 29
ABBV-951	673.09		SC /CONTINUOUS	[redacted] / 30	[redacted] / 30
ABBV-951		64.88	SC /ONCE	[redacted] / 42	
ABBV-951	320.15		SC /CONTINUOUS	[redacted] / 42	[redacted] / 42
ABBV-951		129.77	SC /ONCE	[redacted] / 43	
ABBV-951	950.22		SC /CONTINUOUS	[redacted] / 43	[redacted] / 43
ABBV-951		32.44	SC /ONCE	[redacted] / 44	
ABBV-951	949.37		SC /CONTINUOUS	[redacted] / 44	[redacted] / 44
ABBV-951		64.88	SC /ONCE	[redacted] / 45	
ABBV-951	947.66		SC /CONTINUOUS	[redacted] / 45	[redacted] / 45
ABBV-951		64.88	SC /ONCE	[redacted] / 46	

ABBV-951	947.66		SC /CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 47	
ABBV-951	950.22		SC /CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 48	
ABBV-951	951.93		SC /CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 49	
ABBV-951	977.54		SC /CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 50	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 51	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 52	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 53	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 54	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 55	
ABBV-951	988.64		SC /CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 56	
ABBV-951	987.78		SC /CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 57	
ABBV-951	1022.62		SC /CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 58	
ABBV-951	1070.09		SC /CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
ABBV-951		129.77	SC /ONCE	[redacted]20[redacted] / 59	
ABBV-951	1046.69		SC /CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 60	
ABBV-951	1046.69		SC /CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
ABBV-951	1050.96		SC /CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 62	
ABBV-951	1050.96		SC /CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
ABBV-951		32.44	SC /ONCE	[redacted]20[redacted] / 63	
ABBV-951	1071.62		SC /CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
ABBV-951		64.88	SC /ONCE	[redacted]20[redacted] / 64	
ABBV-951	1087.67		SC /CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
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ABBV-951	1709.89		SC /CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 304	
ABBV-951	1823.61		SC /CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 305	
ABBV-951	1762.82		SC /CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 306	
ABBV-951	1736.86		SC /CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 307	
ABBV-951	1800.04		SC /CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 308	
ABBV-951	1763.16		SC /CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 309	
ABBV-951	1792.87		SC /CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
ABBV-951	1798.68		SC /CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 311	
ABBV-951	1998.79		SC /CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 312	
ABBV-951	1909.66		SC /CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
ABBV-951	2130.96		SC /CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 314	
ABBV-951	1921.62		SC /CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 315	
ABBV-951	1766.23		SC /CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315

ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 316	
ABBV-951	1735.50		SC /CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 317	
ABBV-951	1722.18		SC /CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 318	
ABBV-951	1726.62		SC /CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 319	
ABBV-951	1683.93		SC /CONTINUOUS	[redacted]20[redacted] / 319	[redacted]20[redacted] / 319
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 320	
ABBV-951	1735.50		SC /CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 321	
ABBV-951	1792.87		SC /CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 322	
ABBV-951	1744.38		SC /CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 323	
ABBV-951	1765.21		SC /CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
ABBV-951		51.22	SC /ONCE	[redacted]20[redacted] / 324	
ABBV-951	1888.15		SC /CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 325	
ABBV-951	2011.09		SC /CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 326	
ABBV-951	1717.40		SC /CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 327	
ABBV-951	1684.96		SC /CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 328	
ABBV-951	1752.23		SC /CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 329	
ABBV-951	1723.20		SC /CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 330	
ABBV-951	1808.24		SC /CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 331	
ABBV-951	1781.26		SC /CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 332	
ABBV-951	1735.50		SC /CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 333	
ABBV-951	1745.06		SC /CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 334	

ABBV-951	1684.96		SC /CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 335	
ABBV-951	1792.87		SC /CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 336	
ABBV-951	1721.84		SC /CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 337	
ABBV-951	1721.84		SC /CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 338	
ABBV-951	1805.85		SC /CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 338
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 339	
ABBV-951	1741.99		SC /CONTINUOUS	[redacted]20[redacted] / 339	[redacted]20[redacted] / 339
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 340	
ABBV-951	1744.72		SC /CONTINUOUS	[redacted]20[redacted] / 340	[redacted]20[redacted] / 340
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 341	
ABBV-951	1814.38		SC /CONTINUOUS	[redacted]20[redacted] / 341	[redacted]20[redacted] / 341
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 342	
ABBV-951	1745.74		SC /CONTINUOUS	[redacted]20[redacted] / 342	[redacted]20[redacted] / 342
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 343	
ABBV-951	1766.23		SC /CONTINUOUS	[redacted]20[redacted] / 343	[redacted]20[redacted] / 343
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 344	
ABBV-951	1754.28		SC /CONTINUOUS	[redacted]20[redacted] / 344	[redacted]20[redacted] / 344
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 345	
ABBV-951	1823.61		SC /CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 346	
ABBV-951	1772.04		SC /CONTINUOUS	[redacted]20[redacted] / 346	[redacted]20[redacted] / 346
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 347	
ABBV-951	1762.14		SC /CONTINUOUS	[redacted]20[redacted] / 347	[redacted]20[redacted] / 347
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 348	
ABBV-951	1786.38		SC /CONTINUOUS	[redacted]20[redacted] / 348	[redacted]20[redacted] / 348
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 349	
ABBV-951	1746.08		SC /CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 350	
ABBV-951	1804.82		SC /CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 351	
ABBV-951	1747.45		SC /CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 352	
ABBV-951	1802.77		SC /CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352

ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 353	
ABBV-951	1726.62		SC /CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 354	
ABBV-951	1732.42		SC /CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
ABBV-951		204.9	SC /ONCE	[redacted]20[redacted] / 355	
ABBV-951	1750.52		SC /CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 356	
ABBV-951	1744.38		SC /CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 357	
ABBV-951	1766.23		SC /CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 358	
ABBV-951	1722.18		SC /CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 359	
ABBV-951	1762.14		SC /CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 360	
ABBV-951	1792.87		SC /CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 361	
ABBV-951	1733.11		SC /CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 362	
ABBV-951	1358.48		SC /CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 363	
ABBV-951	1811.31		SC /CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951		153.67	SC /ONCE	[redacted]20[redacted] / 364	
ABBV-951	1560.65		SC /CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951		102.45	SC /ONCE	[redacted]20[redacted] / 365	
ABBV-951	1946.55		SC /CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LIMAPROST ALFADEX	5 ug	TID	Y-M: 20[redacted]-[redacted]
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted]-[redacted]
APOMORPHINE HYDROCHLORIDE	3.000 mg	PRN	Y-M: 20[redacted]-[redacted]
ENTACAPONE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
ROTIGOTINE	18.000 mg	QD	Y-M: 20[redacted]-[redacted]
CABERGOLINE	2.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted]-[redacted]
BORIC ACID;EPHEDRINE HYDROCHLORIDE;MAFENIDE	APPLICATION OTHER:	PRN	Y-M: 20[redacted]

HYDROCHLORIDE;TAURINE;ZINC SULFATE	APPLICATION		
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]
UNSPECIFIED HERBAL	5 OTHER: TABLET	PRN	Y-M: 20[redacted]
SELEGILINE	2.500 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	QD	Y-M: 20[redacted]
CARBIDOPA;LEVODOPA	50.000 mg	BID	Y-M: 20[redacted] / -357
ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -294
CARBIDOPA;LEVODOPA	100.000 mg	QID	Y-M: 20[redacted] / -210
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	6.8523 g	TID	Y-M: 20[redacted] / -49
CLONAZEPAM	1.0 mg	PRN	Y-M: 20[redacted] / -15

Other Medications - Medications taken within 30 days prior to each narrative event until AE stopped or end of study

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LIMAPROST ALFADEX	5 ug	TID	Y-M: 20[redacted]	ONGOING
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted]	ONGOING
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted]	ONGOING
UNSPECIFIED HERBAL	5 OTHER: TABLET	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / -7
BORIC ACID;EPHEDRINE HYDROCHLORIDE;MAFENIDE HYDROCHLORIDE;TAURINE;ZINC SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 62
ELOBIXIBAT	10 mg	QD	Y-M: 20[redacted] / -294	ONGOING
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	6.8523 g	TID	Y-M: 20[redacted] / -49	ONGOING
CLONAZEPAM	1.0 mg	PRN	Y-M: 20[redacted] / -15	Y-M: 20[redacted] / -2
SENNOSIDE A+B	24 mg	PRN	Y-M: 20[redacted] / 3	Y-M: 20[redacted] / 84
ZOLPIDEM TARTRATE	5 mg	PRN	Y-M: 20[redacted] / 8	Y-M: 20[redacted] / 84
QUETIAPINE	12.5 mg	PRN	Y-M: 20[redacted] / 9	Y-M: 20[redacted] / 15

LOXOPROFEN	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 15	Y-M: 20[redacted] / 71
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 16	Y-M: 20[redacted] / 25
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 26	Y-M: 20[redacted] / 27
QUETIAPINE	100 mg	QD	Y-M: 20[redacted] / 28	Y-M: 20[redacted] / 76
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 32	Y-M: 20[redacted] / 43
INFLUENZA VACCINE	0.5 mL	QD	Y-M: 20[redacted] / 37	Y-M: 20[redacted] / 37
SUVOREXANT	20 mg	QD	Y-M: 20[redacted] / 44	Y-M: 20[redacted] / 83
RAMELTEON	8 mg	QD	Y-M: 20[redacted] / 48	ONGOING
HYALURONATE SODIUM	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 62	ONGOING
SODIUM PICOSULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 63	ONGOING
QUETIAPINE	125 mg	QD	Y-M: 20[redacted] / 77	Y-M: 20[redacted] / 153
LEMBOREXANT	5 mg	QD	Y-M: 20[redacted] / 89	ONGOING
OXYBUTYNIN HYDROCHLORIDE	73.5 mg	QD	Y-M: 20[redacted] / 94	ONGOING
KETOPROFEN	30 mg	PRN	Y-M: 20[redacted] / 105	Y-M: 20[redacted] / 105
HEPARIN SODIUM	10 mL	QD	Y-M: 20[redacted] / 121	Y-M: 20[redacted] / 121
AMOXICILLIN TRIHYDRATE	250 mg	TID	Y-M: 20[redacted] / 137	Y-M: 20[redacted] / 137
LOXOPROFEN SODIUM	60 mg	PRN	Y-M: 20[redacted] / 141	Y-M: 20[redacted] / 222
REBAMIPIDE	100 mg	PRN	Y-M: 20[redacted] / 141	Y-M: 20[redacted] / 222
QUETIAPINE	125 mg	QD	Y-M: 20[redacted] / 154	Y-M: 20[redacted] / 209
QUETIAPINE	25 mg	PRN	Y-M: 20[redacted] / 210	ONGOING
QUETIAPINE	75 mg	QD	Y-M: 20[redacted] / 210	Y-M: 20[redacted] / 243
DIPHENHYDRAMINE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 246
QUETIAPINE	50 mg	QD	Y-M: 20[redacted] / 244	Y-M: 20[redacted] / 274
QUETIAPINE	37.5 mg	QD	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 350
BROMFENAC SODIUM	1 OTHER: DROP	BID	Y-M: 20[redacted] / 302	ONGOING
BETAMETHASONE SODIUM PHOSPHATE	1 OTHER: DROP	OTHER: 6 TIMES A DAY	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305
CEFDITOREN	100 mg	TID	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305

PIVOXIL				
GATIFLOXACIN	1 OTHER: DROP	OTHER: 6 TIMES A DAY	Y-M: 20[redacted] / 302	Y-M: 20[redacted] / 305
BETAMETHASONE SODIUM PHOSPHATE	1 OTHER: DROP	BID	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 316
GATIFLOXACIN	1 OTHER: DROP	QID	Y-M: 20[redacted] / 306	Y-M: 20[redacted] / 330
CLOBETASOL PROPIONATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 330
GENTAMICIN SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 330
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 351	ONGOING
QUETIAPINE	37.5 mg	QD	Y-M: 20[redacted] / 351	ONGOING

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSION
Preferred Term	妄想
AE Onset Date / RX Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	153
Duration of AE	146 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATION
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 8
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	153
Duration of AE	146 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 13
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
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 #4: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 15
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	15
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Event of Interest - Falls and Associated Injuries, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	MUSCLE PAIN(NECK AND SHOULDER)
Preferred Term	筋肉痛
AE Onset Date / RX Day	[redacted]20[redacted] / 15
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	76
Duration of AE	62 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF DELUSION
Preferred Term	妄想
AE Onset Date / RX Day	[redacted]20[redacted] / 28
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped RX Day	42

Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #7: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATION
Preferred Term	幻覚
AE Onset Date / RX Day	[redacted]20[redacted] / 28
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
SAE Supplemental Procedure	
NOT REPORTED	
AE Stopped RX Day	42
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	REQUIRES OR PROLONGS HOSPITALIZATION

Event #8: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 46
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	46
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #9: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 48
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	48
Duration of AE	1 DAY

Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 49
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	49
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #11: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL

Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 64
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	64
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #12: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / RX Day	[redacted]20[redacted] / 67
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
SAE Supplemental Procedure	
NOT APPLICABLE	
AE Stopped RX Day	67
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY