TABLE 14.3__1.16.2.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症	10/116 (8.6)	13/112 (11.6)	8/78 (10.3)	6/69 (8.7)
節足動物咬傷	0/116	1/112 (0.9)	0/78	0/69
節足動物刺傷	0/116	1/112 (0.9)	0/78	0/69
挫傷	1/116 (0.9)	0/112	0/78	0/69
顔面骨骨折	1/116 (0.9)	1/112 (0.9)	0/78	0/69
転倒	7/116 (6.0)	5/112 (4.5)	3/78 (3.8)	2/69 (2.9)
大腿骨頚部骨折	0/116	0/112	0/78	1/69 (1.4)
大腿骨骨折	1/116 (0.9)	0/112	0/78	0/69
転位骨折	0/116	1/112 (0.9)	0/78	0/69
手骨折	1/116 (0.9)	1/112 (0.9)	2/78 (2.6)	1/69 (1.4)
股関節部骨折	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	0/69
上腕骨骨折	1/116 (0.9)	1/112 (0.9)	0/78	1/69 (1.4)
靭帯捻挫	0/116	1/112 (0.9)	0/78	0/69
四肢損傷	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
肉離れ	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
開放骨折	1/116 (0.9)	1/112 (0.9)	0/78	0/69
処置による疼痛	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
肩甲骨骨折	1/116 (0.9)	1/112 (0.9)	0/78	0/69
外傷性頭蓋内出血	0/116	1/112 (0.9)	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
傷害、中毒および処置合併症	2/64 (3.1)	1/32 (3.1)	0/5	21/116 (18.1)
節足動物咬傷	0/64	0/32	0/5	1/116 (0.9)
節足動物刺傷	0/64	0/32	0/5	1/116 (0.9)
挫傷	0/64	0/32	0/5	1/116 (0.9)
顔面骨骨折	0/64	0/32	0/5	1/116 (0.9)
転倒	0/64	0/32	0/5	14/116 (12.1)
大腿骨頚部骨折	0/64	0/32	0/5	1/116 (0.9)
大腿骨骨折	0/64	0/32	0/5	1/116 (0.9)
転位骨折	0/64	0/32	0/5	1/116 (0.9)
手骨折	1/64 (1.6)	1/32 (3.1)	0/5	3/116 (2.6)
股関節部骨折	0/64	0/32	0/5	2/116 (1.7)
上腕骨骨折	0/64	0/32	0/5	2/116 (1.7)
靭帯捻挫	0/64	0/32	0/5	1/116 (0.9)
四肢損傷	0/64	0/32	0/5	1/116 (0.9)
肉離れ	1/64 (1.6)	0/32	0/5	1/116 (0.9)
開放骨折	0/64	0/32	0/5	1/116 (0.9)
処置による疼痛	0/64	0/32	0/5	1/116 (0.9)
肩甲骨骨折	0/64	0/32	0/5	1/116 (0.9)
外傷性頭蓋内出血	0/64	0/32	0/5	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
臨床検査	5/116 (4.3)	7/112 (6.3)	7/78 (9.0)	10/69 (14.5)
血中葉酸減少	1/116 (0.9)	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
血中ホモシステイン増加	2/116 (1.7)	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
血中ナトリウム減少	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
ヘモグロビン減少	0/116	1/112 (0.9)	0/78	0/69
リンパ球数減少	0/116	0/112	1/78 (1.3)	1/69 (1.4)
プロトロンビン時間延長	1/116 (0.9)	0/112	0/78	0/69
ビタミンB12減少	0/116	1/112 (0.9)	1/78 (1.3)	2/69 (2.9)
ビタミンB6減少	0/116	0/112	2/78 (2.6)	2/69 (2.9)
ビタミンB6増加	0/116	0/112	0/78	1/69 (1.4)
ビタミンD減少	0/116	0/112	0/78	1/69 (1.4)
体重減少	1/116 (0.9)	2/112 (1.8)	2/78 (2.6)	2/69 (2.9)
代謝および栄養障害	3/116 (2.6)	5/112 (4.5)	7/78 (9.0)	8/69 (11.6)
食欲減退	1/116 (0.9)	1/112 (0.9)	0/78	0/69
高ナトリウム血症	0/116	1/112 (0.9)	0/78	0/69
低カリウム血症	1/116 (0.9)	1/112 (0.9)	0/78	0/69
低マグネシウム血症	1/116 (0.9)	1/112 (0.9)	0/78	0/69
鉄欠乏	0/116	2/112 (1.8)	2/78 (2.6)	2/69 (2.9)
ビタミンB群欠乏	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
ビタミンB12欠乏	1/116 (0.9)	1/112 (0.9)	4/78 (5.1)	4/69 (5.8)

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
臨床検査	8/64 (12.5)	1/32 (3.1)	0/5	13/116 (11.2)
血中葉酸減少	1/64 (1.6)	0/32	0/5	2/116 (1.7)
血中ホモシステイン増加	1/64 (1.6)	0/32	0/5	2/116 (1.7)
血中ナトリウム減少	1/64 (1.6)	0/32	0/5	1/116 (0.9)
ヘモグロビン減少	0/64	0/32	0/5	1/116 (0.9)
リンパ球数減少	0/64	0/32	0/5	1/116 (0.9)
プロトロンビン時間延長	0/64	0/32	0/5	1/116 (0.9)
ビタミンB12減少	2/64 (3.1)	0/32	0/5	2/116 (1.7)
ビタミンB6減少	1/64 (1.6)	0/32	0/5	2/116 (1.7)
ビタミンB6増加	1/64 (1.6)	0/32	0/5	1/116 (0.9)
ビタミンD減少	1/64 (1.6)	0/32	0/5	1/116 (0.9)
体重減少	2/64 (3.1)	1/32 (3.1)	0/5	3/116 (2.6)
代謝および栄養障害	8/64 (12.5)	5/32 (15.6)	0/5	9/116 (7.8)
食欲減退	0/64	0/32	0/5	1/116 (0.9)
高ナトリウム血症	0/64	0/32	0/5	1/116 (0.9)
低カリウム血症	1/64 (1.6)	1/32 (3.1)	0/5	2/116 (1.7)
低マグネシウム血症	1/64 (1.6)	0/32	0/5	2/116 (1.7)
鉄欠乏	2/64 (3.1)	1/32 (3.1)	0/5	2/116 (1.7)
ビタミンB群欠乏	1/64 (1.6)	0/32	0/5	1/116 (0.9)
ビタミンB12欠乏	4/64 (6.3)	4/32 (12.5)	0/5	4/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB6欠乏	0/116	0/112	0/78	1/69 (1.4)
筋骨格系および結合組織障害	4/116 (3.4)	9/112 (8.0)	9/78 (11.5)	9/69 (13.0)
関節痛	0/116	1/112 (0.9)	0/78	0/69
背部痛	0/116	1/112 (0.9)	2/78 (2.6)	3/69 (4.3)
滑液包炎	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
出血性関節症	0/116	1/112 (0.9)	0/78	0/69
椎間板変性症	0/116	0/112	1/78 (1.3)	1/69 (1.4)
腰部脊柱管狭窄症	0/116	0/112	1/78 (1.3)	1/69 (1.4)
筋力低下	0/116	1/112 (0.9)	1/78 (1.3)	0/69
筋骨格系胸痛	1/116 (0.9)	1/112 (0.9)	0/78	0/69
筋骨格硬直	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
変形性関節症	1/116 (0.9)	2/112 (1.8)	2/78 (2.6)	2/69 (2.9)
骨粗鬆症	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	2/69 (2.9)
四肢痛	1/116 (0.9)	1/112 (0.9)	0/78	1/69 (1.4)
肩回旋筋腱板症候群	0/116	0/112	0/78	0/69
変形性脊椎症	0/116	0/112	1/78 (1.3)	0/69
腱鞘炎	1/116 (0.9)	0/112	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
代謝および栄養障害 (Cont.)				
ビタミンB6欠乏	1/64 (1.6)	0/32	0/5	1/116 (0.9)
筋骨格系および結合組織障害	10/64 (15.6)	4/32 (12.5)	2/5 (40.0)	17/116 (14.7)
関節痛	0/64	0/32	0/5	1/116 (0.9)
背部痛	3/64 (4.7)	1/32 (3.1)	0/5	3/116 (2.6)
滑液包炎	1/64 (1.6)	0/32	0/5	1/116 (0.9)
出血性関節症	0/64	0/32	0/5	1/116 (0.9)
椎間板変性症	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
腰部脊柱管狭窄症	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
筋力低下	0/64	0/32	1/5 (20.0)	2/116 (1.7)
筋骨格系胸痛	0/64	0/32	0/5	1/116 (0.9)
筋骨格硬直	1/64 (1.6)	0/32	0/5	1/116 (0.9)
変形性関節症	2/64 (3.1)	1/32 (3.1)	1/5 (20.0)	3/116 (2.6)
骨粗鬆症	2/64 (3.1)	0/32	0/5	2/116 (1.7)
四肢痛	0/64	0/32	0/5	2/116 (1.7)
肩回旋筋腱板症候群	1/64 (1.6)	1/32 (3.1)	1/5 (20.0)	2/116 (1.7)
変形性脊椎症	0/64	0/32	0/5	1/116 (0.9)
腱鞘炎	0/64	0/32	0/5	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
斜頚	0/116	1/112 (0.9)	1/78 (1.3)	0/69
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）	0/116	0/112	1/78 (1.3)	0/69
ケラトアカントーマ	0/116	0/112	1/78 (1.3)	0/69
神経系障害	12/116 (10.3)	15/112 (13.4)	14/78 (17.9)	14/69 (20.3)
健忘	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	0/69
平衡障害	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
運動緩慢	0/116	0/112	0/78	0/69
認知障害	2/116 (1.7)	2/112 (1.8)	2/78 (2.6)	3/69 (4.3)
注意力障害	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
浮動性めまい	1/116 (0.9)	0/112	0/78	0/69
薬物離脱性頭痛	0/116	1/112 (0.9)	0/78	0/69
ジスキネジア	0/116	0/112	0/78	1/69 (1.4)
ジストニア	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
伸展性足底反応	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
すくみ現象	0/116	2/112 (1.8)	1/78 (1.3)	2/69 (2.9)
頭蓋内出血	0/116	0/112	1/78 (1.3)	1/69 (1.4)
頭部不快感	1/116 (0.9)	0/112	1/78 (1.3)	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
筋骨格系および結合組織障害 (Cont.)				
斜頚	0/64	0/32	0/5	1/116 (0.9)
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)	0/64	0/32	0/5	1/116 (0.9)
ケラトアカントーマ	0/64	0/32	0/5	1/116 (0.9)
神経系障害	14/64 (21.9)	5/32 (15.6)	1/5 (20.0)	27/116 (23.3)
健忘	0/64	0/32	0/5	1/116 (0.9)
平衡障害	1/64 (1.6)	0/32	0/5	1/116 (0.9)
運動緩慢	1/64 (1.6)	0/32	0/5	1/116 (0.9)
認知障害	3/64 (4.7)	0/32	0/5	3/116 (2.6)
注意力障害	1/64 (1.6)	0/32	0/5	1/116 (0.9)
浮動性めまい	1/64 (1.6)	0/32	0/5	2/116 (1.7)
薬物離脱性頭痛	0/64	0/32	0/5	1/116 (0.9)
ジスキネジア	0/64	0/32	0/5	1/116 (0.9)
ジストニア	1/64 (1.6)	0/32	0/5	1/116 (0.9)
伸展性足底反応	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
すくみ現象	1/64 (1.6)	0/32	0/5	3/116 (2.6)
頭蓋内出血	1/64 (1.6)	0/32	0/5	1/116 (0.9)
頭部不快感	1/64 (1.6)	0/32	0/5	2/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
頭痛	0/116	1/112 (0.9)	0/78	0/69
感覚鈍麻	0/116	0/112	1/78 (1.3)	1/69 (1.4)
反射減弱	1/116 (0.9)	2/112 (1.8)	2/78 (2.6)	1/69 (1.4)
記憶障害	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
オンオフ現象	2/116 (1.7)	5/112 (4.5)	4/78 (5.1)	2/69 (2.9)
錯感覚	1/116 (0.9)	1/112 (0.9)	0/78	0/69
パーキンソン病	2/116 (1.7)	3/112 (2.7)	3/78 (3.8)	3/69 (4.3)
精神運動亢進	0/116	0/112	1/78 (1.3)	0/69
呼吸器ジスキネジア	0/116	0/112	0/78	0/69
痙攣発作	0/116	1/112 (0.9)	0/78	0/69
失神	1/116 (0.9)	2/112 (1.8)	1/78 (1.3)	1/69 (1.4)
一過性脳虚血発作	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
振戦	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
精神障害	13/116 (11.2)	20/112 (17.9)	22/78 (28.2)	22/69 (31.9)
異常な夢	0/116	1/112 (0.9)	0/78	0/69
適応障害	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
攻撃性	1/116 (0.9)	1/112 (0.9)	0/78	0/69
激越	1/116 (0.9)	0/112	0/78	0/69
不安	1/116 (0.9)	2/112 (1.8)	5/78 (6.4)	6/69 (8.7)
歯ぎしり	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
神経系障害 (Cont.)				
頭痛	1/64 (1.6)	0/32	0/5	2/116 (1.7)
感覚鈍麻	0/64	1/32 (3.1)	0/5	2/116 (1.7)
反射減弱	1/64 (1.6)	0/32	0/5	2/116 (1.7)
記憶障害	1/64 (1.6)	1/32 (3.1)	1/5 (20.0)	2/116 (1.7)
オンオフ現象	2/64 (3.1)	0/32	0/5	7/116 (6.0)
錯感覚	0/64	1/32 (3.1)	0/5	2/116 (1.7)
パーキンソン病	2/64 (3.1)	0/32	0/5	7/116 (6.0)
精神運動亢進	0/64	0/32	0/5	1/116 (0.9)
呼吸器ジスキネジア	0/64	1/32 (3.1)	0/5	1/116 (0.9)
痙攣発作	0/64	0/32	0/5	1/116 (0.9)
失神	2/64 (3.1)	1/32 (3.1)	0/5	2/116 (1.7)
一過性脳虚血発作	1/64 (1.6)	0/32	0/5	1/116 (0.9)
振戦	1/64 (1.6)	0/32	0/5	1/116 (0.9)
精神障害	19/64 (29.7)	7/32 (21.9)	1/5 (20.0)	33/116 (28.4)
異常な夢	0/64	0/32	0/5	1/116 (0.9)
適応障害	1/64 (1.6)	0/32	0/5	1/116 (0.9)
攻撃性	0/64	0/32	0/5	1/116 (0.9)
激越	0/64	0/32	0/5	1/116 (0.9)
不安	5/64 (7.8)	1/32 (3.1)	1/5 (20.0)	8/116 (6.9)
歯ぎしり	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
錯乱状態	0/116	0/112	1/78 (1.3)	1/69 (1.4)
譫妄	1/116 (0.9)	2/112 (1.8)	0/78	0/69
妄想	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
抑うつ気分	0/116	0/112	1/78 (1.3)	1/69 (1.4)
うつ病	2/116 (1.7)	3/112 (2.7)	3/78 (3.8)	3/69 (4.3)
自傷性皮膚症	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
失見当識	0/116	0/112	0/78	0/69
ギャンブル障害	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
幻覚	4/116 (3.4)	5/112 (4.5)	5/78 (6.4)	5/69 (7.2)
幻嗅	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
幻視	0/116	1/112 (0.9)	1/78 (1.3)	2/69 (2.9)
軽躁	1/116 (0.9)	0/112	0/78	0/69
錯覚	0/116	0/112	2/78 (2.6)	2/69 (2.9)
衝動制御障害	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
衝動行為	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
不眠症	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
消極的思考	0/116	0/112	1/78 (1.3)	1/69 (1.4)
パニック発作	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
妄想症	0/116	0/112	1/78 (1.3)	1/69 (1.4)
精神病性障害	0/116	2/112 (1.8)	2/78 (2.6)	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
錯乱状態	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
譫妄	0/64	0/32	0/5	2/116 (1.7)
妄想	1/64 (1.6)	1/32 (3.1)	0/5	2/116 (1.7)
抑うつ気分	1/64 (1.6)	0/32	0/5	1/116 (0.9)
うつ病	2/64 (3.1)	0/32	0/5	3/116 (2.6)
自傷性皮膚症	0/64	0/32	0/5	1/116 (0.9)
失見当識	1/64 (1.6)	0/32	0/5	1/116 (0.9)
ギャンブル障害	0/64	0/32	0/5	1/116 (0.9)
幻覚	4/64 (6.3)	1/32 (3.1)	0/5	9/116 (7.8)
幻嗅	1/64 (1.6)	0/32	0/5	1/116 (0.9)
幻視	2/64 (3.1)	2/32 (6.3)	0/5	2/116 (1.7)
軽躁	0/64	0/32	0/5	1/116 (0.9)
錯覚	2/64 (3.1)	0/32	0/5	2/116 (1.7)
衝動制御障害	0/64	0/32	0/5	1/116 (0.9)
衝動行為	1/64 (1.6)	0/32	0/5	1/116 (0.9)
不眠症	1/64 (1.6)	0/32	0/5	2/116 (1.7)
消極的思考	1/64 (1.6)	0/32	0/5	1/116 (0.9)
パニック発作	0/64	0/32	0/5	2/116 (1.7)
妄想症	1/64 (1.6)	0/32	0/5	1/116 (0.9)
精神病性障害	1/64 (1.6)	0/32	0/5	2/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
レム睡眠行動障害	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
睡眠障害	1/116 (0.9)	1/112 (0.9)	0/78	0/69
腎および尿路障害	2/116 (1.7)	3/112 (2.7)	2/78 (2.6)	3/69 (4.3)
急性腎障害	1/116 (0.9)	0/112	0/78	0/69
膀胱痙縮	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
血尿	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
水腎症	1/116 (0.9)	1/112 (0.9)	0/78	0/69
水尿管症	1/116 (0.9)	1/112 (0.9)	0/78	0/69
緊張性膀胱	0/116	0/112	0/78	0/69
腎結石症	0/116	0/112	0/78	0/69
蛋白尿	0/116	0/112	0/78	1/69 (1.4)
尿失禁	0/116	0/112	0/78	0/69
生殖系および乳房障害	3/116 (2.6)	4/112 (3.6)	3/78 (3.8)	3/69 (4.3)
良性前立腺肥大症	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
膀胱瘤	0/116	0/112	0/78	0/69
勃起不全	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
生殖器萎縮	0/116	0/112	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
精神障害 (Cont.)				
レム睡眠行動障害	1/64 (1.6)	0/32	0/5	1/116 (0.9)
睡眠障害	0/64	0/32	0/5	1/116 (0.9)
腎および尿路障害	5/64 (7.8)	2/32 (6.3)	0/5	7/116 (6.0)
急性腎障害	0/64	0/32	0/5	1/116 (0.9)
膀胱痙縮	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
血尿	0/64	0/32	0/5	1/116 (0.9)
水腎症	0/64	0/32	0/5	1/116 (0.9)
水尿管症	0/64	0/32	0/5	1/116 (0.9)
緊張性膀胱	1/64 (1.6)	0/32	0/5	1/116 (0.9)
腎結石症	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
蛋白尿	1/64 (1.6)	0/32	0/5	1/116 (0.9)
尿失禁	1/64 (1.6)	0/32	0/5	1/116 (0.9)
生殖系および乳房障害	4/64 (6.3)	1/32 (3.1)	0/5	5/116 (4.3)
良性前立腺肥大症	1/64 (1.6)	0/32	0/5	1/116 (0.9)
膀胱瘤	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
勃起不全	1/64 (1.6)	0/32	0/5	1/116 (0.9)
生殖器萎縮	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
腟脱	0/116	1/112 (0.9)	0/78	0/69
外陰腟乾燥	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
呼吸器、胸郭および縦隔障害	0/116	0/112	1/78 (1.3)	1/69 (1.4)
窒息	0/116	0/112	1/78 (1.3)	0/69
誤嚥	0/116	0/112	1/78 (1.3)	0/69
呼吸困難	0/116	0/112	0/78	1/69 (1.4)
痰貯留	0/116	0/112	0/78	0/69
皮膚および皮下組織障害	0/116	2/112 (1.8)	3/78 (3.8)	4/69 (5.8)
光線角化症	0/116	0/112	1/78 (1.3)	0/69
脱毛症	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
湿疹	0/116	1/112 (0.9)	1/78 (1.3)	2/69 (2.9)
発疹	0/116	1/112 (0.9)	0/78	0/69
蕁麻疹	0/116	0/112	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
生殖系および乳房障害 (Cont.)				
腟脱	0/64	0/32	0/5	1/116 (0.9)
外陰腟乾燥	1/64 (1.6)	0/32	0/5	1/116 (0.9)
呼吸器、胸郭および縦隔障害	1/64 (1.6)	1/32 (3.1)	0/5	3/116 (2.6)
窒息	0/64	0/32	0/5	1/116 (0.9)
誤嚥	0/64	0/32	0/5	1/116 (0.9)
呼吸困難	0/64	0/32	0/5	1/116 (0.9)
痰貯留	1/64 (1.6)	1/32 (3.1)	0/5	1/116 (0.9)
皮膚および皮下組織障害	2/64 (3.1)	0/32	0/5	5/116 (4.3)
光線角化症	0/64	0/32	0/5	1/116 (0.9)
脱毛症	0/64	0/32	0/5	1/116 (0.9)
湿疹	2/64 (3.1)	0/32	0/5	2/116 (1.7)
発疹	0/64	0/32	0/5	1/116 (0.9)
蕁麻疹	0/64	0/32	0/5	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Total (Any Dose)				
血管障害	3/116 (2.6)	7/112 (6.3)	6/78 (7.7)	7/69 (10.1)
血腫	0/116	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
高血圧	0/116	1/112 (0.9)	0/78	0/69
低血圧	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	2/69 (2.9)
起立性高血圧	1/116 (0.9)	1/112 (0.9)	1/78 (1.3)	1/69 (1.4)
起立性低血圧	1/116 (0.9)	3/112 (2.7)	2/78 (2.6)	2/69 (2.9)
表在性血栓性静脈炎	0/116	0/112	1/78 (1.3)	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.
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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Total (Any Dose)				
血管障害	6/64 (9.4)	2/32 (6.3)	1/5 (20.0)	9/116 (7.8)
血腫	1/64 (1.6)	0/32	0/5	1/116 (0.9)
高血圧	0/64	0/32	0/5	1/116 (0.9)
低血圧	1/64 (1.6)	0/32	0/5	2/116 (1.7)
起立性高血圧	1/64 (1.6)	0/32	0/5	1/116 (0.9)
起立性低血圧	2/64 (3.1)	1/32 (3.1)	0/5	3/116 (2.6)
表在性血栓性静脈炎	1/64 (1.6)	1/32 (3.1)	1/5 (20.0)	1/116 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
Any adverse event	28/55 (50.9)	32/51 (62.7)	28/33 (84.8)	23/30 (76.7)
心臓障害	0/55	0/51	0/33	1/30 (3.3)
急性心筋梗塞	0/55	0/51	0/33	0/30
徐脈	0/55	0/51	0/33	1/30 (3.3)
洞性頻脈	0/55	0/51	0/33	0/30
眼障害	0/55	0/51	0/33	1/30 (3.3)
黄斑症	0/55	0/51	0/33	1/30 (3.3)
胃腸障害	5/55 (9.1)	4/51 (7.8)	3/33 (9.1)	4/30 (13.3)
便秘	2/55 (3.6)	2/51 (3.9)	2/33 (6.1)	2/30 (6.7)
嚥下障害	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
胃潰瘍	0/55	0/51	0/33	1/30 (3.3)
胃食道逆流性疾患	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	0/30
悪心	1/55 (1.8)	0/51	0/33	1/30 (3.3)
嘔吐	1/55 (1.8)	0/51	0/33	0/30
一般・全身障害および投与部位の状態	11/55 (20.0)	17/51 (33.3)	11/33 (33.3)	12/30 (40.0)
投与部位漏出	0/55	1/51 (2.0)	1/33 (3.0)	0/30
カテーテル留置部位内出血	0/55	0/51	0/33	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
Any adverse event	21/26 (80.8)	10/12 (83.3)	1/1 (100)	39/55 (70.9)
心臓障害	2/26 (7.7)	0/12	0/1	3/55 (5.5)
急性心筋梗塞	1/26 (3.8)	0/12	0/1	1/55 (1.8)
徐脈	0/26	0/12	0/1	1/55 (1.8)
洞性頻脈	1/26 (3.8)	0/12	0/1	1/55 (1.8)
眼障害	1/26 (3.8)	0/12	0/1	1/55 (1.8)
黄斑症	1/26 (3.8)	0/12	0/1	1/55 (1.8)
胃腸障害	3/26 (11.5)	1/12 (8.3)	0/1	7/55 (12.7)
便秘	2/26 (7.7)	0/12	0/1	3/55 (5.5)
嚥下障害	1/26 (3.8)	0/12	0/1	1/55 (1.8)
胃潰瘍	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
胃食道逆流性疾患	0/26	0/12	0/1	1/55 (1.8)
悪心	0/26	0/12	0/1	2/55 (3.6)
嘔吐	0/26	0/12	0/1	1/55 (1.8)
一般・全身障害および投与部位の状態	10/26 (38.5)	3/12 (25.0)	0/1	21/55 (38.2)
投与部位漏出	0/26	0/12	0/1	1/55 (1.8)
カテーテル留置部位内出血	1/26 (3.8)	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
カテーテル留置部位紅斑	1/55 (1.8)	1/51 (2.0)	0/33	0/30
カテーテル留置部位疼痛	0/55	0/51	0/33	1/30 (3.3)
カテーテル留置部位腫脹	0/55	0/51	0/33	0/30
薬効欠如	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
薬物相互作用	0/55	0/51	0/33	1/30 (3.3)
疲労	1/55 (1.8)	1/51 (2.0)	0/33	2/30 (6.7)
注入部位内出血	1/55 (1.8)	1/51 (2.0)	2/33 (6.1)	1/30 (3.3)
注入部位皮膚炎	0/55	1/51 (2.0)	1/33 (3.0)	0/30
注入部位紅斑	3/55 (5.5)	7/51 (13.7)	4/33 (12.1)	5/30 (16.7)
注入部位血腫	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
注入部位硬結	1/55 (1.8)	1/51 (2.0)	0/33	0/30
注入部位刺激感	0/55	2/51 (3.9)	1/33 (3.0)	1/30 (3.3)
注入部位腫瘤	0/55	0/51	1/33 (3.0)	0/30
注入部位結節	1/55 (1.8)	1/51 (2.0)	0/33	1/30 (3.3)
注入部位浮腫	1/55 (1.8)	0/51	1/33 (3.0)	1/30 (3.3)
注入部位疼痛	1/55 (1.8)	0/51	0/33	0/30
注入部位丘疹	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
注入部位腫脹	0/55	0/51	0/33	1/30 (3.3)
注入部位熱感	1/55 (1.8)	1/51 (2.0)	0/33	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
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	0/26	0/12	0/1	1/55 (1.8)
カテーテル留置部位疼痛	0/26	0/12	0/1	1/55 (1.8)
カテーテル留置部位腫脹	1/26 (3.8)	0/12	0/1	1/55 (1.8)
薬効欠如	1/26 (3.8)	0/12	0/1	1/55 (1.8)
薬物相互作用	0/26	0/12	0/1	1/55 (1.8)
疲労	0/26	0/12	0/1	3/55 (5.5)
注入部位内出血	1/26 (3.8)	1/12 (8.3)	0/1	2/55 (3.6)
注入部位皮膚炎	0/26	0/12	0/1	1/55 (1.8)
注入部位紅斑	3/26 (11.5)	1/12 (8.3)	0/1	11/55 (20.0)
注入部位血腫	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
注入部位硬結	0/26	0/12	0/1	1/55 (1.8)
注入部位刺激感	1/26 (3.8)	0/12	0/1	2/55 (3.6)
注入部位腫瘤	0/26	0/12	0/1	1/55 (1.8)
注入部位結節	1/26 (3.8)	0/12	0/1	2/55 (3.6)
注入部位浮腫	0/26	0/12	0/1	1/55 (1.8)
注入部位疼痛	1/26 (3.8)	0/12	0/1	1/55 (1.8)
注入部位丘疹	1/26 (3.8)	0/12	0/1	1/55 (1.8)
注入部位腫脹	0/26	0/12	0/1	1/55 (1.8)
注入部位熱感	0/26	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位内出血	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
注射部位紅斑	1/55 (1.8)	1/51 (2.0)	0/33	0/30
注射部位結節	1/55 (1.8)	1/51 (2.0)	0/33	0/30
末梢性浮腫	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
穿刺部位紅斑	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
感染症および寄生虫症	4/55 (7.3)	7/51 (13.7)	8/33 (24.2)	9/30 (30.0)
COVID-19	0/55	1/51 (2.0)	0/33	0/30
膀胱炎	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
胃腸炎	1/55 (1.8)	0/51	1/33 (3.0)	0/30
ヘリコバクター性胃炎	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	0/30
ヘリコバクター感染	0/55	0/51	0/33	1/30 (3.3)
注入部位膿瘍	0/55	0/51	1/33 (3.0)	3/30 (10.0)
注入部位蜂巣炎	2/55 (3.6)	2/51 (3.9)	1/33 (3.0)	4/30 (13.3)
注入部位感染	0/55	2/51 (3.9)	1/33 (3.0)	2/30 (6.7)
上咽頭炎	0/55	0/51	1/33 (3.0)	0/30
RSウイルス感染	0/55	0/51	1/33 (3.0)	1/30 (3.3)
上気道感染	0/55	1/51 (2.0)	0/33	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注射部位内出血	1/26 (3.8)	0/12	0/1	1/55 (1.8)
注射部位紅斑	0/26	0/12	0/1	1/55 (1.8)
注射部位結節	0/26	0/12	0/1	1/55 (1.8)
末梢性浮腫	1/26 (3.8)	0/12	0/1	1/55 (1.8)
穿刺部位紅斑	1/26 (3.8)	0/12	0/1	1/55 (1.8)
感染症および寄生虫症	7/26 (26.9)	4/12 (33.3)	0/1	15/55 (27.3)
COVID-19	0/26	0/12	0/1	1/55 (1.8)
膀胱炎	0/26	0/12	0/1	1/55 (1.8)
胃腸炎	0/26	0/12	0/1	1/55 (1.8)
ヘリコバクター性胃炎	0/26	0/12	0/1	1/55 (1.8)
ヘリコバクター感染	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
注入部位膿瘍	2/26 (7.7)	0/12	0/1	3/55 (5.5)
注入部位蜂巣炎	3/26 (11.5)	2/12 (16.7)	0/1	6/55 (10.9)
注入部位感染	2/26 (7.7)	1/12 (8.3)	0/1	3/55 (5.5)
上咽頭炎	0/26	0/12	0/1	1/55 (1.8)
RSウイルス感染	0/26	0/12	0/1	1/55 (1.8)
上気道感染	0/26	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	0/55	0/51	0/33	0/30
傷害、中毒および処置合併症	4/55 (7.3)	4/51 (7.8)	3/33 (9.1)	2/30 (6.7)
節足動物刺傷	0/55	1/51 (2.0)	0/33	0/30
転倒	2/55 (3.6)	2/51 (3.9)	1/33 (3.0)	1/30 (3.3)
大腿骨骨折	1/55 (1.8)	0/51	0/33	0/30
手骨折	1/55 (1.8)	0/51	0/33	0/30
股関節部骨折	0/55	1/51 (2.0)	1/33 (3.0)	0/30
上腕骨骨折	0/55	0/51	0/33	1/30 (3.3)
肉離れ	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
臨床検査	3/55 (5.5)	3/51 (5.9)	4/33 (12.1)	5/30 (16.7)
血中ホモシステイン増加	2/55 (3.6)	2/51 (3.9)	1/33 (3.0)	1/30 (3.3)
血中ナトリウム減少	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
リンパ球数減少	0/55	0/51	1/33 (3.0)	1/30 (3.3)
ビタミンB12減少	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
ビタミンB6減少	0/55	0/51	2/33 (6.1)	2/30 (6.7)
ビタミンB6増加	0/55	0/51	0/33	1/30 (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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
感染症および寄生虫症 (Cont.)				
尿路感染	1/26 (3.8)	0/12	0/1	1/55 (1.8)
傷害、中毒および処置合併症	1/26 (3.8)	0/12	0/1	8/55 (14.5)
節足動物刺傷	0/26	0/12	0/1	1/55 (1.8)
転倒	0/26	0/12	0/1	5/55 (9.1)
大腿骨骨折	0/26	0/12	0/1	1/55 (1.8)
手骨折	0/26	0/12	0/1	1/55 (1.8)
股関節部骨折	0/26	0/12	0/1	1/55 (1.8)
上腕骨骨折	0/26	0/12	0/1	1/55 (1.8)
肉離れ	1/26 (3.8)	0/12	0/1	1/55 (1.8)
臨床検査	3/26 (11.5)	0/12	0/1	6/55 (10.9)
血中ホモシステイン増加	1/26 (3.8)	0/12	0/1	2/55 (3.6)
血中ナトリウム減少	1/26 (3.8)	0/12	0/1	1/55 (1.8)
リンパ球数減少	0/26	0/12	0/1	1/55 (1.8)
ビタミンB12減少	1/26 (3.8)	0/12	0/1	1/55 (1.8)
ビタミンB6減少	1/26 (3.8)	0/12	0/1	2/55 (3.6)
ビタミンB6増加	1/26 (3.8)	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
代謝および栄養障害	1/55 (1.8)	2/51 (3.9)	3/33 (9.1)	4/30 (13.3)
低カリウム血症	0/55	0/51	0/33	0/30
低マグネシウム血症	0/55	0/51	0/33	0/30
鉄欠乏	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
ビタミンB群欠乏	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
ビタミンB12欠乏	0/55	0/51	1/33 (3.0)	1/30 (3.3)
ビタミンB6欠乏	0/55	0/51	0/33	1/30 (3.3)
筋骨格系および結合組織障害	4/55 (7.3)	5/51 (9.8)	5/33 (15.2)	5/30 (16.7)
背部痛	0/55	0/51	0/33	1/30 (3.3)
滑液包炎	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
腰部脊柱管狭窄症	0/55	0/51	1/33 (3.0)	1/30 (3.3)
筋骨格系胸痛	1/55 (1.8)	1/51 (2.0)	0/33	0/30
変形性関節症	1/55 (1.8)	2/51 (3.9)	2/33 (6.1)	2/30 (6.7)
骨粗鬆症	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	2/30 (6.7)
四肢痛	1/55 (1.8)	1/51 (2.0)	0/33	1/30 (3.3)
肩回旋筋腱板症候群	0/55	0/51	0/33	0/30
変形性脊椎症	0/55	0/51	1/33 (3.0)	0/30
腱鞘炎	1/55 (1.8)	0/51	0/33	0/30
斜頸	0/55	1/51 (2.0)	1/33 (3.0)	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
代謝および栄養障害	4/26 (15.4)	2/12 (16.7)	0/1	4/55 (7.3)
低カリウム血症	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
低マグネシウム血症	1/26 (3.8)	0/12	0/1	1/55 (1.8)
鉄欠乏	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
ビタミンB群欠乏	1/26 (3.8)	0/12	0/1	1/55 (1.8)
ビタミンB12欠乏	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
ビタミンB6欠乏	1/26 (3.8)	0/12	0/1	1/55 (1.8)
筋骨格系および結合組織障害	6/26 (23.1)	2/12 (16.7)	1/1 (100)	10/55 (18.2)
背部痛	1/26 (3.8)	0/12	0/1	1/55 (1.8)
滑液包炎	1/26 (3.8)	0/12	0/1	1/55 (1.8)
腰部脊柱管狭窄症	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
筋骨格系胸痛	0/26	0/12	0/1	1/55 (1.8)
変形性関節症	2/26 (7.7)	1/12 (8.3)	1/1 (100)	3/55 (5.5)
骨粗鬆症	2/26 (7.7)	0/12	0/1	2/55 (3.6)
四肢痛	0/26	0/12	0/1	2/55 (3.6)
肩回旋筋腱板症候群	1/26 (3.8)	1/12 (8.3)	1/1 (100)	2/55 (3.6)
変形性脊椎症	0/26	0/12	0/1	1/55 (1.8)
腱鞘炎	0/26	0/12	0/1	1/55 (1.8)
斜頚	0/26	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
神経系障害	4/55 (7.3)	6/51 (11.8)	6/33 (18.2)	7/30 (23.3)
健忘	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	0/30
運動緩慢	0/55	0/51	0/33	0/30
認知障害	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
浮動性めまい	1/55 (1.8)	0/51	0/33	0/30
ジスキネジア	0/55	0/51	0/33	1/30 (3.3)
伸展性足底反応	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
すくみ現象	0/55	2/51 (3.9)	1/33 (3.0)	2/30 (6.7)
頭蓋内出血	0/55	0/51	1/33 (3.0)	1/30 (3.3)
頭痛	0/55	0/51	0/33	0/30
感覚鈍麻	0/55	0/51	0/33	0/30
反射減弱	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	0/30
オンオフ現象	0/55	1/51 (2.0)	2/33 (6.1)	1/30 (3.3)
錯感覚	1/55 (1.8)	1/51 (2.0)	0/33	0/30
パーキンソン病	0/55	1/51 (2.0)	1/33 (3.0)	2/30 (6.7)
呼吸器ジスキネジア	0/55	0/51	0/33	0/30
振戦	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
精神障害	7/55 (12.7)	13/51 (25.5)	11/33 (33.3)	9/30 (30.0)
不安	0/55	2/51 (3.9)	2/33 (6.1)	3/30 (10.0)
歯ぎしり	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
妄想	0/55	1/51 (2.0)	0/33	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
神経系障害	6/26 (23.1)	2/12 (16.7)	0/1	11/55 (20.0)
健忘	0/26	0/12	0/1	1/55 (1.8)
運動緩慢	1/26 (3.8)	0/12	0/1	1/55 (1.8)
認知障害	1/26 (3.8)	0/12	0/1	1/55 (1.8)
浮動性めまい	0/26	0/12	0/1	1/55 (1.8)
ジスキネジア	0/26	0/12	0/1	1/55 (1.8)
伸展性足底反応	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
すくみ現象	1/26 (3.8)	0/12	0/1	3/55 (5.5)
頭蓋内出血	1/26 (3.8)	0/12	0/1	1/55 (1.8)
頭痛	1/26 (3.8)	0/12	0/1	1/55 (1.8)
感覚鈍麻	0/26	1/12 (8.3)	0/1	1/55 (1.8)
反射減弱	0/26	0/12	0/1	1/55 (1.8)
オンオフ現象	1/26 (3.8)	0/12	0/1	2/55 (3.6)
錯感覚	0/26	0/12	0/1	1/55 (1.8)
パーキンソン病	1/26 (3.8)	0/12	0/1	2/55 (3.6)
呼吸器ジスキネジア	0/26	1/12 (8.3)	0/1	1/55 (1.8)
振戦	1/26 (3.8)	0/12	0/1	1/55 (1.8)
精神障害	8/26 (30.8)	3/12 (25.0)	0/1	15/55 (27.3)
不安	2/26 (7.7)	0/12	0/1	4/55 (7.3)
歯ぎしり	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
妄想	0/26	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ気分	0/55	0/51	1/33 (3.0)	1/30 (3.3)
うつ病	1/55 (1.8)	2/51 (3.9)	2/33 (6.1)	2/30 (6.7)
失見当識	0/55	0/51	0/33	0/30
ギャンブル障害	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
幻覚	2/55 (3.6)	4/51 (7.8)	2/33 (6.1)	1/30 (3.3)
幻嗅	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
幻視	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
軽躁	1/55 (1.8)	0/51	0/33	0/30
錯覚	0/55	0/51	1/33 (3.0)	1/30 (3.3)
衝動行為	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
不眠症	0/55	1/51 (2.0)	0/33	0/30
消極的思考	0/55	0/51	1/33 (3.0)	1/30 (3.3)
パニック発作	0/55	0/51	0/33	1/30 (3.3)
妄想症	0/55	0/51	1/33 (3.0)	1/30 (3.3)
精神病性障害	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
レム睡眠行動障害	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
腎および尿路障害	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
膀胱痙縮	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
緊張性膀胱	0/55	0/51	0/33	0/30

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
精神障害 (Cont.)				
抑うつ気分	1/26 (3.8)	0/12	0/1	1/55 (1.8)
うつ病	2/26 (7.7)	0/12	0/1	2/55 (3.6)
失見当識	1/26 (3.8)	0/12	0/1	1/55 (1.8)
ギャンブル障害	0/26	0/12	0/1	1/55 (1.8)
幻覚	1/26 (3.8)	1/12 (8.3)	0/1	4/55 (7.3)
幻嗅	1/26 (3.8)	0/12	0/1	1/55 (1.8)
幻視	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
軽躁	0/26	0/12	0/1	1/55 (1.8)
錯覚	1/26 (3.8)	0/12	0/1	1/55 (1.8)
衝動行為	1/26 (3.8)	0/12	0/1	1/55 (1.8)
不眠症	0/26	0/12	0/1	1/55 (1.8)
消極的思考	1/26 (3.8)	0/12	0/1	1/55 (1.8)
パニック発作	0/26	0/12	0/1	1/55 (1.8)
妄想症	1/26 (3.8)	0/12	0/1	1/55 (1.8)
精神病性障害	1/26 (3.8)	0/12	0/1	1/55 (1.8)
レム睡眠行動障害	1/26 (3.8)	0/12	0/1	1/55 (1.8)
腎および尿路障害	3/26 (11.5)	1/12 (8.3)	0/1	3/55 (5.5)
膀胱痙縮	1/26 (3.8)	1/12 (8.3)	0/1	1/55 (1.8)
緊張性膀胱	1/26 (3.8)	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
腎および尿路障害 (Cont.)				
尿失禁	0/55	0/51	0/33	0/30
生殖系および乳房障害	2/55 (3.6)	2/51 (3.9)	2/33 (6.1)	2/30 (6.7)
良性前立腺肥大症	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
外陰腟乾燥	1/55 (1.8)	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
呼吸器、胸郭および縦隔障害	0/55	0/51	1/33 (3.0)	1/30 (3.3)
窒息	0/55	0/51	1/33 (3.0)	0/30
誤嚥	0/55	0/51	1/33 (3.0)	0/30
呼吸困難	0/55	0/51	0/33	1/30 (3.3)
皮膚および皮下組織障害	0/55	2/51 (3.9)	3/33 (9.1)	3/30 (10.0)
光線角化症	0/55	0/51	1/33 (3.0)	0/30
脱毛症	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
湿疹	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
発疹	0/55	1/51 (2.0)	0/33	0/30
蕁麻疹	0/55	0/51	0/33	1/30 (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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
腎および尿路障害 (Cont.)				
尿失禁	1/26 (3.8)	0/12	0/1	1/55 (1.8)
生殖系および乳房障害	2/26 (7.7)	0/12	0/1	2/55 (3.6)
良性前立腺肥大症	1/26 (3.8)	0/12	0/1	1/55 (1.8)
外陰腟乾燥	1/26 (3.8)	0/12	0/1	1/55 (1.8)
呼吸器、胸郭および縦隔障害	0/26	0/12	0/1	2/55 (3.6)
窒息	0/26	0/12	0/1	1/55 (1.8)
誤嚥	0/26	0/12	0/1	1/55 (1.8)
呼吸困難	0/26	0/12	0/1	1/55 (1.8)
皮膚および皮下組織障害	1/26 (3.8)	0/12	0/1	4/55 (7.3)
光線角化症	0/26	0/12	0/1	1/55 (1.8)
脱毛症	0/26	0/12	0/1	1/55 (1.8)
湿疹	1/26 (3.8)	0/12	0/1	1/55 (1.8)
発疹	0/26	0/12	0/1	1/55 (1.8)
蕁麻疹	0/26	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
Low Dose				
血管障害	0/55	2/51 (3.9)	2/33 (6.1)	3/30 (10.0)
血腫	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (3.3)
低血圧	0/55	0/51	0/33	1/30 (3.3)
起立性低血圧	0/55	1/51 (2.0)	1/33 (3.0)	1/30 (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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
Low Dose				
血管障害	2/26 (7.7)	0/12	0/1	3/55 (5.5)
血腫	1/26 (3.8)	0/12	0/1	1/55 (1.8)
低血圧	0/26	0/12	0/1	1/55 (1.8)
起立性低血圧	1/26 (3.8)	0/12	0/1	1/55 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
Any adverse event	29/61 (47.5)	33/61 (54.1)	29/45 (64.4)	29/39 (74.4)
心臓障害	0/61	0/61	1/45 (2.2)	1/39 (2.6)
左脚ブロック	0/61	0/61	1/45 (2.2)	1/39 (2.6)
耳および迷路障害	0/61	1/61 (1.6)	0/45	0/39
回転性めまい	0/61	1/61 (1.6)	0/45	0/39
眼障害	0/61	2/61 (3.3)	2/45 (4.4)	2/39 (5.1)
眼瞼痙攣	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
眼の異物感	0/61	0/61	0/45	1/39 (2.6)
眼部不快感	0/61	0/61	1/45 (2.2)	1/39 (2.6)
眼充血	0/61	1/61 (1.6)	0/45	1/39 (2.6)
霧視	0/61	0/61	1/45 (2.2)	1/39 (2.6)
胃腸障害	4/61 (6.6)	5/61 (8.2)	3/45 (6.7)	3/39 (7.7)
腹部不快感	0/61	0/61	1/45 (2.2)	0/39
腹部膨満	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
腹痛	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
便秘	2/61 (3.3)	2/61 (3.3)	1/45 (2.2)	1/39 (2.6)
出血性腸憩室	1/61 (1.6)	1/61 (1.6)	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
Any adverse event	30/38 (78.9)	14/20 (70.0)	2/4 (50.0)	49/61 (80.3)
心臓障害	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
左脚ブロック	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
耳および迷路障害	1/38 (2.6)	0/20	0/4	2/61 (3.3)
回転性めまい	1/38 (2.6)	0/20	0/4	2/61 (3.3)
眼障害	2/38 (5.3)	1/20 (5.0)	0/4	3/61 (4.9)
眼瞼痙攣	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
眼の異物感	1/38 (2.6)	0/20	0/4	1/61 (1.6)
眼部不快感	1/38 (2.6)	0/20	0/4	1/61 (1.6)
眼充血	1/38 (2.6)	0/20	0/4	2/61 (3.3)
霧視	1/38 (2.6)	0/20	0/4	1/61 (1.6)
胃腸障害	3/38 (7.9)	1/20 (5.0)	1/4 (25.0)	7/61 (11.5)
腹部不快感	0/38	0/20	0/4	1/61 (1.6)
腹部膨満	0/38	0/20	0/4	1/61 (1.6)
腹痛	1/38 (2.6)	0/20	0/4	1/61 (1.6)
便秘	1/38 (2.6)	1/20 (5.0)	0/4	2/61 (3.3)
出血性腸憩室	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
嚥下障害	1/61 (1.6)	1/61 (1.6)	0/45	0/39
悪心	1/61 (1.6)	2/61 (3.3)	0/45	0/39
吐き戻し	1/61 (1.6)	1/61 (1.6)	0/45	0/39
流涎過多	0/61	0/61	1/45 (2.2)	1/39 (2.6)
一般・全身障害および投与部位の状態	12/61 (19.7)	13/61 (21.3)	8/45 (17.8)	8/39 (20.5)
投与部位内出血	1/61 (1.6)	1/61 (1.6)	0/45	0/39
カテーテル留置部位内出血	0/61	2/61 (3.3)	0/45	0/39
カテーテル留置部位漏出	0/61	1/61 (1.6)	0/45	0/39
カテーテル留置部位炎症	0/61	0/61	0/45	1/39 (2.6)
注入部位内出血	2/61 (3.3)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
注入部位変色	0/61	1/61 (1.6)	0/45	0/39
注入部位紅斑	5/61 (8.2)	4/61 (6.6)	4/45 (8.9)	3/39 (7.7)
注入部位血管外漏出	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
注入部位血腫	1/61 (1.6)	0/61	0/45	0/39
注入部位硬結	0/61	1/61 (1.6)	1/45 (2.2)	2/39 (5.1)
注入部位炎症	0/61	1/61 (1.6)	0/45	0/39
注入部位結節	2/61 (3.3)	1/61 (1.6)	1/45 (2.2)	2/39 (5.1)
注入部位浮腫	1/61 (1.6)	0/61	0/45	0/39
注入部位疼痛	0/61	0/61	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
胃腸障害 (Cont.)				
嚥下障害	0/38	0/20	1/4 (25.0)	2/61 (3.3)
悪心	0/38	0/20	0/4	2/61 (3.3)
吐き戻し	0/38	0/20	0/4	1/61 (1.6)
流涎過多	1/38 (2.6)	0/20	0/4	1/61 (1.6)
一般・全身障害および投与部位の状態	7/38 (18.4)	1/20 (5.0)	0/4	21/61 (34.4)
投与部位内出血	0/38	0/20	0/4	1/61 (1.6)
カテーテル留置部位内出血	0/38	0/20	0/4	2/61 (3.3)
カテーテル留置部位漏出	0/38	0/20	0/4	1/61 (1.6)
カテーテル留置部位炎症	0/38	0/20	0/4	1/61 (1.6)
注入部位内出血	1/38 (2.6)	0/20	0/4	3/61 (4.9)
注入部位変色	0/38	0/20	0/4	1/61 (1.6)
注入部位紅斑	3/38 (7.9)	1/20 (5.0)	0/4	8/61 (13.1)
注入部位血管外漏出	2/38 (5.3)	0/20	0/4	2/61 (3.3)
注入部位血腫	0/38	0/20	0/4	1/61 (1.6)
注入部位硬結	1/38 (2.6)	0/20	0/4	2/61 (3.3)
注入部位炎症	0/38	0/20	0/4	1/61 (1.6)
注入部位結節	2/38 (5.3)	0/20	0/4	3/61 (4.9)
注入部位浮腫	0/38	0/20	0/4	1/61 (1.6)
注入部位疼痛	1/38 (2.6)	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位丘疹	3/61 (4.9)	1/61 (1.6)	0/45	0/39
注入部位異常感覚	1/61 (1.6)	0/61	0/45	0/39
注入部位発疹	1/61 (1.6)	1/61 (1.6)	0/45	0/39
注入部位反応	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
注入部位痂皮	0/61	0/61	0/45	1/39 (2.6)
注入部位腫脹	1/61 (1.6)	0/61	0/45	0/39
注射部位内出血	0/61	0/61	1/45 (2.2)	1/39 (2.6)
注射部位紅斑	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	0/39
注射部位硬結	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	0/39
注射部位炎症	1/61 (1.6)	0/61	0/45	0/39
注射部位浮腫	1/61 (1.6)	0/61	0/45	0/39
感染症および寄生虫症	8/61 (13.1)	8/61 (13.1)	8/45 (17.8)	6/39 (15.4)
ダニ皮膚炎	0/61	0/61	0/45	1/39 (2.6)
無症候性COVID-19	1/61 (1.6)	1/61 (1.6)	0/45	0/39
COVID-19	0/61	0/61	0/45	2/39 (5.1)
大腸菌性尿路感染	0/61	1/61 (1.6)	1/45 (2.2)	0/39
胃腸炎	0/61	0/61	1/45 (2.2)	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
一般・全身障害および投与部位の状態 (Cont.)				
注入部位丘疹	0/38	0/20	0/4	3/61 (4.9)
注入部位異常感覚	0/38	0/20	0/4	1/61 (1.6)
注入部位発疹	0/38	0/20	0/4	1/61 (1.6)
注入部位反応	1/38 (2.6)	0/20	0/4	1/61 (1.6)
注入部位痂皮	1/38 (2.6)	0/20	0/4	1/61 (1.6)
注入部位腫脹	0/38	0/20	0/4	1/61 (1.6)
注射部位内出血	1/38 (2.6)	0/20	0/4	1/61 (1.6)
注射部位紅斑	0/38	0/20	0/4	2/61 (3.3)
注射部位硬結	0/38	0/20	0/4	1/61 (1.6)
注射部位炎症	0/38	0/20	0/4	1/61 (1.6)
注射部位浮腫	0/38	0/20	0/4	1/61 (1.6)
感染症および寄生虫症	6/38 (15.8)	2/20 (10.0)	0/4	19/61 (31.1)
ダニ皮膚炎	0/38	0/20	0/4	1/61 (1.6)
無症候性COVID-19	0/38	0/20	0/4	2/61 (3.3)
COVID-19	2/38 (5.3)	1/20 (5.0)	0/4	4/61 (6.6)
大腸菌性尿路感染	0/38	0/20	0/4	1/61 (1.6)
胃腸炎	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
帯状疱疹	0/61	1/61 (1.6)	1/45 (2.2)	0/39
注入部位蜂巣炎	4/61 (6.6)	3/61 (4.9)	5/45 (11.1)	1/39 (2.6)
注射部位蜂巣炎	0/61	0/61	0/45	0/39
注射部位感染	0/61	0/61	1/45 (2.2)	1/39 (2.6)
上咽頭炎	0/61	0/61	1/45 (2.2)	1/39 (2.6)
口腔カンジダ症	0/61	1/61 (1.6)	0/45	0/39
敗血症	0/61	1/61 (1.6)	0/45	0/39
副鼻腔炎	1/61 (1.6)	0/61	0/45	0/39
尿路感染	2/61 (3.3)	3/61 (4.9)	1/45 (2.2)	2/39 (5.1)
尿路性敗血症	1/61 (1.6)	0/61	0/45	0/39
傷害、中毒および処置合併症	6/61 (9.8)	9/61 (14.8)	5/45 (11.1)	4/39 (10.3)
節足動物咬傷	0/61	1/61 (1.6)	0/45	0/39
挫傷	1/61 (1.6)	0/61	0/45	0/39
顔面骨骨折	1/61 (1.6)	1/61 (1.6)	0/45	0/39
転倒	5/61 (8.2)	3/61 (4.9)	2/45 (4.4)	1/39 (2.6)
大腿骨頚部骨折	0/61	0/61	0/45	1/39 (2.6)
転位骨折	0/61	1/61 (1.6)	0/45	0/39
手骨折	0/61	1/61 (1.6)	2/45 (4.4)	1/39 (2.6)
股関節部骨折	1/61 (1.6)	0/61	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
感染症および寄生虫症 (Cont.)				
帯状疱疹	0/38	0/20	0/4	1/61 (1.6)
注入部位蜂巣炎	3/38 (7.9)	1/20 (5.0)	0/4	10/61 (16.4)
注射部位蜂巣炎	0/38	1/20 (5.0)	0/4	1/61 (1.6)
注射部位感染	0/38	0/20	0/4	1/61 (1.6)
上咽頭炎	0/38	0/20	0/4	1/61 (1.6)
口腔カンジダ症	0/38	0/20	0/4	1/61 (1.6)
敗血症	0/38	0/20	0/4	1/61 (1.6)
副鼻腔炎	0/38	0/20	0/4	1/61 (1.6)
尿路感染	1/38 (2.6)	0/20	0/4	4/61 (6.6)
尿路性敗血症	0/38	0/20	0/4	1/61 (1.6)
傷害、中毒および処置合併症	1/38 (2.6)	1/20 (5.0)	0/4	13/61 (21.3)
節足動物咬傷	0/38	0/20	0/4	1/61 (1.6)
挫傷	0/38	0/20	0/4	1/61 (1.6)
顔面骨骨折	0/38	0/20	0/4	1/61 (1.6)
転倒	0/38	0/20	0/4	9/61 (14.8)
大腿骨頚部骨折	0/38	0/20	0/4	1/61 (1.6)
転位骨折	0/38	0/20	0/4	1/61 (1.6)
手骨折	1/38 (2.6)	1/20 (5.0)	0/4	2/61 (3.3)
股関節部骨折	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
上腕骨骨折	1/61 (1.6)	1/61 (1.6)	0/45	0/39
靭帯捻挫	0/61	1/61 (1.6)	0/45	0/39
四肢損傷	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
開放骨折	1/61 (1.6)	1/61 (1.6)	0/45	0/39
処置による疼痛	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
肩甲骨骨折	1/61 (1.6)	1/61 (1.6)	0/45	0/39
外傷性頭蓋内出血	0/61	1/61 (1.6)	0/45	0/39
臨床検査	2/61 (3.3)	4/61 (6.6)	3/45 (6.7)	5/39 (12.8)
血中葉酸減少	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	1/39 (2.6)
ヘモグロビン減少	0/61	1/61 (1.6)	0/45	0/39
プロトロンビン時間延長	1/61 (1.6)	0/61	0/45	0/39
ビタミンB12減少	0/61	0/61	0/45	1/39 (2.6)
ビタミンD減少	0/61	0/61	0/45	1/39 (2.6)
体重減少	1/61 (1.6)	2/61 (3.3)	2/45 (4.4)	2/39 (5.1)
代謝および栄養障害	2/61 (3.3)	3/61 (4.9)	4/45 (8.9)	4/39 (10.3)
食欲減退	1/61 (1.6)	1/61 (1.6)	0/45	0/39
高ナトリウム血症	0/61	1/61 (1.6)	0/45	0/39
低カリウム血症	1/61 (1.6)	1/61 (1.6)	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
傷害、中毒および処置合併症 (Cont.)				
上腕骨骨折	0/38	0/20	0/4	1/61 (1.6)
靭帯捻挫	0/38	0/20	0/4	1/61 (1.6)
四肢損傷	0/38	0/20	0/4	1/61 (1.6)
開放骨折	0/38	0/20	0/4	1/61 (1.6)
処置による疼痛	0/38	0/20	0/4	1/61 (1.6)
肩甲骨骨折	0/38	0/20	0/4	1/61 (1.6)
外傷性頭蓋内出血	0/38	0/20	0/4	1/61 (1.6)
臨床検査	5/38 (13.2)	1/20 (5.0)	0/4	7/61 (11.5)
血中葉酸減少	1/38 (2.6)	0/20	0/4	2/61 (3.3)
ヘモグロビン減少	0/38	0/20	0/4	1/61 (1.6)
プロトロンビン時間延長	0/38	0/20	0/4	1/61 (1.6)
ビタミンB12減少	1/38 (2.6)	0/20	0/4	1/61 (1.6)
ビタミンD減少	1/38 (2.6)	0/20	0/4	1/61 (1.6)
体重減少	2/38 (5.3)	1/20 (5.0)	0/4	3/61 (4.9)
代謝および栄養障害	4/38 (10.5)	3/20 (15.0)	0/4	5/61 (8.2)
食欲減退	0/38	0/20	0/4	1/61 (1.6)
高ナトリウム血症	0/38	0/20	0/4	1/61 (1.6)
低カリウム血症	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
代謝および栄養障害 (Cont.)				
低マグネシウム血症	1/61 (1.6)	1/61 (1.6)	0/45	0/39
鉄欠乏	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
ビタミンB12欠乏	1/61 (1.6)	1/61 (1.6)	3/45 (6.7)	3/39 (7.7)
筋骨格系および結合組織障害	0/61	4/61 (6.6)	4/45 (8.9)	4/39 (10.3)
関節痛	0/61	1/61 (1.6)	0/45	0/39
背部痛	0/61	1/61 (1.6)	2/45 (4.4)	2/39 (5.1)
出血性関節症	0/61	1/61 (1.6)	0/45	0/39
椎間板変性症	0/61	0/61	1/45 (2.2)	1/39 (2.6)
筋力低下	0/61	1/61 (1.6)	1/45 (2.2)	0/39
筋骨格硬直	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
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)	0/61	0/61	1/45 (2.2)	0/39
ケラトアカントーマ	0/61	0/61	1/45 (2.2)	0/39
神経系障害	8/61 (13.1)	9/61 (14.8)	8/45 (17.8)	7/39 (17.9)
平衡障害	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
認知障害	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	2/39 (5.1)

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
代謝および栄養障害 (Cont.)				
低マグネシウム血症	0/38	0/20	0/4	1/61 (1.6)
鉄欠乏	1/38 (2.6)	0/20	0/4	1/61 (1.6)
ビタミンB12欠乏	3/38 (7.9)	3/20 (15.0)	0/4	3/61 (4.9)
筋骨格系および結合組織障害	4/38 (10.5)	2/20 (10.0)	1/4 (25.0)	7/61 (11.5)
関節痛	0/38	0/20	0/4	1/61 (1.6)
背部痛	2/38 (5.3)	1/20 (5.0)	0/4	2/61 (3.3)
出血性関節症	0/38	0/20	0/4	1/61 (1.6)
椎間板変性症	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
筋力低下	0/38	0/20	1/4 (25.0)	2/61 (3.3)
筋骨格硬直	1/38 (2.6)	0/20	0/4	1/61 (1.6)
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)	0/38	0/20	0/4	1/61 (1.6)
ケラトアカントーマ	0/38	0/20	0/4	1/61 (1.6)
神経系障害	8/38 (21.1)	3/20 (15.0)	1/4 (25.0)	16/61 (26.2)
平衡障害	1/38 (2.6)	0/20	0/4	1/61 (1.6)
認知障害	2/38 (5.3)	0/20	0/4	2/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
注意力障害	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
浮動性めまい	0/61	0/61	0/45	0/39
薬物離脱性頭痛	0/61	1/61 (1.6)	0/45	0/39
ジストニア	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
頭部不快感	1/61 (1.6)	0/61	1/45 (2.2)	1/39 (2.6)
頭痛	0/61	1/61 (1.6)	0/45	0/39
感覚鈍麻	0/61	0/61	1/45 (2.2)	1/39 (2.6)
反射減弱	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
記憶障害	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
オンオフ現象	2/61 (3.3)	4/61 (6.6)	2/45 (4.4)	1/39 (2.6)
錯感覚	0/61	0/61	0/45	0/39
パーキンソン病	2/61 (3.3)	2/61 (3.3)	2/45 (4.4)	1/39 (2.6)
精神運動亢進	0/61	0/61	1/45 (2.2)	0/39
痙攣発作	0/61	1/61 (1.6)	0/45	0/39
失神	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	1/39 (2.6)
一過性脳虚血発作	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
精神障害	6/61 (9.8)	7/61 (11.5)	11/45 (24.4)	13/39 (33.3)
異常な夢	0/61	1/61 (1.6)	0/45	0/39
適応障害	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
攻撃性	1/61 (1.6)	1/61 (1.6)	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
神経系障害 (Cont.)				
注意力障害	1/38 (2.6)	0/20	0/4	1/61 (1.6)
浮動性めまい	1/38 (2.6)	0/20	0/4	1/61 (1.6)
薬物離脱性頭痛	0/38	0/20	0/4	1/61 (1.6)
ジストニア	1/38 (2.6)	0/20	0/4	1/61 (1.6)
頭部不快感	1/38 (2.6)	0/20	0/4	2/61 (3.3)
頭痛	0/38	0/20	0/4	1/61 (1.6)
感覚鈍麻	0/38	0/20	0/4	1/61 (1.6)
反射減弱	1/38 (2.6)	0/20	0/4	1/61 (1.6)
記憶障害	1/38 (2.6)	1/20 (5.0)	1/4 (25.0)	2/61 (3.3)
オンオフ現象	1/38 (2.6)	0/20	0/4	5/61 (8.2)
錯感覚	0/38	1/20 (5.0)	0/4	1/61 (1.6)
パーキンソン病	1/38 (2.6)	0/20	0/4	5/61 (8.2)
精神運動亢進	0/38	0/20	0/4	1/61 (1.6)
痙攣発作	0/38	0/20	0/4	1/61 (1.6)
失神	2/38 (5.3)	1/20 (5.0)	0/4	2/61 (3.3)
一過性脳虚血発作	1/38 (2.6)	0/20	0/4	1/61 (1.6)
精神障害	11/38 (28.9)	4/20 (20.0)	1/4 (25.0)	18/61 (29.5)
異常な夢	0/38	0/20	0/4	1/61 (1.6)
適応障害	1/38 (2.6)	0/20	0/4	1/61 (1.6)
攻撃性	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
精神障害 (Cont.)				
激越	1/61 (1.6)	0/61	0/45	0/39
不安	1/61 (1.6)	0/61	3/45 (6.7)	3/39 (7.7)
錯乱状態	0/61	0/61	1/45 (2.2)	1/39 (2.6)
譫妄	1/61 (1.6)	2/61 (3.3)	0/45	0/39
妄想	0/61	0/61	1/45 (2.2)	1/39 (2.6)
うつ病	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
自傷性皮膚症	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
幻覚	2/61 (3.3)	1/61 (1.6)	3/45 (6.7)	4/39 (10.3)
幻視	0/61	0/61	0/45	1/39 (2.6)
錯覚	0/61	0/61	1/45 (2.2)	1/39 (2.6)
衝動制御障害	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
不眠症	0/61	0/61	1/45 (2.2)	1/39 (2.6)
パニック発作	0/61	1/61 (1.6)	1/45 (2.2)	0/39
精神病性障害	0/61	1/61 (1.6)	1/45 (2.2)	0/39
睡眠障害	1/61 (1.6)	1/61 (1.6)	0/45	0/39
腎および尿路障害	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	2/39 (5.1)
急性腎障害	1/61 (1.6)	0/61	0/45	0/39
血尿	0/61	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
水腎症	1/61 (1.6)	1/61 (1.6)	0/45	0/39
水尿管症	1/61 (1.6)	1/61 (1.6)	0/45	0/39

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
精神障害 (Cont.)				
激越	0/38	0/20	0/4	1/61 (1.6)
不安	3/38 (7.9)	1/20 (5.0)	1/4 (25.0)	4/61 (6.6)
錯乱状態	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
譫妄	0/38	0/20	0/4	2/61 (3.3)
妄想	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
うつ病	0/38	0/20	0/4	1/61 (1.6)
自傷性皮膚症	0/38	0/20	0/4	1/61 (1.6)
幻覚	3/38 (7.9)	0/20	0/4	5/61 (8.2)
幻視	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
錯覚	1/38 (2.6)	0/20	0/4	1/61 (1.6)
衝動制御障害	0/38	0/20	0/4	1/61 (1.6)
不眠症	1/38 (2.6)	0/20	0/4	1/61 (1.6)
パニック発作	0/38	0/20	0/4	1/61 (1.6)
精神病性障害	0/38	0/20	0/4	1/61 (1.6)
睡眠障害	0/38	0/20	0/4	1/61 (1.6)
腎および尿路障害	2/38 (5.3)	1/20 (5.0)	0/4	4/61 (6.6)
急性腎障害	0/38	0/20	0/4	1/61 (1.6)
血尿	0/38	0/20	0/4	1/61 (1.6)
水腎症	0/38	0/20	0/4	1/61 (1.6)
水尿管症	0/38	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
腎結石症	0/61	0/61	0/45	0/39
蛋白尿	0/61	0/61	0/45	1/39 (2.6)
生殖系および乳房障害	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	1/39 (2.6)
膀胱瘤	0/61	0/61	0/45	0/39
勃起不全	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
生殖器萎縮	0/61	0/61	0/45	0/39
膣脱	0/61	1/61 (1.6)	0/45	0/39
呼吸器、胸郭および縦隔障害	0/61	0/61	0/45	0/39
痰貯留	0/61	0/61	0/45	0/39
皮膚および皮下組織障害	0/61	0/61	0/45	1/39 (2.6)
湿疹	0/61	0/61	0/45	1/39 (2.6)
血管障害	3/61 (4.9)	5/61 (8.2)	4/45 (8.9)	4/39 (10.3)
高血圧	0/61	1/61 (1.6)	0/45	0/39
低血圧	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
腎および尿路障害 (Cont.)				
腎結石症	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
蛋白尿	1/38 (2.6)	0/20	0/4	1/61 (1.6)
生殖系および乳房障害	2/38 (5.3)	1/20 (5.0)	0/4	3/61 (4.9)
膀胱瘤	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
勃起不全	1/38 (2.6)	0/20	0/4	1/61 (1.6)
生殖器萎縮	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
腟脱	0/38	0/20	0/4	1/61 (1.6)
呼吸器、胸郭および縦隔障害	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
痰貯留	1/38 (2.6)	1/20 (5.0)	0/4	1/61 (1.6)
皮膚および皮下組織障害	1/38 (2.6)	0/20	0/4	1/61 (1.6)
湿疹	1/38 (2.6)	0/20	0/4	1/61 (1.6)
血管障害	4/38 (10.5)	2/20 (10.0)	1/4 (25.0)	6/61 (9.8)
高血圧	0/38	0/20	0/4	1/61 (1.6)
低血圧	1/38 (2.6)	0/20	0/4	1/61 (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.J

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=116) n/N eval (%)	 Days 91 to 180 (N=112) n/N eval (%)	 Days 181 to 270 (N=78) n/N eval (%)	 Days 271 to 360 (N=69) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	1/61 (1.6)	1/61 (1.6)	1/45 (2.2)	1/39 (2.6)
起立性低血圧	1/61 (1.6)	2/61 (3.3)	1/45 (2.2)	1/39 (2.6)
表在性血栓性静脈炎	0/61	0/61	1/45 (2.2)	1/39 (2.6)

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.J

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=64) n/N eval (%)	 Days 451 to 540 (N=32) n/N eval (%)	 After Day 540 (N=5) n/N eval (%)	 At Any Time (N=116) n/N eval (%)
High Dose				
血管障害 (Cont.)				
起立性高血圧	1/38 (2.6)	0/20	0/4	1/61 (1.6)
起立性低血圧	1/38 (2.6)	1/20 (5.0)	0/4	2/61 (3.3)
表在性血栓性静脈炎	1/38 (2.6)	1/20 (5.0)	1/4 (25.0)	1/61 (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]

表41　有害事象の概要（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Subjects with:			
Any TEAE	5 (62.5)	4 (100)	9 (75.0)
Any severe TEAE	1 (12.5)	0	1 (8.3)
Any TEAE that is considered associated with study drug$	4 (50.0)	3 (75.0)	7 (58.3)
Any TEAE that is considered associated with product complaint$	3 (37.5)	3 (75.0)	6 (50.0)
ABBV-951	2 (25.0)	2 (50.0)	4 (33.3)
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)	1 (12.5)	2 (50.0)	3 (25.0)
Neria guard infusion set 6 mm	0	0	0
Neria guard infusion set 9 mm	1 (12.5)	2 (50.0)	3 (25.0)
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	1 (12.5)	0	1 (8.3)
Any TEAE leading to prematurely discontinuation of study drug	1 (12.5)	0	1 (8.3)
Any TEAE leading to death (fatal TEAE)	1 (12.5)	0	1 (8.3)
Any serious TEAE	2 (25.0)	2 (50.0)	4 (33.3)

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
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=47) n (%)	High Dose (N=57) n (%)	All Subjects (N=104) n (%)
Subjects with:			
Any TEAE	34 (72.3)	45 (78.9)	79 (76.0)
Any severe TEAE	9 (19.1)	10 (17.5)	19 (18.3)
Any TEAE that is considered associated with study drug$	23 (48.9)	30 (52.6)	53 (51.0)
Any TEAE that is considered associated with product complaint$	18 (38.3)	19 (33.3)	37 (35.6)
ABBV-951	4 (8.5)	8 (14.0)	12 (11.5)
Infusion pump	3 (6.4)	3 (5.3)	6 (5.8)
Vial adapter	0	0	0
Syringes	0	1 (1.8)	1 (1.0)
[redacted] infusion set (total)	5 (10.6)	4 (7.0)	9 (8.7)
[redacted] infusion set 6 mm	1 (2.1)	3 (5.3)	4 (3.8)
[redacted] infusion set 9 mm	4 (8.5)	1 (1.8)	5 (4.8)
Neria guard infusion set (total)	9 (19.1)	9 (15.8)	18 (17.3)
Neria guard infusion set 6 mm	7 (14.9)	4 (7.0)	11 (10.6)
Neria guard infusion set 9 mm	2 (4.3)	6 (10.5)	8 (7.7)
Any TEAE that is considered associated with loading dose$	0	0	0
Any TEAE that is considered associated with rescue dose$	0	2 (3.5)	2 (1.9)
Any TEAE that is considered associated with COVID-19 infection	0	6 (10.5)	6 (5.8)
Any TEAE leading to prematurely discontinuation of study drug	2 (4.3)	4 (7.0)	6 (5.8)
Any TEAE leading to death (fatal TEAE)	0	2 (3.5)	2 (1.9)
Any serious TEAE	12 (25.5)	10 (17.5)	22 (21.2)

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
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Any SAE that is considered associated with infusion pump$	0	1 (25.0)	1 (8.3)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (25.0)	1 (8.3)
Any SAE that is considered associated with neria guards infusion set$	0	1 (25.0)	1 (8.3)
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	1 (25.0)	1 (8.3)
Any SAE that is considered associated with product complaint$	1 (12.5)	1 (25.0)	2 (16.7)
ABBV-951	1 (12.5)	1 (25.0)	2 (16.7)
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

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
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=47) n (%)	High Dose (N=57) n (%)	All Subjects (N=104) n (%)
Any SAE that is considered associated with infusion pump$	4 (8.5)	1 (1.8)	5 (4.8)
Possible	2 (4.3)	0	2 (1.9)
Probable	0	1 (1.8)	1 (1.0)
Causal relationship	2 (4.3)	0	2 (1.9)
Any SAE that is considered associated with neria guards infusion set$	2 (4.3)	1 (1.8)	3 (2.9)
Possible	0	1 (1.8)	1 (1.0)
Probable	2 (4.3)	0	2 (1.9)
Causal relationship	0	0	0
Any SAE that is considered associated with product complaint$	5 (10.6)	3 (5.3)	8 (7.7)
ABBV-951	1 (2.1)	2 (3.5)	3 (2.9)
Infusion pump	2 (4.3)	1 (1.8)	3 (2.9)
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)	3 (6.4)	1 (1.8)	4 (3.8)
Neria guard infusion set 6 mm	2 (4.3)	0	2 (1.9)
Neria guard infusion set 9 mm	1 (2.1)	1 (1.8)	2 (1.9)

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
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	1 (12.5)	2 (50.0)	3 (25.0)
Possible	0	0	0
Probable	0	0	0
Causal relationship	1 (12.5)	2 (50.0)	3 (25.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=47) n (%)	High Dose (N=57) n (%)	All Subjects (N=104) n (%)
Any AE (non-SAE) that is considered associated with infusion pump$&	2 (4.3)	3 (5.3)	5 (4.8)
Possible	2 (4.3)	2 (3.5)	4 (3.8)
Probable	0	0	0
Causal relationship	0	1 (1.8)	1 (1.0)
Any AE (non-SAE) that is considered associated with [redacted] infusion set$&	0	0	0
Possible	0	0	0
Probable	0	0	0
Causal relationship	0	0	0
Any AE (non-SAE) that is considered associated with neria guards infusion set$&	7 (14.9)	5 (8.8)	12 (11.5)
Possible	3 (6.4)	3 (5.3)	6 (5.8)
Probable	3 (6.4)	3 (5.3)	6 (5.8)
Causal relationship	2 (4.3)	2 (3.5)	4 (3.8)

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

Program Source Code: [redacted]

TABLE 14.3 1.1.J

Overview of Treatment-Emergent Adverse Events and All Deaths for Japan and Non-Japan subjects
(Safety Analysis Set)

	Japan		
	Dose Category		
	Low Dose (N=8) n (%)	High Dose (N=4) n (%)	All Subjects (N=12) n (%)
All deaths#	1 (12.5)	0	1 (8.3)
All TE-deaths	1 (12.5)	0	1 (8.3)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	0	0	0
AESI: hallucinations/psychosis	2 (25.0)	0	2 (16.7)
AESI: somnolence	0	0	0
AESI: infusion site related infections	1 (12.5)	2 (50.0)	3 (25.0)
AESI: infusion site related non infection reactions	2 (25.0)	3 (75.0)	5 (41.7)
AESI: falls and associated injuries	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set)

	Non-Japan		
	Dose Category		
	Low Dose (N=47) n (%)	High Dose (N=57) n (%)	All Subjects (N=104) n (%)
All deaths#	0	2 (3.5)	2 (1.9)
All TE-deaths	0	2 (3.5)	2 (1.9)
Deaths related to COVID-19 infection	0	0	0
AESI: polyneuropathy (narrow)	0	0	0
AESI: weight loss	1 (2.1)	5 (8.8)	6 (5.8)
AESI: hallucinations/psychosis	6 (12.8)	8 (14.0)	14 (13.5)
AESI: somnolence	0	0	0
AESI: infusion site related infections	10 (21.3)	9 (15.8)	19 (18.3)
AESI: infusion site related non infection reactions	16 (34.0)	18 (31.6)	34 (32.7)
AESI: falls and associated injuries	8 (17.0)	14 (24.6)	22 (21.2)

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]

表42　すべての有害事象（安全性解析対象集団，部分集団別）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male	N=28	N=46	N=74
Any adverse event	18 (64.3)	36 (78.3)	54 (73.0)
心臓障害	1 (3.6)	0	1 (1.4)
急性心筋梗塞	1 (3.6)	0	1 (1.4)
眼障害	0	3 (6.5)	3 (4.1)
眼瞼痙攣	0	1 (2.2)	1 (1.4)
眼の異物感	0	1 (2.2)	1 (1.4)
眼部不快感	0	1 (2.2)	1 (1.4)
眼充血	0	2 (4.3)	2 (2.7)
霧視	0	1 (2.2)	1 (1.4)
胃腸障害	2 (7.1)	4 (8.7)	6 (8.1)
腹部膨満	0	1 (2.2)	1 (1.4)
腹痛	0	1 (2.2)	1 (1.4)
便秘	2 (7.1)	1 (2.2)	3 (4.1)
出血性腸憩室	0	1 (2.2)	1 (1.4)
嚥下障害	1 (3.6)	1 (2.2)	2 (2.7)
流涎過多	0	1 (2.2)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
一般・全身障害および投与部位の状態	11 (39.3)	17 (37.0)	28 (37.8)
投与部位内出血	0	1 (2.2)	1 (1.4)
投与部位漏出	1 (3.6)	0	1 (1.4)
カテーテル留置部位内出血	1 (3.6)	1 (2.2)	2 (2.7)
カテーテル留置部位紅斑	1 (3.6)	0	1 (1.4)
カテーテル留置部位漏出	0	1 (2.2)	1 (1.4)
カテーテル留置部位炎症	0	1 (2.2)	1 (1.4)
カテーテル留置部位疼痛	1 (3.6)	0	1 (1.4)
カテーテル留置部位腫脹	1 (3.6)	0	1 (1.4)
薬効欠如	1 (3.6)	0	1 (1.4)
疲労	1 (3.6)	0	1 (1.4)
注入部位内出血	1 (3.6)	3 (6.5)	4 (5.4)
注入部位変色	0	1 (2.2)	1 (1.4)
注入部位紅斑	6 (21.4)	7 (15.2)	13 (17.6)
注入部位血管外漏出	0	1 (2.2)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血腫	0	1 (2.2)	1 (1.4)
注入部位硬結	1 (3.6)	2 (4.3)	3 (4.1)
注入部位炎症	0	1 (2.2)	1 (1.4)
注入部位刺激感	2 (7.1)	0	2 (2.7)
注入部位結節	2 (7.1)	3 (6.5)	5 (6.8)
注入部位浮腫	0	1 (2.2)	1 (1.4)
注入部位丘疹	0	2 (4.3)	2 (2.7)
注入部位異常感覚	0	1 (2.2)	1 (1.4)
注入部位発疹	0	1 (2.2)	1 (1.4)
注入部位反応	0	1 (2.2)	1 (1.4)
注入部位痂皮	0	1 (2.2)	1 (1.4)
注入部位腫脹	0	1 (2.2)	1 (1.4)
注入部位熱感	1 (3.6)	0	1 (1.4)
注射部位内出血	0	1 (2.2)	1 (1.4)
注射部位紅斑	0	2 (4.3)	2 (2.7)
注射部位硬結	0	1 (2.2)	1 (1.4)
注射部位炎症	0	1 (2.2)	1 (1.4)
注射部位結節	1 (3.6)	0	1 (1.4)
注射部位浮腫	0	1 (2.2)	1 (1.4)
末梢性浮腫	1 (3.6)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
感染症および寄生虫症	8 (28.6)	14 (30.4)	22 (29.7)
ダニ皮膚炎	0	1 (2.2)	1 (1.4)
無症候性COVID-19	0	1 (2.2)	1 (1.4)
COVID-19	1 (3.6)	3 (6.5)	4 (5.4)
胃腸炎	1 (3.6)	1 (2.2)	2 (2.7)
帯状疱疹	0	1 (2.2)	1 (1.4)
注入部位蜂巣炎	1 (3.6)	7 (15.2)	8 (10.8)
注入部位感染	3 (10.7)	0	3 (4.1)
注射部位蜂巣炎	0	1 (2.2)	1 (1.4)
注射部位感染	0	1 (2.2)	1 (1.4)
上咽頭炎	1 (3.6)	1 (2.2)	2 (2.7)
RSウイルス感染	1 (3.6)	0	1 (1.4)
副鼻腔炎	0	1 (2.2)	1 (1.4)
上気道感染	1 (3.6)	0	1 (1.4)
傷害、中毒および処置合併症	4 (14.3)	9 (19.6)	13 (17.6)
節足動物咬傷	0	1 (2.2)	1 (1.4)
節足動物刺傷	1 (3.6)	0	1 (1.4)
顔面骨骨折	0	1 (2.2)	1 (1.4)
転倒	2 (7.1)	5 (10.9)	7 (9.5)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
傷害、中毒および処置合併症 (Cont.)			
手骨折	0	2 (4.3)	2 (2.7)
股関節部骨折	1 (3.6)	1 (2.2)	2 (2.7)
上腕骨骨折	0	1 (2.2)	1 (1.4)
靱帯捻挫	0	1 (2.2)	1 (1.4)
四肢損傷	0	1 (2.2)	1 (1.4)
肉離れ	1 (3.6)	0	1 (1.4)
開放骨折	0	1 (2.2)	1 (1.4)
処置による疼痛	0	1 (2.2)	1 (1.4)
肩甲骨骨折	0	1 (2.2)	1 (1.4)
臨床検査	3 (10.7)	5 (10.9)	8 (10.8)
血中葉酸減少	0	1 (2.2)	1 (1.4)
血中ホモシステイン増加	2 (7.1)	0	2 (2.7)
血中ナトリウム減少	1 (3.6)	0	1 (1.4)
プロトロンビン時間延長	0	1 (2.2)	1 (1.4)
ビタミンB12減少	1 (3.6)	1 (2.2)	2 (2.7)
ビタミンB6減少	1 (3.6)	0	1 (1.4)
体重減少	0	3 (6.5)	3 (4.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
代謝および栄養障害	2 (7.1)	3 (6.5)	5 (6.8)
鉄欠乏	0	1 (2.2)	1 (1.4)
ビタミンB群欠乏	1 (3.6)	0	1 (1.4)
ビタミンB12欠乏	0	2 (4.3)	2 (2.7)
ビタミンB6欠乏	1 (3.6)	0	1 (1.4)
筋骨格系および結合組織障害	3 (10.7)	5 (10.9)	8 (10.8)
背部痛	0	1 (2.2)	1 (1.4)
滑液包炎	1 (3.6)	0	1 (1.4)
出血性関節症	0	1 (2.2)	1 (1.4)
椎間板変性症	0	1 (2.2)	1 (1.4)
腰部脊柱管狭窄症	1 (3.6)	0	1 (1.4)
筋力低下	0	2 (4.3)	2 (2.7)
筋骨格硬直	0	1 (2.2)	1 (1.4)
骨粗鬆症	1 (3.6)	0	1 (1.4)
肩回旋筋腱板症候群	1 (3.6)	0	1 (1.4)
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	1 (2.2)	1 (1.4)
ケラトアカントーマ	0	1 (2.2)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
神経系障害	4 (14.3)	9 (19.6)	13 (17.6)
運動緩慢	1 (3.6)	0	1 (1.4)
認知障害	1 (3.6)	0	1 (1.4)
注意力障害	0	1 (2.2)	1 (1.4)
浮動性めまい	1 (3.6)	0	1 (1.4)
薬物離脱性頭痛	0	1 (2.2)	1 (1.4)
ジストニア	0	1 (2.2)	1 (1.4)
すくみ現象	2 (7.1)	0	2 (2.7)
頭部不快感	0	2 (4.3)	2 (2.7)
感覚鈍麻	0	1 (2.2)	1 (1.4)
反射減弱	0	1 (2.2)	1 (1.4)
記憶障害	0	2 (4.3)	2 (2.7)
オンオフ現象	1 (3.6)	2 (4.3)	3 (4.1)
錯感覚	0	1 (2.2)	1 (1.4)
パーキンソン病	2 (7.1)	3 (6.5)	5 (6.8)
精神運動亢進	0	1 (2.2)	1 (1.4)
失神	0	1 (2.2)	1 (1.4)
一過性脳虚血発作	0	1 (2.2)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
精神障害	5 (17.9)	13 (28.3)	18 (24.3)
異常な夢	0	1 (2.2)	1 (1.4)
適応障害	0	1 (2.2)	1 (1.4)
攻撃性	0	1 (2.2)	1 (1.4)
不安	1 (3.6)	2 (4.3)	3 (4.1)
錯乱状態	0	1 (2.2)	1 (1.4)
譫妄	0	1 (2.2)	1 (1.4)
妄想	0	1 (2.2)	1 (1.4)
抑うつ気分	1 (3.6)	0	1 (1.4)
うつ病	0	1 (2.2)	1 (1.4)
自傷性皮膚症	0	1 (2.2)	1 (1.4)
失見当識	1 (3.6)	0	1 (1.4)
ギャンブル障害	1 (3.6)	0	1 (1.4)
幻覚	2 (7.1)	2 (4.3)	4 (5.4)
幻嗅	1 (3.6)	0	1 (1.4)
幻視	0	1 (2.2)	1 (1.4)
錯覚	1 (3.6)	1 (2.2)	2 (2.7)
衝動制御障害	0	1 (2.2)	1 (1.4)
不眠症	0	1 (2.2)	1 (1.4)
消極的思考	1 (3.6)	0	1 (1.4)
パニック発作	1 (3.6)	0	1 (1.4)
妄想症	1 (3.6)	0	1 (1.4)
レム睡眠行動障害	1 (3.6)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Male (Cont.)	N=28	N=46	N=74
腎および尿路障害	2 (7.1)	1 (2.2)	3 (4.1)
緊張性膀胱	1 (3.6)	0	1 (1.4)
腎結石症	0	1 (2.2)	1 (1.4)
尿失禁	1 (3.6)	0	1 (1.4)
生殖系および乳房障害	1 (3.6)	1 (2.2)	2 (2.7)
良性前立腺肥大症	1 (3.6)	0	1 (1.4)
勃起不全	0	1 (2.2)	1 (1.4)
呼吸器、胸郭および縦隔障害	0	1 (2.2)	1 (1.4)
痰貯留	0	1 (2.2)	1 (1.4)
皮膚および皮下組織障害	2 (7.1)	1 (2.2)	3 (4.1)
光線角化症	1 (3.6)	0	1 (1.4)
湿疹	1 (3.6)	1 (2.2)	2 (2.7)
血管障害	1 (3.6)	3 (6.5)	4 (5.4)
起立性高血圧	0	1 (2.2)	1 (1.4)
起立性低血圧	1 (3.6)	2 (4.3)	3 (4.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female	N=27	N=15	N=42
Any adverse event	21 (77.8)	13 (86.7)	34 (81.0)
心臓障害	2 (7.4)	1 (6.7)	3 (7.1)
徐脈	1 (3.7)	0	1 (2.4)
左脚ブロック	0	1 (6.7)	1 (2.4)
洞性頻脈	1 (3.7)	0	1 (2.4)
耳および迷路障害	0	2 (13.3)	2 (4.8)
回転性めまい	0	2 (13.3)	2 (4.8)
眼障害	1 (3.7)	0	1 (2.4)
黄斑症	1 (3.7)	0	1 (2.4)
胃腸障害	5 (18.5)	3 (20.0)	8 (19.0)
腹部不快感	0	1 (6.7)	1 (2.4)
便秘	1 (3.7)	1 (6.7)	2 (4.8)
嚥下障害	0	1 (6.7)	1 (2.4)
胃潰瘍	1 (3.7)	0	1 (2.4)
胃食道逆流性疾患	1 (3.7)	0	1 (2.4)
悪心	2 (7.4)	2 (13.3)	4 (9.5)
吐き戻し	0	1 (6.7)	1 (2.4)
嘔吐	1 (3.7)	0	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
一般・全身障害および投与部位の状態	10 (37.0)	4 (26.7)	14 (33.3)
カテーテル留置部位内出血	0	1 (6.7)	1 (2.4)
薬物相互作用	1 (3.7)	0	1 (2.4)
疲労	2 (7.4)	0	2 (4.8)
注入部位内出血	1 (3.7)	0	1 (2.4)
注入部位皮膚炎	1 (3.7)	0	1 (2.4)
注入部位紅斑	5 (18.5)	1 (6.7)	6 (14.3)
注入部位血管外漏出	0	1 (6.7)	1 (2.4)
注入部位血腫	1 (3.7)	0	1 (2.4)
注入部位腫瘤	1 (3.7)	0	1 (2.4)
注入部位浮腫	1 (3.7)	0	1 (2.4)
注入部位疼痛	1 (3.7)	1 (6.7)	2 (4.8)
注入部位丘疹	1 (3.7)	1 (6.7)	2 (4.8)
注入部位腫脹	1 (3.7)	0	1 (2.4)
注射部位内出血	1 (3.7)	0	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
一般・全身障害および投与部位の状態 (Cont.)			
注射部位紅斑	1 (3.7)	0	1 (2.4)
穿刺部位紅斑	1 (3.7)	0	1 (2.4)
感染症および寄生虫症	7 (25.9)	5 (33.3)	12 (28.6)
無症候性COVID-19	0	1 (6.7)	1 (2.4)
COVID-19	0	1 (6.7)	1 (2.4)
膀胱炎	1 (3.7)	0	1 (2.4)
大腸菌性尿路感染	0	1 (6.7)	1 (2.4)
ヘリコバクター性胃炎	1 (3.7)	0	1 (2.4)
ヘリコバクター感染	1 (3.7)	0	1 (2.4)
注入部位膿瘍	3 (11.1)	0	3 (7.1)
注入部位蜂巣炎	5 (18.5)	3 (20.0)	8 (19.0)
口腔カンジダ症	0	1 (6.7)	1 (2.4)
敗血症	0	1 (6.7)	1 (2.4)
尿路感染	1 (3.7)	4 (26.7)	5 (11.9)
尿路性敗血症	0	1 (6.7)	1 (2.4)
傷害、中毒および処置合併症	4 (14.8)	4 (26.7)	8 (19.0)
挫傷	0	1 (6.7)	1 (2.4)
転倒	3 (11.1)	4 (26.7)	7 (16.7)
大腿骨頚部骨折	0	1 (6.7)	1 (2.4)
大腿骨骨折	1 (3.7)	0	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
傷害、中毒および処置合併症 (Cont.)			
転位骨折	0	1 (6.7)	1 (2.4)
手骨折	1 (3.7)	0	1 (2.4)
上腕骨骨折	1 (3.7)	0	1 (2.4)
外傷性頭蓋内出血	0	1 (6.7)	1 (2.4)
臨床検査	3 (11.1)	2 (13.3)	5 (11.9)
血中葉酸減少	0	1 (6.7)	1 (2.4)
ヘモグロビン減少	0	1 (6.7)	1 (2.4)
リンパ球数減少	1 (3.7)	0	1 (2.4)
ビタミンB6減少	1 (3.7)	0	1 (2.4)
ビタミンB6増加	1 (3.7)	0	1 (2.4)
ビタミンD減少	0	1 (6.7)	1 (2.4)
代謝および栄養障害	2 (7.4)	2 (13.3)	4 (9.5)
食欲減退	0	1 (6.7)	1 (2.4)
高ナトリウム血症	0	1 (6.7)	1 (2.4)
低カリウム血症	1 (3.7)	1 (6.7)	2 (4.8)
低マグネシウム血症	1 (3.7)	1 (6.7)	2 (4.8)
鉄欠乏	1 (3.7)	0	1 (2.4)
ビタミンB12欠乏	1 (3.7)	1 (6.7)	2 (4.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
筋骨格系および結合組織障害	7 (25.9)	2 (13.3)	9 (21.4)
関節痛	0	1 (6.7)	1 (2.4)
背部痛	1 (3.7)	1 (6.7)	2 (4.8)
筋骨格系胸痛	1 (3.7)	0	1 (2.4)
変形性関節症	3 (11.1)	0	3 (7.1)
骨粗鬆症	1 (3.7)	0	1 (2.4)
四肢痛	2 (7.4)	0	2 (4.8)
肩回旋筋腱板症候群	1 (3.7)	0	1 (2.4)
変形性脊椎症	1 (3.7)	0	1 (2.4)
腱鞘炎	1 (3.7)	0	1 (2.4)
斜頚	1 (3.7)	0	1 (2.4)
神経系障害	7 (25.9)	7 (46.7)	14 (33.3)
健忘	1 (3.7)	0	1 (2.4)
平衡障害	0	1 (6.7)	1 (2.4)
認知障害	0	2 (13.3)	2 (4.8)
浮動性めまい	0	1 (6.7)	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
神経系障害 (Cont.)			
ジスキネジア	1 (3.7)	0	1 (2.4)
伸展性足底反応	1 (3.7)	0	1 (2.4)
すくみ現象	1 (3.7)	0	1 (2.4)
頭蓋内出血	1 (3.7)	0	1 (2.4)
頭痛	1 (3.7)	1 (6.7)	2 (4.8)
感覚鈍麻	1 (3.7)	0	1 (2.4)
反射減弱	1 (3.7)	0	1 (2.4)
オンオフ現象	1 (3.7)	3 (20.0)	4 (9.5)
錯感覚	1 (3.7)	0	1 (2.4)
パーキンソン病	0	2 (13.3)	2 (4.8)
呼吸器ジスキネジア	1 (3.7)	0	1 (2.4)
痙攣発作	0	1 (6.7)	1 (2.4)
失神	0	1 (6.7)	1 (2.4)
振戦	1 (3.7)	0	1 (2.4)
精神障害	10 (37.0)	5 (33.3)	15 (35.7)
激越	0	1 (6.7)	1 (2.4)
不安	3 (11.1)	2 (13.3)	5 (11.9)
歯ぎしり	1 (3.7)	0	1 (2.4)
譫妄	0	1 (6.7)	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
精神障害 (Cont.)			
妄想	1 (3.7)	0	1 (2.4)
うつ病	2 (7.4)	0	2 (4.8)
幻覚	2 (7.4)	3 (20.0)	5 (11.9)
幻視	1 (3.7)	0	1 (2.4)
軽躁	1 (3.7)	0	1 (2.4)
衝動行為	1 (3.7)	0	1 (2.4)
不眠症	1 (3.7)	0	1 (2.4)
パニック発作	0	1 (6.7)	1 (2.4)
精神病性障害	1 (3.7)	1 (6.7)	2 (4.8)
睡眠障害	0	1 (6.7)	1 (2.4)
腎および尿路障害	1 (3.7)	3 (20.0)	4 (9.5)
急性腎障害	0	1 (6.7)	1 (2.4)
膀胱痙縮	1 (3.7)	0	1 (2.4)
血尿	0	1 (6.7)	1 (2.4)
水腎症	0	1 (6.7)	1 (2.4)
水尿管症	0	1 (6.7)	1 (2.4)
蛋白尿	0	1 (6.7)	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Sex: Female (Cont.)	N=27	N=15	N=42
生殖系および乳房障害	1 (3.7)	2 (13.3)	3 (7.1)
膀胱瘤	0	1 (6.7)	1 (2.4)
生殖器萎縮	0	1 (6.7)	1 (2.4)
腟脱	0	1 (6.7)	1 (2.4)
外陰腟乾燥	1 (3.7)	0	1 (2.4)
呼吸器、胸郭および縦隔障害	2 (7.4)	0	2 (4.8)
窒息	1 (3.7)	0	1 (2.4)
誤嚥	1 (3.7)	0	1 (2.4)
呼吸困難	1 (3.7)	0	1 (2.4)
皮膚および皮下組織障害	2 (7.4)	0	2 (4.8)
脱毛症	1 (3.7)	0	1 (2.4)
発疹	1 (3.7)	0	1 (2.4)
蕁麻疹	1 (3.7)	0	1 (2.4)
血管障害	2 (7.4)	3 (20.0)	5 (11.9)
血腫	1 (3.7)	0	1 (2.4)
高血圧	0	1 (6.7)	1 (2.4)
低血圧	1 (3.7)	1 (6.7)	2 (4.8)
表在性血栓性静脈炎	0	1 (6.7)	1 (2.4)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White	N=44	N=55	N=99
Any adverse event	31 (70.5)	44 (80.0)	75 (75.8)
心臓障害	3 (6.8)	1 (1.8)	4 (4.0)
急性心筋梗塞	1 (2.3)	0	1 (1.0)
徐脈	1 (2.3)	0	1 (1.0)
左脚ブロック	0	1 (1.8)	1 (1.0)
洞性頻脈	1 (2.3)	0	1 (1.0)
耳および迷路障害	0	2 (3.6)	2 (2.0)
回転性めまい	0	2 (3.6)	2 (2.0)
眼障害	1 (2.3)	2 (3.6)	3 (3.0)
眼瞼痙攣	0	1 (1.8)	1 (1.0)
眼の異物感	0	1 (1.8)	1 (1.0)
黄斑症	1 (2.3)	0	1 (1.0)
眼部不快感	0	1 (1.8)	1 (1.0)
眼充血	0	1 (1.8)	1 (1.0)
霧視	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
胃腸障害	5 (11.4)	7 (12.7)	12 (12.1)
腹部不快感	0	1 (1.8)	1 (1.0)
腹部膨満	0	1 (1.8)	1 (1.0)
腹痛	0	1 (1.8)	1 (1.0)
便秘	2 (4.5)	2 (3.6)	4 (4.0)
出血性腸憩室	0	1 (1.8)	1 (1.0)
嚥下障害	1 (2.3)	2 (3.6)	3 (3.0)
胃潰瘍	1 (2.3)	0	1 (1.0)
胃食道逆流性疾患	1 (2.3)	0	1 (1.0)
悪心	1 (2.3)	2 (3.6)	3 (3.0)
吐き戻し	0	1 (1.8)	1 (1.0)
流涎過多	0	1 (1.8)	1 (1.0)
一般・全身障害および投与部位の状態	18 (40.9)	18 (32.7)	36 (36.4)
投与部位内出血	0	1 (1.8)	1 (1.0)
投与部位漏出	1 (2.3)	0	1 (1.0)
カテーテル留置部位内出血	1 (2.3)	2 (3.6)	3 (3.0)
カテーテル留置部位紅斑	1 (2.3)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
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漏出	0	1 (1.8)	1 (1.0)
カテーテル留置部位炎症	0	1 (1.8)	1 (1.0)
カテーテル留置部位疼痛	1 (2.3)	0	1 (1.0)
カテーテル留置部位腫脹	1 (2.3)	0	1 (1.0)
薬効欠如	1 (2.3)	0	1 (1.0)
薬物相互作用	1 (2.3)	0	1 (1.0)
疲労	3 (6.8)	0	3 (3.0)
注入部位内出血	2 (4.5)	3 (5.5)	5 (5.1)
注入部位変色	0	1 (1.8)	1 (1.0)
注入部位紅斑	10 (22.7)	8 (14.5)	18 (18.2)
注入部位血管外漏出	0	2 (3.6)	2 (2.0)
注入部位血腫	1 (2.3)	1 (1.8)	2 (2.0)
注入部位硬結	0	1 (1.8)	1 (1.0)
注入部位炎症	0	1 (1.8)	1 (1.0)
注入部位刺激感	2 (4.5)	0	2 (2.0)
注入部位腫瘤	1 (2.3)	0	1 (1.0)
注入部位結節	2 (4.5)	3 (5.5)	5 (5.1)
注入部位浮腫	1 (2.3)	1 (1.8)	2 (2.0)
注入部位疼痛	1 (2.3)	1 (1.8)	2 (2.0)
注入部位丘疹	1 (2.3)	3 (5.5)	4 (4.0)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
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	1 (1.8)	1 (1.0)
注入部位発疹	0	1 (1.8)	1 (1.0)
注入部位反応	0	1 (1.8)	1 (1.0)
注入部位痂皮	0	1 (1.8)	1 (1.0)
注入部位腫脹	1 (2.3)	1 (1.8)	2 (2.0)
注入部位熱感	1 (2.3)	0	1 (1.0)
注射部位内出血	1 (2.3)	1 (1.8)	2 (2.0)
注射部位紅斑	1 (2.3)	0	1 (1.0)
注射部位炎症	0	1 (1.8)	1 (1.0)
注射部位結節	1 (2.3)	0	1 (1.0)
注射部位浮腫	0	1 (1.8)	1 (1.0)
末梢性浮腫	1 (2.3)	0	1 (1.0)
穿刺部位紅斑	1 (2.3)	0	1 (1.0)
感染症および寄生虫症	13 (29.5)	17 (30.9)	30 (30.3)
ダニ皮膚炎	0	1 (1.8)	1 (1.0)
無症候性COVID-19	0	2 (3.6)	2 (2.0)
COVID-19	0	4 (7.3)	4 (4.0)
膀胱炎	1 (2.3)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
感染症および寄生虫症 (Cont.)			
大腸菌性尿路感染	0	1 (1.8)	1 (1.0)
胃腸炎	1 (2.3)	1 (1.8)	2 (2.0)
ヘリコバクター性胃炎	1 (2.3)	0	1 (1.0)
ヘリコバクター感染	1 (2.3)	0	1 (1.0)
帯状疱疹	0	1 (1.8)	1 (1.0)
注入部位膿瘍	3 (6.8)	0	3 (3.0)
注入部位蜂巣炎	5 (11.4)	8 (14.5)	13 (13.1)
注入部位感染	3 (6.8)	0	3 (3.0)
注射部位感染	0	1 (1.8)	1 (1.0)
上咽頭炎	1 (2.3)	1 (1.8)	2 (2.0)
口腔カンジダ症	0	1 (1.8)	1 (1.0)
RSウイルス感染	1 (2.3)	0	1 (1.0)
敗血症	0	1 (1.8)	1 (1.0)
副鼻腔炎	0	1 (1.8)	1 (1.0)
上気道感染	1 (2.3)	0	1 (1.0)
尿路感染	1 (2.3)	4 (7.3)	5 (5.1)
尿路性敗血症	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
傷害、中毒および処置合併症	8 (18.2)	12 (21.8)	20 (20.2)
節足動物咬傷	0	1 (1.8)	1 (1.0)
節足動物刺傷	1 (2.3)	0	1 (1.0)
挫傷	0	1 (1.8)	1 (1.0)
顔面骨骨折	0	1 (1.8)	1 (1.0)
転倒	5 (11.4)	8 (14.5)	13 (13.1)
大腿骨頚部骨折	0	1 (1.8)	1 (1.0)
大腿骨骨折	1 (2.3)	0	1 (1.0)
転位骨折	0	1 (1.8)	1 (1.0)
手骨折	1 (2.3)	2 (3.6)	3 (3.0)
股関節部骨折	1 (2.3)	1 (1.8)	2 (2.0)
上腕骨骨折	1 (2.3)	1 (1.8)	2 (2.0)
靱帯捻挫	0	1 (1.8)	1 (1.0)
四肢損傷	0	1 (1.8)	1 (1.0)
肉離れ	1 (2.3)	0	1 (1.0)
開放骨折	0	1 (1.8)	1 (1.0)
処置による疼痛	0	1 (1.8)	1 (1.0)
外傷性頭蓋内出血	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
臨床検査	4 (9.1)	7 (12.7)	11 (11.1)
血中葉酸減少	0	2 (3.6)	2 (2.0)
血中ホモシステイン増加	1 (2.3)	0	1 (1.0)
ヘモグロビン減少	0	1 (1.8)	1 (1.0)
リンパ球数減少	1 (2.3)	0	1 (1.0)
プロトロンビン時間延長	0	1 (1.8)	1 (1.0)
ビタミンB12減少	1 (2.3)	1 (1.8)	2 (2.0)
ビタミンB6減少	2 (4.5)	0	2 (2.0)
ビタミンB6増加	1 (2.3)	0	1 (1.0)
ビタミンD減少	0	1 (1.8)	1 (1.0)
体重減少	0	3 (5.5)	3 (3.0)
代謝および栄養障害	4 (9.1)	4 (7.3)	8 (8.1)
食欲減退	0	1 (1.8)	1 (1.0)
高ナトリウム血症	0	1 (1.8)	1 (1.0)
低カリウム血症	1 (2.3)	1 (1.8)	2 (2.0)
低マグネシウム血症	1 (2.3)	1 (1.8)	2 (2.0)
鉄欠乏	1 (2.3)	1 (1.8)	2 (2.0)
ビタミンB群欠乏	1 (2.3)	0	1 (1.0)
ビタミンB12欠乏	1 (2.3)	2 (3.6)	3 (3.0)
ビタミンB6欠乏	1 (2.3)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
筋骨格系および結合組織障害	8 (18.2)	7 (12.7)	15 (15.2)
関節痛	0	1 (1.8)	1 (1.0)
背部痛	1 (2.3)	2 (3.6)	3 (3.0)
滑液包炎	1 (2.3)	0	1 (1.0)
出血性関節症	0	1 (1.8)	1 (1.0)
椎間板変性症	0	1 (1.8)	1 (1.0)
腰部脊柱管狭窄症	1 (2.3)	0	1 (1.0)
筋力低下	0	2 (3.6)	2 (2.0)
筋骨格系胸痛	1 (2.3)	0	1 (1.0)
筋骨格硬直	0	1 (1.8)	1 (1.0)
変形性関節症	3 (6.8)	0	3 (3.0)
骨粗鬆症	2 (4.5)	0	2 (2.0)
四肢痛	2 (4.5)	0	2 (2.0)
肩回旋筋腱板症候群	2 (4.5)	0	2 (2.0)
変形性脊椎症	1 (2.3)	0	1 (1.0)
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	1 (1.8)	1 (1.0)
ケラトアカントーマ	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
神経系障害	10 (22.7)	15 (27.3)	25 (25.3)
健忘	1 (2.3)	0	1 (1.0)
平衡障害	0	1 (1.8)	1 (1.0)
運動緩慢	1 (2.3)	0	1 (1.0)
認知障害	1 (2.3)	2 (3.6)	3 (3.0)
注意力障害	0	1 (1.8)	1 (1.0)
浮動性めまい	1 (2.3)	1 (1.8)	2 (2.0)
薬物離脱性頭痛	0	1 (1.8)	1 (1.0)
ジスキネジア	1 (2.3)	0	1 (1.0)
ジストニア	0	1 (1.8)	1 (1.0)
伸展性足底反応	1 (2.3)	0	1 (1.0)
すくみ現象	3 (6.8)	0	3 (3.0)
頭蓋内出血	1 (2.3)	0	1 (1.0)
頭部不快感	0	2 (3.6)	2 (2.0)
頭痛	1 (2.3)	1 (1.8)	2 (2.0)
感覚鈍麻	1 (2.3)	0	1 (1.0)
反射減弱	1 (2.3)	1 (1.8)	2 (2.0)
記憶障害	0	2 (3.6)	2 (2.0)
オンオフ現象	2 (4.5)	5 (9.1)	7 (7.1)
パーキンソン病	2 (4.5)	5 (9.1)	7 (7.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
神経系障害 (Cont.)			
精神運動亢進	0	1 (1.8)	1 (1.0)
呼吸器ジスキネジア	1 (2.3)	0	1 (1.0)
痙攣発作	0	1 (1.8)	1 (1.0)
失神	0	2 (3.6)	2 (2.0)
一過性脳虚血発作	0	1 (1.8)	1 (1.0)
振戦	1 (2.3)	0	1 (1.0)
精神障害	11 (25.0)	18 (32.7)	29 (29.3)
異常な夢	0	1 (1.8)	1 (1.0)
適応障害	0	1 (1.8)	1 (1.0)
攻撃性	0	1 (1.8)	1 (1.0)
激越	0	1 (1.8)	1 (1.0)
不安	4 (9.1)	4 (7.3)	8 (8.1)
歯ぎしり	1 (2.3)	0	1 (1.0)
錯乱状態	0	1 (1.8)	1 (1.0)
譫妄	0	2 (3.6)	2 (2.0)
妄想	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
精神障害 (Cont.)			
抑うつ気分	1 (2.3)	0	1 (1.0)
うつ病	2 (4.5)	1 (1.8)	3 (3.0)
自傷性皮膚症	0	1 (1.8)	1 (1.0)
失見当識	1 (2.3)	0	1 (1.0)
ギャンブル障害	1 (2.3)	0	1 (1.0)
幻覚	2 (4.5)	5 (9.1)	7 (7.1)
幻嗅	1 (2.3)	0	1 (1.0)
幻視	1 (2.3)	1 (1.8)	2 (2.0)
錯覚	1 (2.3)	1 (1.8)	2 (2.0)
衝動制御障害	0	1 (1.8)	1 (1.0)
衝動行為	1 (2.3)	0	1 (1.0)
不眠症	1 (2.3)	1 (1.8)	2 (2.0)
消極的思考	1 (2.3)	0	1 (1.0)
パニック発作	1 (2.3)	1 (1.8)	2 (2.0)
妄想症	1 (2.3)	0	1 (1.0)
精神病性障害	1 (2.3)	1 (1.8)	2 (2.0)
レム睡眠行動障害	1 (2.3)	0	1 (1.0)
睡眠障害	0	1 (1.8)	1 (1.0)
腎および尿路障害	2 (4.5)	4 (7.3)	6 (6.1)
急性腎障害	0	1 (1.8)	1 (1.0)
膀胱痙縮	1 (2.3)	0	1 (1.0)
血尿	0	1 (1.8)	1 (1.0)
水腎症	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
腎および尿路障害 (Cont.)			
水尿管症	0	1 (1.8)	1 (1.0)
緊張性膀胱	1 (2.3)	0	1 (1.0)
腎結石症	0	1 (1.8)	1 (1.0)
蛋白尿	0	1 (1.8)	1 (1.0)
生殖系および乳房障害	2 (4.5)	3 (5.5)	5 (5.1)
良性前立腺肥大症	1 (2.3)	0	1 (1.0)
膀胱瘤	0	1 (1.8)	1 (1.0)
勃起不全	0	1 (1.8)	1 (1.0)
生殖器萎縮	0	1 (1.8)	1 (1.0)
腟脱	0	1 (1.8)	1 (1.0)
外陰腟乾燥	1 (2.3)	0	1 (1.0)
呼吸器、胸郭および縦隔障害	1 (2.3)	0	1 (1.0)
呼吸困難	1 (2.3)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: White (Cont.)	N=44	N=55	N=99
皮膚および皮下組織障害	4 (9.1)	0	4 (4.0)
光線角化症	1 (2.3)	0	1 (1.0)
脱毛症	1 (2.3)	0	1 (1.0)
湿疹	1 (2.3)	0	1 (1.0)
発疹	1 (2.3)	0	1 (1.0)
蕁麻疹	1 (2.3)	0	1 (1.0)
血管障害	3 (6.8)	5 (9.1)	8 (8.1)
血腫	1 (2.3)	0	1 (1.0)
高血圧	0	1 (1.8)	1 (1.0)
低血圧	1 (2.3)	1 (1.8)	2 (2.0)
起立性高血圧	0	1 (1.8)	1 (1.0)
起立性低血圧	1 (2.3)	1 (1.8)	2 (2.0)
表在性血栓性静脈炎	0	1 (1.8)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: Asian	N=10	N=6	N=16
Any adverse event	7 (70.0)	5 (83.3)	12 (75.0)
眼障害	0	1 (16.7)	1 (6.3)
眼充血	0	1 (16.7)	1 (6.3)
胃腸障害	2 (20.0)	0	2 (12.5)
便秘	1 (10.0)	0	1 (6.3)
悪心	1 (10.0)	0	1 (6.3)
嘔吐	1 (10.0)	0	1 (6.3)
一般・全身障害および投与部位の状態	3 (30.0)	3 (50.0)	6 (37.5)
注入部位皮膚炎	1 (10.0)	0	1 (6.3)
注入部位紅斑	1 (10.0)	0	1 (6.3)
注入部位硬結	1 (10.0)	1 (16.7)	2 (12.5)
注射部位紅斑	0	2 (33.3)	2 (12.5)
注射部位硬結	0	1 (16.7)	1 (6.3)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: Asian (Cont.)	N=10	N=6	N=16
感染症および寄生虫症	2 (20.0)	2 (33.3)	4 (25.0)
COVID-19	1 (10.0)	0	1 (6.3)
注入部位蜂巣炎	1 (10.0)	2 (33.3)	3 (18.8)
注射部位蜂巣炎	0	1 (16.7)	1 (6.3)
傷害、中毒および処置合併症	0	1 (16.7)	1 (6.3)
転倒	0	1 (16.7)	1 (6.3)
肩甲骨骨折	0	1 (16.7)	1 (6.3)
臨床検査	1 (10.0)	0	1 (6.3)
血中ホモシステイン増加	1 (10.0)	0	1 (6.3)
代謝および栄養障害	0	1 (16.7)	1 (6.3)
ビタミンB12欠乏	0	1 (16.7)	1 (6.3)
筋骨格系および結合組織障害	2 (20.0)	0	2 (12.5)
腱鞘炎	1 (10.0)	0	1 (6.3)
斜頚	1 (10.0)	0	1 (6.3)
神経系障害	1 (10.0)	1 (16.7)	2 (12.5)
感覚鈍麻	0	1 (16.7)	1 (6.3)
錯感覚	1 (10.0)	1 (16.7)	2 (12.5)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: Asian (Cont.)	N=10	N=6	N=16
精神障害	4 (40.0)	0	4 (25.0)
妄想	1 (10.0)	0	1 (6.3)
幻覚	2 (20.0)	0	2 (12.5)
軽躁	1 (10.0)	0	1 (6.3)
腎および尿路障害	1 (10.0)	0	1 (6.3)
尿失禁	1 (10.0)	0	1 (6.3)
呼吸器、胸郭および縦隔障害	1 (10.0)	1 (16.7)	2 (12.5)
窒息	1 (10.0)	0	1 (6.3)
誤嚥	1 (10.0)	0	1 (6.3)
痰貯留	0	1 (16.7)	1 (6.3)
皮膚および皮下組織障害	0	1 (16.7)	1 (6.3)
湿疹	0	1 (16.7)	1 (6.3)
血管障害	0	1 (16.7)	1 (6.3)
起立性低血圧	0	1 (16.7)	1 (6.3)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Race: Other	N=1	N=0	N=1
Any adverse event	1 (100)	0	1 (100)
臨床検査	1 (100)	0	1 (100)
血中ナトリウム減少	1 (100)	0	1 (100)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65	N=29	N=35	N=64
Any adverse event	21 (72.4)	26 (74.3)	47 (73.4)
心臓障害	2 (6.9)	0	2 (3.1)
徐脈	1 (3.4)	0	1 (1.6)
洞性頻脈	1 (3.4)	0	1 (1.6)
耳および迷路障害	0	1 (2.9)	1 (1.6)
回転性めまい	0	1 (2.9)	1 (1.6)
眼障害	0	2 (5.7)	2 (3.1)
眼瞼痙攣	0	1 (2.9)	1 (1.6)
眼の異物感	0	1 (2.9)	1 (1.6)
眼部不快感	0	1 (2.9)	1 (1.6)
眼充血	0	1 (2.9)	1 (1.6)
霧視	0	1 (2.9)	1 (1.6)
胃腸障害	4 (13.8)	2 (5.7)	6 (9.4)
腹部膨満	0	1 (2.9)	1 (1.6)
腹痛	0	1 (2.9)	1 (1.6)
便秘	1 (3.4)	0	1 (1.6)
嚥下障害	0	1 (2.9)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
胃腸障害 (Cont.)			
胃潰瘍	1 (3.4)	0	1 (1.6)
悪心	2 (6.9)	1 (2.9)	3 (4.7)
吐き戻し	0	1 (2.9)	1 (1.6)
嘔吐	1 (3.4)	0	1 (1.6)
一般・全身障害および投与部位の状態	12 (41.4)	10 (28.6)	22 (34.4)
投与部位内出血	0	1 (2.9)	1 (1.6)
カテーテル留置部位内出血	0	2 (5.7)	2 (3.1)
カテーテル留置部位紅斑	1 (3.4)	0	1 (1.6)
カテーテル留置部位漏出	0	1 (2.9)	1 (1.6)
カテーテル留置部位炎症	0	1 (2.9)	1 (1.6)
薬物相互作用	1 (3.4)	0	1 (1.6)
疲労	3 (10.3)	0	3 (4.7)
注入部位内出血	1 (3.4)	1 (2.9)	2 (3.1)
注入部位紅斑	5 (17.2)	3 (8.6)	8 (12.5)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血管外漏出	0	2 (5.7)	2 (3.1)
注入部位血腫	1 (3.4)	1 (2.9)	2 (3.1)
注入部位硬結	1 (3.4)	1 (2.9)	2 (3.1)
注入部位結節	1 (3.4)	1 (2.9)	2 (3.1)
注入部位浮腫	0	1 (2.9)	1 (1.6)
注入部位疼痛	0	1 (2.9)	1 (1.6)
注入部位丘疹	0	1 (2.9)	1 (1.6)
注入部位発疹	0	1 (2.9)	1 (1.6)
注入部位痂皮	0	1 (2.9)	1 (1.6)
注入部位腫脹	1 (3.4)	0	1 (1.6)
注入部位熱感	1 (3.4)	0	1 (1.6)
注射部位内出血	1 (3.4)	0	1 (1.6)
注射部位紅斑	1 (3.4)	1 (2.9)	2 (3.1)
注射部位炎症	0	1 (2.9)	1 (1.6)
注射部位結節	1 (3.4)	0	1 (1.6)
感染症および寄生虫症	9 (31.0)	13 (37.1)	22 (34.4)
ダニ皮膚炎	0	1 (2.9)	1 (1.6)
無症候性COVID-19	0	2 (5.7)	2 (3.1)
COVID-19	1 (3.4)	2 (5.7)	3 (4.7)
胃腸炎	1 (3.4)	1 (2.9)	2 (3.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
感染症および寄生虫症 (Cont.)			
ヘリコバクター感染	1 (3.4)	0	1 (1.6)
注入部位膿瘍	2 (6.9)	0	2 (3.1)
注入部位蜂巣炎	3 (10.3)	7 (20.0)	10 (15.6)
注入部位感染	1 (3.4)	0	1 (1.6)
注射部位蜂巣炎	0	1 (2.9)	1 (1.6)
上咽頭炎	1 (3.4)	1 (2.9)	2 (3.1)
口腔カンジダ症	0	1 (2.9)	1 (1.6)
RSウイルス感染	1 (3.4)	0	1 (1.6)
敗血症	0	1 (2.9)	1 (1.6)
上気道感染	1 (3.4)	0	1 (1.6)
尿路感染	1 (3.4)	3 (8.6)	4 (6.3)
尿路性敗血症	0	1 (2.9)	1 (1.6)
傷害、中毒および処置合併症	4 (13.8)	5 (14.3)	9 (14.1)
節足動物刺傷	1 (3.4)	0	1 (1.6)
挫傷	0	1 (2.9)	1 (1.6)
転倒	1 (3.4)	3 (8.6)	4 (6.3)
手骨折	1 (3.4)	1 (2.9)	2 (3.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
傷害、中毒および処置合併症 (Cont.)			
肉離れ	1 (3.4)	0	1 (1.6)
開放骨折	0	1 (2.9)	1 (1.6)
処置による疼痛	0	1 (2.9)	1 (1.6)
外傷性頭蓋内出血	0	1 (2.9)	1 (1.6)
臨床検査	2 (6.9)	5 (14.3)	7 (10.9)
血中葉酸減少	0	1 (2.9)	1 (1.6)
血中ホモシステイン増加	1 (3.4)	0	1 (1.6)
ヘモグロビン減少	0	1 (2.9)	1 (1.6)
リンパ球数減少	1 (3.4)	0	1 (1.6)
プロトロンビン時間延長	0	1 (2.9)	1 (1.6)
ビタミンB12減少	0	1 (2.9)	1 (1.6)
ビタミンD減少	0	1 (2.9)	1 (1.6)
体重減少	0	2 (5.7)	2 (3.1)
代謝および栄養障害	4 (13.8)	5 (14.3)	9 (14.1)
食欲減退	0	1 (2.9)	1 (1.6)
高ナトリウム血症	0	1 (2.9)	1 (1.6)
低カリウム血症	1 (3.4)	1 (2.9)	2 (3.1)
低マグネシウム血症	1 (3.4)	1 (2.9)	2 (3.1)
鉄欠乏	1 (3.4)	1 (2.9)	2 (3.1)
ビタミンB群欠乏	1 (3.4)	0	1 (1.6)
ビタミンB12欠乏	1 (3.4)	3 (8.6)	4 (6.3)
ビタミンB6欠乏	1 (3.4)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
筋骨格系および結合組織障害	4 (13.8)	4 (11.4)	8 (12.5)
関節痛	0	1 (2.9)	1 (1.6)
背部痛	0	1 (2.9)	1 (1.6)
椎間板変性症	0	1 (2.9)	1 (1.6)
筋力低下	0	1 (2.9)	1 (1.6)
筋骨格系胸痛	1 (3.4)	0	1 (1.6)
筋骨格硬直	0	1 (2.9)	1 (1.6)
変形性関節症	1 (3.4)	0	1 (1.6)
四肢痛	1 (3.4)	0	1 (1.6)
肩回旋筋腱板症候群	1 (3.4)	0	1 (1.6)
腱鞘炎	1 (3.4)	0	1 (1.6)
斜頚	1 (3.4)	0	1 (1.6)
神経系障害	5 (17.2)	8 (22.9)	13 (20.3)
平衡障害	0	1 (2.9)	1 (1.6)
運動緩慢	1 (3.4)	0	1 (1.6)
注意力障害	0	1 (2.9)	1 (1.6)
浮動性めまい	1 (3.4)	0	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
神経系障害 (Cont.)			
薬物離脱性頭痛	0	1 (2.9)	1 (1.6)
ジスキネジア	1 (3.4)	0	1 (1.6)
ジストニア	0	1 (2.9)	1 (1.6)
伸展性足底反応	1 (3.4)	0	1 (1.6)
すくみ現象	1 (3.4)	0	1 (1.6)
頭部不快感	0	2 (5.7)	2 (3.1)
頭痛	1 (3.4)	1 (2.9)	2 (3.1)
感覚鈍麻	1 (3.4)	1 (2.9)	2 (3.1)
反射減弱	0	1 (2.9)	1 (1.6)
記憶障害	0	1 (2.9)	1 (1.6)
オンオフ現象	0	3 (8.6)	3 (4.7)
錯感覚	0	1 (2.9)	1 (1.6)
パーキンソン病	0	3 (8.6)	3 (4.7)
精神運動亢進	0	1 (2.9)	1 (1.6)
呼吸器ジスキネジア	1 (3.4)	0	1 (1.6)
痙攣発作	0	1 (2.9)	1 (1.6)
失神	0	2 (5.7)	2 (3.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
精神障害	6 (20.7)	9 (25.7)	15 (23.4)
異常な夢	0	1 (2.9)	1 (1.6)
適応障害	0	1 (2.9)	1 (1.6)
不安	2 (6.9)	1 (2.9)	3 (4.7)
歯ぎしり	1 (3.4)	0	1 (1.6)
譫妄	0	1 (2.9)	1 (1.6)
妄想	0	1 (2.9)	1 (1.6)
うつ病	0	1 (2.9)	1 (1.6)
幻覚	2 (6.9)	1 (2.9)	3 (4.7)
幻視	1 (3.4)	1 (2.9)	2 (3.1)
錯覚	1 (3.4)	1 (2.9)	2 (3.1)
衝動制御障害	0	1 (2.9)	1 (1.6)
不眠症	1 (3.4)	1 (2.9)	2 (3.1)
消極的思考	1 (3.4)	0	1 (1.6)
パニック発作	1 (3.4)	0	1 (1.6)
妄想症	1 (3.4)	0	1 (1.6)
睡眠障害	0	1 (2.9)	1 (1.6)
腎および尿路障害	3 (10.3)	1 (2.9)	4 (6.3)
急性腎障害	0	1 (2.9)	1 (1.6)
膀胱痙縮	1 (3.4)	0	1 (1.6)
水腎症	0	1 (2.9)	1 (1.6)
水尿管症	0	1 (2.9)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: <65 (Cont.)	N=29	N=35	N=64
腎および尿路障害 (Cont.)			
緊張性膀胱	1 (3.4)	0	1 (1.6)
尿失禁	1 (3.4)	0	1 (1.6)
生殖系および乳房障害	1 (3.4)	1 (2.9)	2 (3.1)
良性前立腺肥大症	1 (3.4)	0	1 (1.6)
膣脱	0	1 (2.9)	1 (1.6)
呼吸器、胸郭および縦隔障害	1 (3.4)	0	1 (1.6)
呼吸困難	1 (3.4)	0	1 (1.6)
皮膚および皮下組織障害	2 (6.9)	0	2 (3.1)
光線角化症	1 (3.4)	0	1 (1.6)
蕁麻疹	1 (3.4)	0	1 (1.6)
血管障害	1 (3.4)	3 (8.6)	4 (6.3)
低血圧	1 (3.4)	1 (2.9)	2 (3.1)
起立性高血圧	0	1 (2.9)	1 (1.6)
起立性低血圧	0	1 (2.9)	1 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65	N=26	N=26	N=52
Any adverse event	18 (69.2)	23 (88.5)	41 (78.8)
心臓障害	1 (3.8)	1 (3.8)	2 (3.8)
急性心筋梗塞	1 (3.8)	0	1 (1.9)
左脚ブロック	0	1 (3.8)	1 (1.9)
耳および迷路障害	0	1 (3.8)	1 (1.9)
回転性めまい	0	1 (3.8)	1 (1.9)
眼障害	1 (3.8)	1 (3.8)	2 (3.8)
黄斑症	1 (3.8)	0	1 (1.9)
眼充血	0	1 (3.8)	1 (1.9)
胃腸障害	3 (11.5)	5 (19.2)	8 (15.4)
腹部不快感	0	1 (3.8)	1 (1.9)
便秘	2 (7.7)	2 (7.7)	4 (7.7)
出血性腸憩室	0	1 (3.8)	1 (1.9)
嚥下障害	1 (3.8)	1 (3.8)	2 (3.8)
胃食道逆流性疾患	1 (3.8)	0	1 (1.9)
悪心	0	1 (3.8)	1 (1.9)
流涎過多	0	1 (3.8)	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
一般・全身障害および投与部位の状態	9 (34.6)	11 (42.3)	20 (38.5)
投与部位漏出	1 (3.8)	0	1 (1.9)
カテーテル留置部位内出血	1 (3.8)	0	1 (1.9)
カテーテル留置部位疼痛	1 (3.8)	0	1 (1.9)
カテーテル留置部位腫脹	1 (3.8)	0	1 (1.9)
薬効欠如	1 (3.8)	0	1 (1.9)
注入部位内出血	1 (3.8)	2 (7.7)	3 (5.8)
注入部位皮膚炎	1 (3.8)	0	1 (1.9)
注入部位変色	0	1 (3.8)	1 (1.9)
注入部位紅斑	6 (23.1)	5 (19.2)	11 (21.2)
注入部位硬結	0	1 (3.8)	1 (1.9)
注入部位炎症	0	1 (3.8)	1 (1.9)
注入部位刺激感	2 (7.7)	0	2 (3.8)
注入部位腫瘤	1 (3.8)	0	1 (1.9)
注入部位結節	1 (3.8)	2 (7.7)	3 (5.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
一般・全身障害および投与部位の状態 (Cont.)			
注入部位浮腫	1 (3.8)	0	1 (1.9)
注入部位疼痛	1 (3.8)	0	1 (1.9)
注入部位丘疹	1 (3.8)	2 (7.7)	3 (5.8)
注入部位異常感覚	0	1 (3.8)	1 (1.9)
注入部位反応	0	1 (3.8)	1 (1.9)
注入部位腫脹	0	1 (3.8)	1 (1.9)
注射部位内出血	0	1 (3.8)	1 (1.9)
注射部位紅斑	0	1 (3.8)	1 (1.9)
注射部位硬結	0	1 (3.8)	1 (1.9)
注射部位浮腫	0	1 (3.8)	1 (1.9)
末梢性浮腫	1 (3.8)	0	1 (1.9)
穿刺部位紅斑	1 (3.8)	0	1 (1.9)
感染症および寄生虫症	6 (23.1)	6 (23.1)	12 (23.1)
COVID-19	0	2 (7.7)	2 (3.8)
膀胱炎	1 (3.8)	0	1 (1.9)
大腸菌性尿路感染	0	1 (3.8)	1 (1.9)
ヘリコバクター性胃炎	1 (3.8)	0	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
感染症および寄生虫症 (Cont.)			
帯状疱疹	0	1 (3.8)	1 (1.9)
注入部位膿瘍	1 (3.8)	0	1 (1.9)
注入部位蜂巣炎	3 (11.5)	3 (11.5)	6 (11.5)
注入部位感染	2 (7.7)	0	2 (3.8)
注射部位感染	0	1 (3.8)	1 (1.9)
副鼻腔炎	0	1 (3.8)	1 (1.9)
尿路感染	0	1 (3.8)	1 (1.9)
傷害、中毒および処置合併症	4 (15.4)	8 (30.8)	12 (23.1)
節足動物咬傷	0	1 (3.8)	1 (1.9)
顔面骨骨折	0	1 (3.8)	1 (1.9)
転倒	4 (15.4)	6 (23.1)	10 (19.2)
大腿骨頚部骨折	0	1 (3.8)	1 (1.9)
大腿骨骨折	1 (3.8)	0	1 (1.9)
転位骨折	0	1 (3.8)	1 (1.9)
手骨折	0	1 (3.8)	1 (1.9)
股関節部骨折	1 (3.8)	1 (3.8)	2 (3.8)
上腕骨骨折	1 (3.8)	1 (3.8)	2 (3.8)
靭帯捻挫	0	1 (3.8)	1 (1.9)
四肢損傷	0	1 (3.8)	1 (1.9)
肩甲骨骨折	0	1 (3.8)	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
臨床検査	4 (15.4)	2 (7.7)	6 (11.5)
血中葉酸減少	0	1 (3.8)	1 (1.9)
血中ホモシステイン増加	1 (3.8)	0	1 (1.9)
血中ナトリウム減少	1 (3.8)	0	1 (1.9)
ビタミンB12減少	1 (3.8)	0	1 (1.9)
ビタミンB6減少	2 (7.7)	0	2 (3.8)
ビタミンB6増加	1 (3.8)	0	1 (1.9)
体重減少	0	1 (3.8)	1 (1.9)
筋骨格系および結合組織障害	6 (23.1)	3 (11.5)	9 (17.3)
背部痛	1 (3.8)	1 (3.8)	2 (3.8)
滑液包炎	1 (3.8)	0	1 (1.9)
出血性関節症	0	1 (3.8)	1 (1.9)
腰部脊柱管狭窄症	1 (3.8)	0	1 (1.9)
筋力低下	0	1 (3.8)	1 (1.9)
変形性関節症	2 (7.7)	0	2 (3.8)
骨粗鬆症	2 (7.7)	0	2 (3.8)
四肢痛	1 (3.8)	0	1 (1.9)
肩回旋筋腱板症候群	1 (3.8)	0	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
筋骨格系および結合組織障害 (Cont.)			
変形性脊椎症	1 (3.8)	0	1 (1.9)
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	1 (3.8)	1 (1.9)
ケラトアカントーマ	0	1 (3.8)	1 (1.9)
神経系障害	6 (23.1)	8 (30.8)	14 (26.9)
健忘	1 (3.8)	0	1 (1.9)
認知障害	1 (3.8)	2 (7.7)	3 (5.8)
浮動性めまい	0	1 (3.8)	1 (1.9)
すくみ現象	2 (7.7)	0	2 (3.8)
頭蓋内出血	1 (3.8)	0	1 (1.9)
反射減弱	1 (3.8)	0	1 (1.9)
記憶障害	0	1 (3.8)	1 (1.9)
オンオフ現象	2 (7.7)	2 (7.7)	4 (7.7)
錯感覚	1 (3.8)	0	1 (1.9)
パーキンソン病	2 (7.7)	2 (7.7)	4 (7.7)
一過性脳虚血発作	0	1 (3.8)	1 (1.9)
振戦	1 (3.8)	0	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
精神障害	9 (34.6)	9 (34.6)	18 (34.6)
攻撃性	0	1 (3.8)	1 (1.9)
激越	0	1 (3.8)	1 (1.9)
不安	2 (7.7)	3 (11.5)	5 (9.6)
錯乱状態	0	1 (3.8)	1 (1.9)
譫妄	0	1 (3.8)	1 (1.9)
妄想	1 (3.8)	0	1 (1.9)
抑うつ気分	1 (3.8)	0	1 (1.9)
うつ病	2 (7.7)	0	2 (3.8)
自傷性皮膚症	0	1 (3.8)	1 (1.9)
失見当識	1 (3.8)	0	1 (1.9)
ギャンブル障害	1 (3.8)	0	1 (1.9)
幻覚	2 (7.7)	4 (15.4)	6 (11.5)
幻嗅	1 (3.8)	0	1 (1.9)
軽躁	1 (3.8)	0	1 (1.9)
衝動行為	1 (3.8)	0	1 (1.9)
パニック発作	0	1 (3.8)	1 (1.9)
精神病性障害	1 (3.8)	1 (3.8)	2 (3.8)
レム睡眠行動障害	1 (3.8)	0	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
腎および尿路障害	0	3 (11.5)	3 (5.8)
血尿	0	1 (3.8)	1 (1.9)
腎結石症	0	1 (3.8)	1 (1.9)
蛋白尿	0	1 (3.8)	1 (1.9)
生殖系および乳房障害	1 (3.8)	2 (7.7)	3 (5.8)
膀胱瘤	0	1 (3.8)	1 (1.9)
勃起不全	0	1 (3.8)	1 (1.9)
生殖器萎縮	0	1 (3.8)	1 (1.9)
外陰腟乾燥	1 (3.8)	0	1 (1.9)
呼吸器、胸郭および縦隔障害	1 (3.8)	1 (3.8)	2 (3.8)
窒息	1 (3.8)	0	1 (1.9)
誤嚥	1 (3.8)	0	1 (1.9)
痰貯留	0	1 (3.8)	1 (1.9)
皮膚および皮下組織障害	2 (7.7)	1 (3.8)	3 (5.8)
脱毛症	1 (3.8)	0	1 (1.9)
湿疹	1 (3.8)	1 (3.8)	2 (3.8)
発疹	1 (3.8)	0	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Age category: >=65 (Cont.)	N=26	N=26	N=52
血管障害	2 (7.7)	3 (11.5)	5 (9.6)
血腫	1 (3.8)	0	1 (1.9)
高血圧	0	1 (3.8)	1 (1.9)
起立性低血圧	1 (3.8)	1 (3.8)	2 (3.8)
表在性血栓性静脈炎	0	1 (3.8)	1 (1.9)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: North America	N=20	N=29	N=49
Any adverse event	11 (55.0)	25 (86.2)	36 (73.5)
心臓障害	0	1 (3.4)	1 (2.0)
左脚ブロック	0	1 (3.4)	1 (2.0)
胃腸障害	0	2 (6.9)	2 (4.1)
腹部不快感	0	1 (3.4)	1 (2.0)
便秘	0	1 (3.4)	1 (2.0)
嚥下障害	0	1 (3.4)	1 (2.0)
一般・全身障害および投与部位の状態	7 (35.0)	11 (37.9)	18 (36.7)
投与部位漏出	1 (5.0)	0	1 (2.0)
注入部位内出血	1 (5.0)	2 (6.9)	3 (6.1)
注入部位変色	0	1 (3.4)	1 (2.0)
注入部位紅斑	5 (25.0)	8 (27.6)	13 (26.5)
注入部位血管外漏出	0	2 (6.9)	2 (4.1)
注入部位硬結	0	1 (3.4)	1 (2.0)
注入部位結節	0	1 (3.4)	1 (2.0)
注入部位浮腫	0	1 (3.4)	1 (2.0)
注入部位疼痛	1 (5.0)	1 (3.4)	2 (4.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: North America (Cont.)	N=20	N=29	N=49
一般・全身障害および投与部位の状態 (Cont.)			
注入部位丘疹	0	3 (10.3)	3 (6.1)
注入部位異常感覚	0	1 (3.4)	1 (2.0)
注入部位発疹	0	1 (3.4)	1 (2.0)
注入部位反応	0	1 (3.4)	1 (2.0)
注入部位痂皮	0	1 (3.4)	1 (2.0)
注入部位腫脹	0	1 (3.4)	1 (2.0)
注射部位内出血	1 (5.0)	0	1 (2.0)
注射部位紅斑	1 (5.0)	0	1 (2.0)
注射部位浮腫	0	1 (3.4)	1 (2.0)
穿刺部位紅斑	1 (5.0)	0	1 (2.0)
感染症および寄生虫症	3 (15.0)	11 (37.9)	14 (28.6)
COVID-19	0	2 (6.9)	2 (4.1)
大腸菌性尿路感染	0	1 (3.4)	1 (2.0)
胃腸炎	0	1 (3.4)	1 (2.0)
注入部位蜂巣炎	2 (10.0)	7 (24.1)	9 (18.4)
注入部位感染	1 (5.0)	0	1 (2.0)
副鼻腔炎	0	1 (3.4)	1 (2.0)
尿路感染	0	3 (10.3)	3 (6.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: North America (Cont.)	N=20	N=29	N=49
傷害、中毒および処置合併症	3 (15.0)	7 (24.1)	10 (20.4)
節足動物咬傷	0	1 (3.4)	1 (2.0)
転倒	3 (15.0)	5 (17.2)	8 (16.3)
大腿骨頚部骨折	0	1 (3.4)	1 (2.0)
転位骨折	0	1 (3.4)	1 (2.0)
手骨折	0	1 (3.4)	1 (2.0)
股関節部骨折	1 (5.0)	0	1 (2.0)
上腕骨骨折	1 (5.0)	0	1 (2.0)
靱帯捻挫	0	1 (3.4)	1 (2.0)
四肢損傷	0	1 (3.4)	1 (2.0)
臨床検査	1 (5.0)	4 (13.8)	5 (10.2)
血中葉酸減少	0	1 (3.4)	1 (2.0)
血中ナトリウム減少	1 (5.0)	0	1 (2.0)
ビタミンB12減少	0	1 (3.4)	1 (2.0)
ビタミンD減少	0	1 (3.4)	1 (2.0)
体重減少	0	1 (3.4)	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Geographic region: North America (Cont.)	N=20	N=29	N=49
筋骨格系および結合組織障害	2 (10.0)	3 (10.3)	5 (10.2)
背部痛	0	1 (3.4)	1 (2.0)
椎間板変性症	0	1 (3.4)	1 (2.0)
筋力低下	0	1 (3.4)	1 (2.0)
変形性関節症	2 (10.0)	0	2 (4.1)
肩回旋筋腱板症候群	1 (5.0)	0	1 (2.0)
変形性脊椎症	1 (5.0)	0	1 (2.0)
神経系障害	3 (15.0)	7 (24.1)	10 (20.4)
健忘	1 (5.0)	0	1 (2.0)
平衡障害	0	1 (3.4)	1 (2.0)
認知障害	0	2 (6.9)	2 (4.1)
頭蓋内出血	1 (5.0)	0	1 (2.0)
感覚鈍麻	1 (5.0)	0	1 (2.0)
反射減弱	1 (5.0)	0	1 (2.0)
記憶障害	0	1 (3.4)	1 (2.0)
オンオフ現象	1 (5.0)	2 (6.9)	3 (6.1)
パーキンソン病	0	1 (3.4)	1 (2.0)
精神運動亢進	0	1 (3.4)	1 (2.0)
失神	0	1 (3.4)	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: North America (Cont.)	N=20	N=29	N=49
精神障害	2 (10.0)	7 (24.1)	9 (18.4)
不安	1 (5.0)	1 (3.4)	2 (4.1)
錯乱状態	0	1 (3.4)	1 (2.0)
妄想	0	1 (3.4)	1 (2.0)
うつ病	1 (5.0)	0	1 (2.0)
自傷性皮膚症	0	1 (3.4)	1 (2.0)
幻覚	0	4 (13.8)	4 (8.2)
パニック発作	0	1 (3.4)	1 (2.0)
精神病性障害	0	1 (3.4)	1 (2.0)
腎および尿路障害	0	3 (10.3)	3 (6.1)
血尿	0	1 (3.4)	1 (2.0)
腎結石症	0	1 (3.4)	1 (2.0)
蛋白尿	0	1 (3.4)	1 (2.0)
血管障害	1 (5.0)	3 (10.3)	4 (8.2)
血腫	1 (5.0)	0	1 (2.0)
高血圧	0	1 (3.4)	1 (2.0)
低血圧	0	1 (3.4)	1 (2.0)
表在性血栓性静脈炎	0	1 (3.4)	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia	N=27	N=28	N=55
Any adverse event	23 (85.2)	20 (71.4)	43 (78.2)
心臓障害	3 (11.1)	0	3 (5.5)
急性心筋梗塞	1 (3.7)	0	1 (1.8)
徐脈	1 (3.7)	0	1 (1.8)
洞性頻脈	1 (3.7)	0	1 (1.8)
耳および迷路障害	0	2 (7.1)	2 (3.6)
回転性めまい	0	2 (7.1)	2 (3.6)
眼障害	1 (3.7)	2 (7.1)	3 (5.5)
眼瞼痙攣	0	1 (3.6)	1 (1.8)
眼の異物感	0	1 (3.6)	1 (1.8)
黄斑症	1 (3.7)	0	1 (1.8)
眼部不快感	0	1 (3.6)	1 (1.8)
眼充血	0	1 (3.6)	1 (1.8)
霧視	0	1 (3.6)	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
胃腸障害	6 (22.2)	5 (17.9)	11 (20.0)
腹部膨満	0	1 (3.6)	1 (1.8)
腹痛	0	1 (3.6)	1 (1.8)
便秘	2 (7.4)	1 (3.6)	3 (5.5)
出血性腸憩室	0	1 (3.6)	1 (1.8)
嚥下障害	1 (3.7)	1 (3.6)	2 (3.6)
胃潰瘍	1 (3.7)	0	1 (1.8)
胃食道逆流性疾患	1 (3.7)	0	1 (1.8)
悪心	2 (7.4)	2 (7.1)	4 (7.3)
吐き戻し	0	1 (3.6)	1 (1.8)
流涎過多	0	1 (3.6)	1 (1.8)
嘔吐	1 (3.7)	0	1 (1.8)
一般・全身障害および投与部位の状態	12 (44.4)	7 (25.0)	19 (34.5)
投与部位内出血	0	1 (3.6)	1 (1.8)
カテーテル留置部位内出血	1 (3.7)	2 (7.1)	3 (5.5)
カテーテル留置部位紅斑	1 (3.7)	0	1 (1.8)
カテーテル留置部位漏出	0	1 (3.6)	1 (1.8)
カテーテル留置部位炎症	0	1 (3.6)	1 (1.8)
カテーテル留置部位疼痛	1 (3.7)	0	1 (1.8)
カテーテル留置部位腫脹	1 (3.7)	0	1 (1.8)
薬効欠如	1 (3.7)	0	1 (1.8)
薬物相互作用	1 (3.7)	0	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
一般・全身障害および投与部位の状態 (Cont.)			
疲労	3 (11.1)	0	3 (5.5)
注入部位内出血	1 (3.7)	1 (3.6)	2 (3.6)
注入部位紅斑	6 (22.2)	0	6 (10.9)
注入部位血腫	1 (3.7)	1 (3.6)	2 (3.6)
注入部位炎症	0	1 (3.6)	1 (1.8)
注入部位刺激感	2 (7.4)	0	2 (3.6)
注入部位腫瘤	1 (3.7)	0	1 (1.8)
注入部位結節	2 (7.4)	2 (7.1)	4 (7.3)
注入部位浮腫	1 (3.7)	0	1 (1.8)
注入部位丘疹	1 (3.7)	0	1 (1.8)
注入部位腫脹	1 (3.7)	0	1 (1.8)
注入部位熱感	1 (3.7)	0	1 (1.8)
注射部位内出血	0	1 (3.6)	1 (1.8)
注射部位炎症	0	1 (3.6)	1 (1.8)
注射部位結節	1 (3.7)	0	1 (1.8)
末梢性浮腫	1 (3.7)	0	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
感染症および寄生虫症	10 (37.0)	6 (21.4)	16 (29.1)
ダニ皮膚炎	0	1 (3.6)	1 (1.8)
無症候性COVID-19	0	2 (7.1)	2 (3.6)
COVID-19	0	2 (7.1)	2 (3.6)
膀胱炎	1 (3.7)	0	1 (1.8)
胃腸炎	1 (3.7)	0	1 (1.8)
ヘリコバクター性胃炎	1 (3.7)	0	1 (1.8)
ヘリコバクター感染	1 (3.7)	0	1 (1.8)
帯状疱疹	0	1 (3.6)	1 (1.8)
注入部位膿瘍	3 (11.1)	0	3 (5.5)
注入部位蜂巣炎	3 (11.1)	1 (3.6)	4 (7.3)
注入部位感染	2 (7.4)	0	2 (3.6)
注射部位感染	0	1 (3.6)	1 (1.8)
上咽頭炎	1 (3.7)	1 (3.6)	2 (3.6)
口腔カンジダ症	0	1 (3.6)	1 (1.8)
RSウイルス感染	1 (3.7)	0	1 (1.8)
敗血症	0	1 (3.6)	1 (1.8)
上気道感染	1 (3.7)	0	1 (1.8)
尿路感染	1 (3.7)	1 (3.6)	2 (3.6)
尿路性敗血症	0	1 (3.6)	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
傷害、中毒および処置合併症	5 (18.5)	5 (17.9)	10 (18.2)
節足動物刺傷	1 (3.7)	0	1 (1.8)
挫傷	0	1 (3.6)	1 (1.8)
顔面骨骨折	0	1 (3.6)	1 (1.8)
転倒	2 (7.4)	3 (10.7)	5 (9.1)
大腿骨骨折	1 (3.7)	0	1 (1.8)
手骨折	1 (3.7)	1 (3.6)	2 (3.6)
股関節部骨折	0	1 (3.6)	1 (1.8)
上腕骨骨折	0	1 (3.6)	1 (1.8)
肉離れ	1 (3.7)	0	1 (1.8)
開放骨折	0	1 (3.6)	1 (1.8)
処置による疼痛	0	1 (3.6)	1 (1.8)
外傷性頭蓋内出血	0	1 (3.6)	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
臨床検査	4 (14.8)	3 (10.7)	7 (12.7)
血中葉酸減少	0	1 (3.6)	1 (1.8)
血中ホモシステイン増加	1 (3.7)	0	1 (1.8)
ヘモグロビン減少	0	1 (3.6)	1 (1.8)
リンパ球数減少	1 (3.7)	0	1 (1.8)
プロトロンビン時間延長	0	1 (3.6)	1 (1.8)
ビタミンB12減少	1 (3.7)	0	1 (1.8)
ビタミンB6減少	2 (7.4)	0	2 (3.6)
ビタミンB6増加	1 (3.7)	0	1 (1.8)
体重減少	0	2 (7.1)	2 (3.6)
代謝および栄養障害	4 (14.8)	4 (14.3)	8 (14.5)
食欲減退	0	1 (3.6)	1 (1.8)
高ナトリウム血症	0	1 (3.6)	1 (1.8)
低カリウム血症	1 (3.7)	1 (3.6)	2 (3.6)
低マグネシウム血症	1 (3.7)	1 (3.6)	2 (3.6)
鉄欠乏	1 (3.7)	1 (3.6)	2 (3.6)
ビタミンB群欠乏	1 (3.7)	0	1 (1.8)
ビタミンB12欠乏	1 (3.7)	2 (7.1)	3 (5.5)
ビタミンB6欠乏	1 (3.7)	0	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
筋骨格系および結合組織障害	7 (25.9)	4 (14.3)	11 (20.0)
関節痛	0	1 (3.6)	1 (1.8)
背部痛	1 (3.7)	1 (3.6)	2 (3.6)
滑液包炎	1 (3.7)	0	1 (1.8)
出血性関節症	0	1 (3.6)	1 (1.8)
腰部脊柱管狭窄症	1 (3.7)	0	1 (1.8)
筋力低下	0	1 (3.6)	1 (1.8)
筋骨格系胸痛	1 (3.7)	0	1 (1.8)
筋骨格硬直	0	1 (3.6)	1 (1.8)
変形性関節症	1 (3.7)	0	1 (1.8)
骨粗鬆症	2 (7.4)	0	2 (3.6)
四肢痛	2 (7.4)	0	2 (3.6)
肩回旋筋腱板症候群	1 (3.7)	0	1 (1.8)
斜頚	1 (3.7)	0	1 (1.8)
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）	0	1 (3.6)	1 (1.8)
ケラトアカントーマ	0	1 (3.6)	1 (1.8)
神経系障害	8 (29.6)	8 (28.6)	16 (29.1)
運動緩慢	1 (3.7)	0	1 (1.8)
認知障害	1 (3.7)	0	1 (1.8)
注意力障害	0	1 (3.6)	1 (1.8)
浮動性めまい	1 (3.7)	1 (3.6)	2 (3.6)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
神経系障害 (Cont.)			
薬物離脱性頭痛	0	1 (3.6)	1 (1.8)
ジスキネジア	1 (3.7)	0	1 (1.8)
ジストニア	0	1 (3.6)	1 (1.8)
伸展性足底反応	1 (3.7)	0	1 (1.8)
すくみ現象	3 (11.1)	0	3 (5.5)
頭部不快感	0	2 (7.1)	2 (3.6)
頭痛	1 (3.7)	1 (3.6)	2 (3.6)
反射減弱	0	1 (3.6)	1 (1.8)
記憶障害	0	1 (3.6)	1 (1.8)
オンオフ現象	1 (3.7)	3 (10.7)	4 (7.3)
錯感覚	1 (3.7)	0	1 (1.8)
パーキンソン病	2 (7.4)	4 (14.3)	6 (10.9)
呼吸器ジスキネジア	1 (3.7)	0	1 (1.8)
痙攣発作	0	1 (3.6)	1 (1.8)
失神	0	1 (3.6)	1 (1.8)
一過性脳虚血発作	0	1 (3.6)	1 (1.8)
振戦	1 (3.7)	0	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
精神障害	11 (40.7)	11 (39.3)	22 (40.0)
異常な夢	0	1 (3.6)	1 (1.8)
適応障害	0	1 (3.6)	1 (1.8)
攻撃性	0	1 (3.6)	1 (1.8)
激越	0	1 (3.6)	1 (1.8)
不安	3 (11.1)	3 (10.7)	6 (10.9)
歯ぎしり	1 (3.7)	0	1 (1.8)
譫妄	0	2 (7.1)	2 (3.6)
抑うつ気分	1 (3.7)	0	1 (1.8)
うつ病	1 (3.7)	1 (3.6)	2 (3.6)
失見当識	1 (3.7)	0	1 (1.8)
ギャンブル障害	1 (3.7)	0	1 (1.8)
幻覚	3 (11.1)	1 (3.6)	4 (7.3)
幻嗅	1 (3.7)	0	1 (1.8)
幻視	1 (3.7)	1 (3.6)	2 (3.6)
軽躁	1 (3.7)	0	1 (1.8)
錯覚	1 (3.7)	1 (3.6)	2 (3.6)
衝動制御障害	0	1 (3.6)	1 (1.8)
衝動行為	1 (3.7)	0	1 (1.8)
不眠症	1 (3.7)	1 (3.6)	2 (3.6)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
精神障害 (Cont.)			
消極的思考	1 (3.7)	0	1 (1.8)
パニック発作	1 (3.7)	0	1 (1.8)
妄想症	1 (3.7)	0	1 (1.8)
精神病性障害	1 (3.7)	0	1 (1.8)
レム睡眠行動障害	1 (3.7)	0	1 (1.8)
睡眠障害	0	1 (3.6)	1 (1.8)
腎および尿路障害	2 (7.4)	1 (3.6)	3 (5.5)
急性腎障害	0	1 (3.6)	1 (1.8)
膀胱痙縮	1 (3.7)	0	1 (1.8)
水腎症	0	1 (3.6)	1 (1.8)
水尿管症	0	1 (3.6)	1 (1.8)
緊張性膀胱	1 (3.7)	0	1 (1.8)
生殖系および乳房障害	2 (7.4)	3 (10.7)	5 (9.1)
良性前立腺肥大症	1 (3.7)	0	1 (1.8)
膀胱瘤	0	1 (3.6)	1 (1.8)
勃起不全	0	1 (3.6)	1 (1.8)
生殖器萎縮	0	1 (3.6)	1 (1.8)
腟脱	0	1 (3.6)	1 (1.8)
外陰腟乾燥	1 (3.7)	0	1 (1.8)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
Geographic region: Europe and Australia (Cont.)	N=27	N=28	N=55
呼吸器、胸郭および縦隔障害	1 (3.7)	0	1 (1.8)
呼吸困難	1 (3.7)	0	1 (1.8)
皮膚および皮下組織障害	4 (14.8)	0	4 (7.3)
光線角化症	1 (3.7)	0	1 (1.8)
脱毛症	1 (3.7)	0	1 (1.8)
湿疹	1 (3.7)	0	1 (1.8)
発疹	1 (3.7)	0	1 (1.8)
蕁麻疹	1 (3.7)	0	1 (1.8)
血管障害	2 (7.4)	3 (10.7)	5 (9.1)
低血圧	1 (3.7)	0	1 (1.8)
起立性高血圧	0	1 (3.6)	1 (1.8)
起立性低血圧	1 (3.7)	2 (7.1)	3 (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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Japan	N=8	N=4	N=12
Any adverse event	5 (62.5)	4 (100)	9 (75.0)
眼障害	0	1 (25.0)	1 (8.3)
眼充血	0	1 (25.0)	1 (8.3)
胃腸障害	1 (12.5)	0	1 (8.3)
便秘	1 (12.5)	0	1 (8.3)
一般・全身障害および投与部位の状態	2 (25.0)	3 (75.0)	5 (41.7)
注入部位皮膚炎	1 (12.5)	0	1 (8.3)
注入部位硬結	1 (12.5)	1 (25.0)	2 (16.7)
注射部位紅斑	0	2 (50.0)	2 (16.7)
注射部位硬結	0	1 (25.0)	1 (8.3)
感染症および寄生虫症	2 (25.0)	2 (50.0)	4 (33.3)
COVID-19	1 (12.5)	0	1 (8.3)
注入部位蜂巣炎	1 (12.5)	2 (50.0)	3 (25.0)
注射部位蜂巣炎	0	1 (25.0)	1 (8.3)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Japan (Cont.)	N=8	N=4	N=12
傷害、中毒および処置合併症	0	1 (25.0)	1 (8.3)
転倒	0	1 (25.0)	1 (8.3)
肩甲骨骨折	0	1 (25.0)	1 (8.3)
臨床検査	1 (12.5)	0	1 (8.3)
血中ホモシステイン増加	1 (12.5)	0	1 (8.3)
代謝および栄養障害	0	1 (25.0)	1 (8.3)
ビタミンB12欠乏	0	1 (25.0)	1 (8.3)
筋骨格系および結合組織障害	1 (12.5)	0	1 (8.3)
腱鞘炎	1 (12.5)	0	1 (8.3)
神経系障害	0	1 (25.0)	1 (8.3)
感覚鈍麻	0	1 (25.0)	1 (8.3)
錯感覚	0	1 (25.0)	1 (8.3)
精神障害	2 (25.0)	0	2 (16.7)
妄想	1 (12.5)	0	1 (8.3)
幻覚	1 (12.5)	0	1 (8.3)
腎および尿路障害	1 (12.5)	0	1 (8.3)
尿失禁	1 (12.5)	0	1 (8.3)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
Geographic region: Japan (Cont.)	N=8	N=4	N=12
呼吸器、胸郭および縦隔障害	1 (12.5)	1 (25.0)	2 (16.7)
窒息	1 (12.5)	0	1 (8.3)
誤嚥	1 (12.5)	0	1 (8.3)
痰貯留	0	1 (25.0)	1 (8.3)
皮膚および皮下組織障害	0	1 (25.0)	1 (8.3)
湿疹	0	1 (25.0)	1 (8.3)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years	N=30	N=35	N=65
Any adverse event	23 (76.7)	27 (77.1)	50 (76.9)
心臓障害	1 (3.3)	0	1 (1.5)
洞性頻脈	1 (3.3)	0	1 (1.5)
耳および迷路障害	0	2 (5.7)	2 (3.1)
回転性めまい	0	2 (5.7)	2 (3.1)
眼障害	1 (3.3)	3 (8.6)	4 (6.2)
眼瞼痙攣	0	1 (2.9)	1 (1.5)
眼の異物感	0	1 (2.9)	1 (1.5)
黄斑症	1 (3.3)	0	1 (1.5)
眼部不快感	0	1 (2.9)	1 (1.5)
眼充血	0	2 (5.7)	2 (3.1)
霧視	0	1 (2.9)	1 (1.5)
胃腸障害	5 (16.7)	2 (5.7)	7 (10.8)
腹部膨満	0	1 (2.9)	1 (1.5)
腹痛	0	1 (2.9)	1 (1.5)
便秘	2 (6.7)	0	2 (3.1)
嚥下障害	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
胃腸障害 (Cont.)			
胃潰瘍	1 (3.3)	0	1 (1.5)
胃食道逆流性疾患	1 (3.3)	0	1 (1.5)
悪心	1 (3.3)	1 (2.9)	2 (3.1)
吐き戻し	0	1 (2.9)	1 (1.5)
嘔吐	1 (3.3)	0	1 (1.5)
一般・全身障害および投与部位の状態	10 (33.3)	10 (28.6)	20 (30.8)
投与部位内出血	0	1 (2.9)	1 (1.5)
投与部位漏出	1 (3.3)	0	1 (1.5)
カテーテル留置部位内出血	0	2 (5.7)	2 (3.1)
カテーテル留置部位紅斑	1 (3.3)	0	1 (1.5)
カテーテル留置部位漏出	0	1 (2.9)	1 (1.5)
疲労	1 (3.3)	0	1 (1.5)
注入部位内出血	1 (3.3)	2 (5.7)	3 (4.6)
注入部位紅斑	6 (20.0)	4 (11.4)	10 (15.4)
注入部位血管外漏出	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
一般・全身障害および投与部位の状態 (Cont.)			
注入部位血腫	0	1 (2.9)	1 (1.5)
注入部位硬結	1 (3.3)	0	1 (1.5)
注入部位結節	1 (3.3)	2 (5.7)	3 (4.6)
注入部位疼痛	1 (3.3)	0	1 (1.5)
注入部位異常感覚	0	1 (2.9)	1 (1.5)
注入部位痂皮	0	1 (2.9)	1 (1.5)
注入部位腫脹	0	1 (2.9)	1 (1.5)
注入部位熱感	1 (3.3)	0	1 (1.5)
注射部位紅斑	0	1 (2.9)	1 (1.5)
注射部位炎症	0	1 (2.9)	1 (1.5)
注射部位結節	1 (3.3)	0	1 (1.5)
注射部位浮腫	0	1 (2.9)	1 (1.5)
穿刺部位紅斑	1 (3.3)	0	1 (1.5)
感染症および寄生虫症	9 (30.0)	13 (37.1)	22 (33.8)
ダニ皮膚炎	0	1 (2.9)	1 (1.5)
無症候性COVID-19	0	2 (5.7)	2 (3.1)
COVID-19	1 (3.3)	3 (8.6)	4 (6.2)
大腸菌性尿路感染	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
感染症および寄生虫症 (Cont.)			
胃腸炎	1 (3.3)	1 (2.9)	2 (3.1)
ヘリコバクター性胃炎	1 (3.3)	0	1 (1.5)
ヘリコバクター感染	1 (3.3)	0	1 (1.5)
帯状疱疹	0	1 (2.9)	1 (1.5)
注入部位膿瘍	1 (3.3)	0	1 (1.5)
注入部位蜂巣炎	3 (10.0)	6 (17.1)	9 (13.8)
注入部位感染	2 (6.7)	0	2 (3.1)
注射部位感染	0	1 (2.9)	1 (1.5)
上咽頭炎	1 (3.3)	1 (2.9)	2 (3.1)
口腔カンジダ症	0	1 (2.9)	1 (1.5)
敗血症	0	1 (2.9)	1 (1.5)
上気道感染	1 (3.3)	0	1 (1.5)
尿路感染	1 (3.3)	3 (8.6)	4 (6.2)
尿路性敗血症	0	1 (2.9)	1 (1.5)
傷害、中毒および処置合併症	5 (16.7)	7 (20.0)	12 (18.5)
節足動物刺傷	1 (3.3)	0	1 (1.5)
挫傷	0	1 (2.9)	1 (1.5)
転倒	2 (6.7)	5 (14.3)	7 (10.8)
大腿骨頚部骨折	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
傷害、中毒および処置合併症 (Cont.)			
転位骨折	0	1 (2.9)	1 (1.5)
手骨折	1 (3.3)	0	1 (1.5)
股関節部骨折	1 (3.3)	0	1 (1.5)
肉離れ	1 (3.3)	0	1 (1.5)
開放骨折	0	1 (2.9)	1 (1.5)
処置による疼痛	0	1 (2.9)	1 (1.5)
肩甲骨骨折	0	1 (2.9)	1 (1.5)
外傷性頭蓋内出血	0	1 (2.9)	1 (1.5)
臨床検査	2 (6.7)	3 (8.6)	5 (7.7)
血中葉酸減少	0	1 (2.9)	1 (1.5)
血中ホモシステイン増加	1 (3.3)	0	1 (1.5)
ヘモグロビン減少	0	1 (2.9)	1 (1.5)
ビタミンB12減少	0	1 (2.9)	1 (1.5)
ビタミンB6増加	1 (3.3)	0	1 (1.5)
体重減少	0	1 (2.9)	1 (1.5)
代謝および栄養障害	3 (10.0)	4 (11.4)	7 (10.8)
食欲減退	0	1 (2.9)	1 (1.5)
高ナトリウム血症	0	1 (2.9)	1 (1.5)
低カリウム血症	1 (3.3)	1 (2.9)	2 (3.1)
低マグネシウム血症	1 (3.3)	1 (2.9)	2 (3.1)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
代謝および栄養障害 (Cont.)			
鉄欠乏	1 (3.3)	1 (2.9)	2 (3.1)
ビタミンB12欠乏	1 (3.3)	2 (5.7)	3 (4.6)
ビタミンB6欠乏	1 (3.3)	0	1 (1.5)
筋骨格系および結合組織障害	5 (16.7)	2 (5.7)	7 (10.8)
関節痛	0	1 (2.9)	1 (1.5)
背部痛	1 (3.3)	1 (2.9)	2 (3.1)
腰部脊柱管狭窄症	1 (3.3)	0	1 (1.5)
変形性関節症	1 (3.3)	0	1 (1.5)
肩回旋筋腱板症候群	1 (3.3)	0	1 (1.5)
腱鞘炎	1 (3.3)	0	1 (1.5)
斜頚	1 (3.3)	0	1 (1.5)
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	1 (2.9)	1 (1.5)
ケラトアカントーマ	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
神経系障害	4 (13.3)	8 (22.9)	12 (18.5)
平衡障害	0	1 (2.9)	1 (1.5)
認知障害	0	2 (5.7)	2 (3.1)
注意力障害	0	1 (2.9)	1 (1.5)
浮動性めまい	1 (3.3)	1 (2.9)	2 (3.1)
薬物離脱性頭痛	0	1 (2.9)	1 (1.5)
伸展性足底反応	1 (3.3)	0	1 (1.5)
頭部不快感	0	2 (5.7)	2 (3.1)
頭痛	1 (3.3)	1 (2.9)	2 (3.1)
感覚鈍麻	1 (3.3)	0	1 (1.5)
記憶障害	0	1 (2.9)	1 (1.5)
オンオフ現象	0	3 (8.6)	3 (4.6)
錯感覚	1 (3.3)	0	1 (1.5)
パーキンソン病	0	2 (5.7)	2 (3.1)
精神運動亢進	0	1 (2.9)	1 (1.5)
呼吸器ジスキネジア	1 (3.3)	0	1 (1.5)
痙攣発作	0	1 (2.9)	1 (1.5)
失神	0	1 (2.9)	1 (1.5)
精神障害	9 (30.0)	10 (28.6)	19 (29.2)
異常な夢	0	1 (2.9)	1 (1.5)
適応障害	0	1 (2.9)	1 (1.5)
激越	0	1 (2.9)	1 (1.5)
不安	1 (3.3)	3 (8.6)	4 (6.2)

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 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	Dose Category High Dose (N=61) n (%)	All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
精神障害 (Cont.)			
歯ぎしり	1 (3.3)	0	1 (1.5)
譫妄	0	1 (2.9)	1 (1.5)
妄想	1 (3.3)	1 (2.9)	2 (3.1)
うつ病	1 (3.3)	1 (2.9)	2 (3.1)
ギャンブル障害	1 (3.3)	0	1 (1.5)
幻覚	3 (10.0)	3 (8.6)	6 (9.2)
軽躁	1 (3.3)	0	1 (1.5)
錯覚	1 (3.3)	0	1 (1.5)
衝動制御障害	0	1 (2.9)	1 (1.5)
不眠症	0	1 (2.9)	1 (1.5)
消極的思考	1 (3.3)	0	1 (1.5)
パニック発作	1 (3.3)	1 (2.9)	2 (3.1)
妄想症	1 (3.3)	0	1 (1.5)
精神病性障害	1 (3.3)	1 (2.9)	2 (3.1)
睡眠障害	0	1 (2.9)	1 (1.5)
腎および尿路障害	1 (3.3)	2 (5.7)	3 (4.6)
急性腎障害	0	1 (2.9)	1 (1.5)
水腎症	0	1 (2.9)	1 (1.5)
水尿管症	0	1 (2.9)	1 (1.5)
蛋白尿	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
腎および尿路障害 (Cont.)			
尿失禁	1 (3.3)	0	1 (1.5)
生殖系および乳房障害	1 (3.3)	2 (5.7)	3 (4.6)
良性前立腺肥大症	1 (3.3)	0	1 (1.5)
膀胱瘤	0	1 (2.9)	1 (1.5)
生殖器萎縮	0	1 (2.9)	1 (1.5)
膣脱	0	1 (2.9)	1 (1.5)
呼吸器、胸郭および縦隔障害	1 (3.3)	1 (2.9)	2 (3.1)
呼吸困難	1 (3.3)	0	1 (1.5)
痰貯留	0	1 (2.9)	1 (1.5)
皮膚および皮下組織障害	3 (10.0)	1 (2.9)	4 (6.2)
光線角化症	1 (3.3)	0	1 (1.5)
脱毛症	1 (3.3)	0	1 (1.5)
湿疹	0	1 (2.9)	1 (1.5)
発疹	1 (3.3)	0	1 (1.5)
蕁麻疹	1 (3.3)	0	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: < 10 years (Cont.)	N=30	N=35	N=65
血管障害	1 (3.3)	3 (8.6)	4 (6.2)
血腫	1 (3.3)	0	1 (1.5)
高血圧	0	1 (2.9)	1 (1.5)
低血圧	0	1 (2.9)	1 (1.5)
表在性血栓性静脈炎	0	1 (2.9)	1 (1.5)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years	N=25	N=26	N=51
Any adverse event	16 (64.0)	22 (84.6)	38 (74.5)
心臓障害	2 (8.0)	1 (3.8)	3 (5.9)
急性心筋梗塞	1 (4.0)	0	1 (2.0)
徐脈	1 (4.0)	0	1 (2.0)
左脚ブロック	0	1 (3.8)	1 (2.0)
胃腸障害	2 (8.0)	5 (19.2)	7 (13.7)
腹部不快感	0	1 (3.8)	1 (2.0)
便秘	1 (4.0)	2 (7.7)	3 (5.9)
出血性腸憩室	0	1 (3.8)	1 (2.0)
嚥下障害	1 (4.0)	1 (3.8)	2 (3.9)
悪心	1 (4.0)	1 (3.8)	2 (3.9)
流涎過多	0	1 (3.8)	1 (2.0)
一般・全身障害および投与部位の状態	11 (44.0)	11 (42.3)	22 (43.1)
カテーテル留置部位内出血	1 (4.0)	0	1 (2.0)
カテーテル留置部位炎症	0	1 (3.8)	1 (2.0)
カテーテル留置部位疼痛	1 (4.0)	0	1 (2.0)
カテーテル留置部位腫脹	1 (4.0)	0	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
一般・全身障害および投与部位の状態 (Cont.)			
薬効欠如	1 (4.0)	0	1 (2.0)
薬物相互作用	1 (4.0)	0	1 (2.0)
疲労	2 (8.0)	0	2 (3.9)
注入部位内出血	1 (4.0)	1 (3.8)	2 (3.9)
注入部位皮膚炎	1 (4.0)	0	1 (2.0)
注入部位変色	0	1 (3.8)	1 (2.0)
注入部位紅斑	5 (20.0)	4 (15.4)	9 (17.6)
注入部位血管外漏出	0	1 (3.8)	1 (2.0)
注入部位血腫	1 (4.0)	0	1 (2.0)
注入部位硬結	0	2 (7.7)	2 (3.9)
注入部位炎症	0	1 (3.8)	1 (2.0)
注入部位刺激感	2 (8.0)	0	2 (3.9)
注入部位腫瘤	1 (4.0)	0	1 (2.0)
注入部位結節	1 (4.0)	1 (3.8)	2 (3.9)
注入部位浮腫	1 (4.0)	1 (3.8)	2 (3.9)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
一般・全身障害および投与部位の状態 (Cont.)			
注入部位疼痛	0	1 (3.8)	1 (2.0)
注入部位丘疹	1 (4.0)	3 (11.5)	4 (7.8)
注入部位発疹	0	1 (3.8)	1 (2.0)
注入部位反応	0	1 (3.8)	1 (2.0)
注入部位腫脹	1 (4.0)	0	1 (2.0)
注射部位内出血	1 (4.0)	1 (3.8)	2 (3.9)
注射部位紅斑	1 (4.0)	1 (3.8)	2 (3.9)
注射部位硬結	0	1 (3.8)	1 (2.0)
末梢性浮腫	1 (4.0)	0	1 (2.0)
感染症および寄生虫症	6 (24.0)	6 (23.1)	12 (23.5)
COVID-19	0	1 (3.8)	1 (2.0)
膀胱炎	1 (4.0)	0	1 (2.0)
注入部位膿瘍	2 (8.0)	0	2 (3.9)
注入部位蜂巣炎	3 (12.0)	4 (15.4)	7 (13.7)
注入部位感染	1 (4.0)	0	1 (2.0)
注射部位蜂巣炎	0	1 (3.8)	1 (2.0)
RSウイルス感染	1 (4.0)	0	1 (2.0)
副鼻腔炎	0	1 (3.8)	1 (2.0)
尿路感染	0	1 (3.8)	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
傷害、中毒および処置合併症	3 (12.0)	6 (23.1)	9 (17.6)
節足動物咬傷	0	1 (3.8)	1 (2.0)
顔面骨骨折	0	1 (3.8)	1 (2.0)
転倒	3 (12.0)	4 (15.4)	7 (13.7)
大腿骨骨折	1 (4.0)	0	1 (2.0)
手骨折	0	2 (7.7)	2 (3.9)
股関節部骨折	0	1 (3.8)	1 (2.0)
上腕骨骨折	1 (4.0)	1 (3.8)	2 (3.9)
靭帯捻挫	0	1 (3.8)	1 (2.0)
四肢損傷	0	1 (3.8)	1 (2.0)
臨床検査	4 (16.0)	4 (15.4)	8 (15.7)
血中葉酸減少	0	1 (3.8)	1 (2.0)
血中ホモシステイン増加	1 (4.0)	0	1 (2.0)
血中ナトリウム減少	1 (4.0)	0	1 (2.0)
リンパ球数減少	1 (4.0)	0	1 (2.0)
プロトロンビン時間延長	0	1 (3.8)	1 (2.0)
ビタミンB12減少	1 (4.0)	0	1 (2.0)
ビタミンB6減少	2 (8.0)	0	2 (3.9)
ビタミンD減少	0	1 (3.8)	1 (2.0)
体重減少	0	2 (7.7)	2 (3.9)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
代謝および栄養障害	1 (4.0)	1 (3.8)	2 (3.9)
ビタミンB群欠乏	1 (4.0)	0	1 (2.0)
ビタミンB12欠乏	0	1 (3.8)	1 (2.0)
筋骨格系および結合組織障害	5 (20.0)	5 (19.2)	10 (19.6)
背部痛	0	1 (3.8)	1 (2.0)
滑液包炎	1 (4.0)	0	1 (2.0)
出血性関節症	0	1 (3.8)	1 (2.0)
椎間板変性症	0	1 (3.8)	1 (2.0)
筋力低下	0	2 (7.7)	2 (3.9)
筋骨格系胸痛	1 (4.0)	0	1 (2.0)
筋骨格硬直	0	1 (3.8)	1 (2.0)
変形性関節症	2 (8.0)	0	2 (3.9)
骨粗鬆症	2 (8.0)	0	2 (3.9)
四肢痛	2 (8.0)	0	2 (3.9)
肩回旋筋腱板症候群	1 (4.0)	0	1 (2.0)
変形性脊椎症	1 (4.0)	0	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
神経系障害	7 (28.0)	8 (30.8)	15 (29.4)
健忘	1 (4.0)	0	1 (2.0)
運動緩慢	1 (4.0)	0	1 (2.0)
認知障害	1 (4.0)	0	1 (2.0)
ジスキネジア	1 (4.0)	0	1 (2.0)
ジストニア	0	1 (3.8)	1 (2.0)
すくみ現象	3 (12.0)	0	3 (5.9)
頭蓋内出血	1 (4.0)	0	1 (2.0)
感覚鈍麻	0	1 (3.8)	1 (2.0)
反射減弱	1 (4.0)	1 (3.8)	2 (3.9)
記憶障害	0	1 (3.8)	1 (2.0)
オンオフ現象	2 (8.0)	2 (7.7)	4 (7.8)
錯感覚	0	1 (3.8)	1 (2.0)
パーキンソン病	2 (8.0)	3 (11.5)	5 (9.8)
失神	0	1 (3.8)	1 (2.0)
一過性脳虚血発作	0	1 (3.8)	1 (2.0)
振戦	1 (4.0)	0	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
精神障害	6 (24.0)	8 (30.8)	14 (27.5)
攻撃性	0	1 (3.8)	1 (2.0)
不安	3 (12.0)	1 (3.8)	4 (7.8)
錯乱状態	0	1 (3.8)	1 (2.0)
譫妄	0	1 (3.8)	1 (2.0)
抑うつ気分	1 (4.0)	0	1 (2.0)
うつ病	1 (4.0)	0	1 (2.0)
自傷性皮膚症	0	1 (3.8)	1 (2.0)
失見当識	1 (4.0)	0	1 (2.0)
幻覚	1 (4.0)	2 (7.7)	3 (5.9)
幻嗅	1 (4.0)	0	1 (2.0)
幻視	1 (4.0)	1 (3.8)	2 (3.9)
錯覚	0	1 (3.8)	1 (2.0)
衝動行為	1 (4.0)	0	1 (2.0)
不眠症	1 (4.0)	0	1 (2.0)
レム睡眠行動障害	1 (4.0)	0	1 (2.0)
腎および尿路障害	2 (8.0)	2 (7.7)	4 (7.8)
膀胱痙縮	1 (4.0)	0	1 (2.0)
血尿	0	1 (3.8)	1 (2.0)
緊張性膀胱	1 (4.0)	0	1 (2.0)
腎結石症	0	1 (3.8)	1 (2.0)

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

Program Source Code: [redacted]

TABLE 14.3 1.3

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=55) n (%)	 High Dose (N=61) n (%)	 All Subjects (N=116) n (%)
PD duration: >= 10 years (Cont.)	N=25	N=26	N=51
生殖系および乳房障害	1 (4.0)	1 (3.8)	2 (3.9)
勃起不全	0	1 (3.8)	1 (2.0)
外陰腟乾燥	1 (4.0)	0	1 (2.0)
呼吸器、胸郭および縦隔障害	1 (4.0)	0	1 (2.0)
窒息	1 (4.0)	0	1 (2.0)
誤嚥	1 (4.0)	0	1 (2.0)
皮膚および皮下組織障害	1 (4.0)	0	1 (2.0)
湿疹	1 (4.0)	0	1 (2.0)
血管障害	2 (8.0)	3 (11.5)	5 (9.8)
低血圧	1 (4.0)	0	1 (2.0)
起立性高血圧	0	1 (3.8)	1 (2.0)
起立性低血圧	1 (4.0)	2 (7.7)	3 (5.9)

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

Program Source Code: [redacted]

表43　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）：M15-737試験

[redacted]20[redacted] 10:48 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - 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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=12) n (%)
Any adverse event	5 (62.5)	4 (100)	9 (75.0)
No reasonable possibility	1 (12.5)	1 (25.0)	2 (16.7)
Reasonable possibility	4 (50.0)	3 (75.0)	7 (58.3)
眼障害	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
眼充血	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
胃腸障害	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
便秘	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
一般・全身障害および投与部位の状態	2 (25.0)	3 (75.0)	5 (41.7)
Reasonable possibility	2 (25.0)	3 (75.0)	5 (41.7)
注入部位皮膚炎	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	0	1 (8.3)
注入部位硬結	1 (12.5)	1 (25.0)	2 (16.7)
Reasonable possibility	1 (12.5)	1 (25.0)	2 (16.7)
注射部位紅斑	0	2 (50.0)	2 (16.7)
Reasonable possibility	0	2 (50.0)	2 (16.7)
注射部位硬結	0	1 (25.0)	1 (8.3)
Reasonable possibility	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=12) n (%)
感染症および寄生虫症	2 (25.0)	2 (50.0)	4 (33.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	2 (50.0)	3 (25.0)
COVID-19	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
注入部位蜂巣炎	1 (12.5)	2 (50.0)	3 (25.0)
Reasonable possibility	1 (12.5)	2 (50.0)	3 (25.0)
注射部位蜂巣炎	0	1 (25.0)	1 (8.3)
Reasonable possibility	0	1 (25.0)	1 (8.3)
傷害、中毒および処置合併症	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
傷害、中毒および処置合併症 (Cont.)			
転倒	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
肩甲骨骨折	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
臨床検査	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	0	1 (8.3)
血中ホモシステイン増加	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	0	1 (8.3)
代謝および栄養障害	0	1 (25.0)	1 (8.3)
Reasonable possibility	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
代謝および栄養障害 (Cont.)			
ビタミンB12欠乏	0	1 (25.0)	1 (8.3)
Reasonable possibility	0	1 (25.0)	1 (8.3)
筋骨格系および結合組織障害	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
腱鞘炎	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
神経系障害	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
感覚鈍麻	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
神経系障害 (Cont.)			
錯感覚	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
精神障害	2 (25.0)	0	2 (16.7)
No reasonable possibility	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	0	1 (8.3)
妄想	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
幻覚	1 (12.5)	0	1 (8.3)
Reasonable possibility	1 (12.5)	0	1 (8.3)
腎および尿路障害	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	Dose Category High Dose (N=4) n (%)	All Subjects (N=12) n (%)
腎および尿路障害 (Cont.)			
尿失禁	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
呼吸器、胸郭および縦隔障害	1 (12.5)	1 (25.0)	2 (16.7)
No reasonable possibility	1 (12.5)	1 (25.0)	2 (16.7)
窒息	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
誤嚥	1 (12.5)	0	1 (8.3)
No reasonable possibility	1 (12.5)	0	1 (8.3)
痰貯留	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)

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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term Relationship	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
皮膚および皮下組織障害	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)
湿疹	0	1 (25.0)	1 (8.3)
No reasonable possibility	0	1 (25.0)	1 (8.3)

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44　重篤な有害事象（安全性解析対象集団，日本人部分集団）：M15-737試験

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - CLINICAL/STATISTICAL

TABLE 14.3__1.11.1.J

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

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
Any adverse event	2 (25.0)	2 (50.0)	4 (33.3)
感染症および寄生虫症	1 (12.5)	1 (25.0)	2 (16.7)
COVID-19	1 (12.5)	0	1 (8.3)
注入部位蜂巣炎	0	1 (25.0)	1 (8.3)
傷害、中毒および処置合併症	0	1 (25.0)	1 (8.3)
肩甲骨骨折	0	1 (25.0)	1 (8.3)
呼吸器、胸郭および縦隔障害	1 (12.5)	0	1 (8.3)
窒息	1 (12.5)	0	1 (8.3)
誤嚥	1 (12.5)	0	1 (8.3)

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

Program Source Code: [redacted]

表45　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）：M15-737試験

[redacted]20[redacted] 10:47 <[redacted]>
ABBV-951
STUDY M15-737 - THIRD INTERIM (CUTOFF [redacted]20[redacted])
R&D/22/0154 - 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
(Safety Analysis Set - Japan Subjects)

System Organ Class MedDRA 24.0 Preferred Term	Dose Category Low Dose (N=8) n (%)	 High Dose (N=4) n (%)	 All Subjects (N=12) n (%)
Any adverse event	1 (12.5)	0	1 (8.3)
呼吸器、胸郭および縦隔障害	1 (12.5)	0	1 (8.3)
窒息	1 (12.5)	0	1 (8.3)
誤嚥	1 (12.5)	0	1 (8.3)

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
変形性関節症	X			
肩回旋筋腱板症候群	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
RESTLESS SLEEP	20[redacted]
VITAMIN D DEFICIENCY	20[redacted]
POST-MENOPAUSAL	20[redacted]
SEASONAL ALLERGIES	20[redacted]
BILATERAL CARPAL TUNNEL	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.33	0.37	0.30	60	0.11	[redacted] / 365
ABBV-951	0.33	0.37	0.30	60	0.11	[redacted] / 540
ABBV-951	0.33	0.37	0.30	60	0.11	[redacted] / 701
ABBV-951	0.33	0.37	0.30	60	0.11	[redacted] / 869

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	552.20		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 3	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
M15-741 /ABBV-951	1453.08		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
M15-741 /ABBV-951	1314.26		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	1175.10		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1179.71		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 9	
M15-741 /ABBV-951	1204.29		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951	1153.07		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 11	[redacted] / 12
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951	834.96		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
M15-741 /ABBV-951	1306.74		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted] / 18	[redacted] / 19
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted] / 20	[redacted] / 21
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	1324.16		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted] / 25	[redacted] / 25
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 26	[redacted] / 26

M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951	1364.29		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951	1352.68		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	1353.02		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 53
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	1200.20		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62

M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 66
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 68	
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 70	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 72
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 72	
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 74
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
M15-741 /ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
M15-741 /ABBV-951	270.46		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 82	
M15-741 /ABBV-951	1042.42		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 91
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 92	
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 94	
M15-741 /ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 96	
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97

M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 100	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 102
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
M15-741 /ABBV-951	1324.16		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 106
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 107	[redacted]20[redacted] / 107
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 108	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 109	
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 110	
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 111	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 112	
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 113	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
M15-741 /ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 116
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 117	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 118	
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] /

					118
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 122
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 123	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 123	[redacted]20[redacted] / 123
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M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 131
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M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] /

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M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
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M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
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M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 225
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 256	
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M15-741 /ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 283	[redacted]20[redacted] / 283
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ABBV-951		56.34	SC / ONCE	[redacted] / 677
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 677 [redacted] / 677
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 678 [redacted] / 678
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 679 [redacted] / 679
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 680 [redacted] / 680
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 681 [redacted] / 681
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 682 [redacted] / 682
ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 683 [redacted] / 683
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 684 [redacted] / 685
ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 686 [redacted] / 688
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 689 [redacted] / 689
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 690 [redacted] / 690
ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 691 [redacted] / 696
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 697 [redacted] / 697
ABBV-951	1335.43		SC / CONTINUOUS	[redacted] / 698 [redacted] / 698
ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 699 [redacted] / 699
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 700 [redacted] / 700
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 701 [redacted] / 701
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 702 [redacted] / 702
ABBV-951	1346.70		SC / CONTINUOUS	[redacted] / 703 [redacted] / 703

ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 704	[redacted]20[redacted] / 704
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 705	[redacted]20[redacted] / 705
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 706	[redacted]20[redacted] / 708
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 709	[redacted]20[redacted] / 710
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 711	[redacted]20[redacted] / 715
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 716	[redacted]20[redacted] / 717
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 718	[redacted]20[redacted] / 786
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 787	[redacted]20[redacted] / 787
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 788	[redacted]20[redacted] / 788
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 789	[redacted]20[redacted] / 789
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 790	[redacted]20[redacted] / 791
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 792	[redacted]20[redacted] / 792
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 793	[redacted]20[redacted] / 793
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 794	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 794	[redacted]20[redacted] / 796
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 795	
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 796	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 797	[redacted]20[redacted] / 798
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 799	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 799	[redacted]20[redacted] / 800
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 800	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 801	[redacted]20[redacted] / 801
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 802	[redacted]20[redacted] / 802
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 803	[redacted]20[redacted] / 803

ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 804	[redacted]20[redacted] / 806
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 807	[redacted]20[redacted] / 809
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 810	[redacted]20[redacted] / 816
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 817	
ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 817	[redacted]20[redacted] / 817
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 818	[redacted]20[redacted] / 835
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 836	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 836	[redacted]20[redacted] / 836
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 837	[redacted]20[redacted] / 837
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 838	[redacted]20[redacted] / 839
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 839	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 840	[redacted]20[redacted] / 840
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 841	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 841	[redacted]20[redacted] / 842
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 842	
ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 843	[redacted]20[redacted] / 844
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 845	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 845	[redacted]20[redacted] / 845
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 846	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 846	[redacted]20[redacted] / 846
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 847	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 847	[redacted]20[redacted] / 849
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 850	
ABBV-951	1329.80		SC / CONTINUOUS	[redacted]20[redacted] / 850	[redacted]20[redacted] / 850
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 851	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 851	[redacted]20[redacted] / 852
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 853	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 853	[redacted]20[redacted] / 853
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 854	

ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 854	[redacted]20[redacted] / 854
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 855	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 855	[redacted]20[redacted] / 855
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 856	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 856	[redacted]20[redacted] / 856
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 857	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 857	[redacted]20[redacted] / 857
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 858	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 858	[redacted]20[redacted] / 858
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 859	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 859	[redacted]20[redacted] / 859
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 860	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 860	[redacted]20[redacted] / 860
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 861	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 861	[redacted]20[redacted] / 861
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 862	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 862	[redacted]20[redacted] / 862
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 863	
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 863	[redacted]20[redacted] / 863
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 864	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 864	[redacted]20[redacted] / 864
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 865	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 865	[redacted]20[redacted] / 866
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 867	[redacted]20[redacted] / 867
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 868	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 868	[redacted]20[redacted] / 868
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 869	

ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 869	[redacted]20[redacted] / 869
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 870	
ABBV-951	1290.35		SC / CONTINUOUS	[redacted]20[redacted] / 870	[redacted]20[redacted] / 870
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 871	[redacted]20[redacted] / 873
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 874	[redacted]20[redacted] / 897
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 898	[redacted]20[redacted] / 899
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 900	[redacted]20[redacted] / 900
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 901	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 901	[redacted]20[redacted] / 901
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 902	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted]20[redacted] / 902	[redacted]20[redacted] / 902
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 903	
ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 903	[redacted]20[redacted] / 904
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 905	[redacted]20[redacted] / 976
ABBV-951	1395.88		SC / CONTINUOUS	[redacted]20[redacted] / 977	[redacted]20[redacted] / 977
ABBV-951	1481.25		SC / CONTINUOUS	[redacted]20[redacted] / 978	[redacted]20[redacted] / 978
ABBV-951	1509.94		SC / CONTINUOUS	[redacted]20[redacted] / 979	[redacted]20[redacted] / 979
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 980	[redacted]20[redacted] / 980
ABBV-951	1509.94		SC / CONTINUOUS	[redacted]20[redacted] / 981	[redacted]20[redacted] / 981
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 982	[redacted]20[redacted] / 982
ABBV-951	1503.62		SC / CONTINUOUS	[redacted]20[redacted] / 983	[redacted]20[redacted] / 983
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 984	[redacted]20[redacted] / 984
ABBV-951	1509.94		SC / CONTINUOUS	[redacted]20[redacted] / 985	[redacted]20[redacted] / 985
ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 986	[redacted]20[redacted] / 986
ABBV-951	1503.62		SC / CONTINUOUS	[redacted]20[redacted] / 987	[redacted]20[redacted] / 988
ABBV-951	1509.94		SC / CONTINUOUS	[redacted]20[redacted] / 989	[redacted]20[redacted] / 990

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted]
CURCUMA LONGA	800 mg	QD	Y-M: 20[redacted]
FISH OIL	1200 mg	QD	Y-M: 20[redacted]
MELATONIN	5 mg	QD	Y-M: 20[redacted]
RESVERATROL	1 OTHER: TABLET	QD	Y-M: 20[redacted]
VITAMINS NOS	1 OTHER: TABLET	QD	Y-M: 20[redacted]
NAPROXEN SODIUM	220 mg	PRN	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
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted]	NOT REPORTED
CURCUMA LONGA	800 mg	QD	Y-M: 20[redacted]	NOT REPORTED
VITAMINS NOS	1 OTHER: TABLET	QD	Y-M: 20[redacted]	NOT REPORTED
NAPROXEN SODIUM	220 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CALCIUM	500 mg	QD	Y-M: 20[redacted] / 534	ONGOING
CELECOXIB	100 mg	BID	Y-M: 20[redacted] / 919	NOT REPORTED
PARACETAMOL	1000 mg	TID	Y-M: 20[redacted] / 919	NOT REPORTED
MACROGOL	17 g	QD	Y-M: 20[redacted] / 919	Y-M: 20[redacted] / 925
METHOCARBAMOL	500 mg	PRN	Y-M: 20[redacted] / 919	Y-M: 20[redacted] / 925
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 919	Y-M: 20[redacted] / 925
SENNA ALEXANDRINA	8.6 mg	BID	Y-M: 20[redacted] / 919	Y-M: 20[redacted] / 925
ACETYLSALICYLIC ACID	81 mg	BID	Y-M: 20[redacted] / 919	Y-M: 20[redacted] / 946

Event #1: Serious Adverse Event

Event Description	RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE
Preferred Term	変形性関節症
AE Onset Date / Rx Day	[redacted]20[redacted] / 918
Age at AE Onset	6[redacted]

Laboratory Testing

NOT REPORTED

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	919
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	AES OF RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR ON [redacted]20[redacted], RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE ON [redacted]20[redacted] REQ. REPAIR WITH RIGHT REVERSE TOTAL SHOULDER ARTHROPLASTY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Serious Adverse Event

Event Description	RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR
Preferred Term	肩回旋筋腱板症候群
AE Onset Date / Rx Day	[redacted]20[redacted] / 918
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	919
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	AES OF RIGHT SHOULDER CHRONIC MASSIVE ROTATOR

	CUFF TEAR ON [redacted]20[redacted], RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE ON [redacted]20[redacted] REQ. REPAIR WITH RIGHT REVERSE TOTAL SHOULDER ARTHROPLASTY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に右肩回旋筋腱板の慢性広範囲断裂及び右肩関節の変形性関節疾患を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，ビタミン D 欠乏，閉経，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 918 日目，被験者は右肩回旋筋腱板の慢性広範囲断裂及び右肩関節の変形性関節疾患を発現した。投与 919 日目，右肩回旋筋腱板の慢性広範囲断裂及び右肩関節の変形性関節疾患は消失した。

本事象の発現前，被験者は投与 451 日目に非重篤な右肩関節の変形性関節疾患，及び投与 918 日目に非重篤な右肩回旋筋腱板の慢性広範囲断裂を発現した。

投与 918 日目，被験者は右肩関節の変形性関節疾患（日常活動によるもの）及び右肩回旋筋腱板の慢性広範囲断裂（高い棚のものを取ろうと手を伸ばした後に発現）による疼痛及び機能障害を伴って来院した。同日，被験者は入院し，右側リバース型人工肩関節置換術が実施された。疼痛管理のため，必要に応じて鎮痛剤が与えられた。投与 919 日目，被験者は退院した。

被験者にセンナエキス，ポリエチレングリコール，オンダンセトロン，メトカルバモール，セレコキシブ，アスピリン腸溶錠，及びアセトアミノフェンが投与された。

Causality for ABBV-951 (Open Label)

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1) Rotator cuff tear (10039229) (Rotator cuff syndrome (10039227)) [v.24.1] [10039229]

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

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

Dechallenge: Not Applicable

2) Shoulder osteoarthritis (10040616) (Osteoarthritis (10031161)) [v.24.1] [10040616]

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 RIGHT SHOULDER CHRONIC MASSIVE ROTATOR CUFF TEAR

- Investigator: AES of right shoulder chronic massive rotator cuff tear on [redacted]20[redacted], right shoulder glenohumoral degenerative joint disease on [redacted]20[redacted] req. Repair with right reverse total shoulder arthroplasty

- AbbVie: Event is more likely related to reported right shoulder chronic massive rotator cuff tear and glenohumoral degenerative joint disease in a 6[redacted] year old female patient with Parkinson's disease and vitamin D deficiency

Event of RIGHT SHOULDER GLENOHUMORAL DEGENERATIVE JOINT DISEASE

- Investigator: AES of right shoulder chronic massive rotator cuff tear on [redacted]20[redacted], right shoulder glenohumoral degenerative joint disease on [redacted]20[redacted] req. Repair with right reverse total shoulder arthroplasty

- AbbVie: Event is more likely related to reported right shoulder chronic massive rotator cuff tear and glenohumoral degenerative joint disease in a 6[redacted] year old female patient with Parkinson's disease and vitamin D deficiency

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			X
大腿骨頚部骨折	X			X
転位骨折	X			X
幻覚				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
OSTEPENIA	20[redacted]
POST-MENOPAUSAL	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.47	0.50	0.43	60	0.19	[redacted] / 364
ABBV-951	0.50	0.54	0.47	60	0.19	[redacted] / 532
ABBV-951	0.50	0.54	0.47	60	0.19	[redacted] / 708

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	908.39		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 2	[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 4	
M15-741 /ABBV-951	1454.79		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	204.9		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 8	[redacted] / 10
M15-741 /ABBV-951	1654.56		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 12	[redacted] / 22
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1541.87		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	240.75		SC / CONTINUOUS	[redacted] / 24	[redacted] / 24

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
NOT REPORTED			

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PARACETAMOL	1000 mg	TID	Y-M: 20[redacted] / 523	NOT REPORTED
MACROGOL 3350	17 g	QD	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 527
OXYCODONE	5 mg	OTHER: EVERY 4 HOURS	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 528
CELECOXIB	100 mg	BID	Y-M: 20[redacted] / 523	Y-M: 20[redacted] / 539
ASCORBIC ACID;BACOPA MONNIERI;BIOTIN;BORON	640 mg	QD	Y-M: 20[redacted] / 527	NOT REPORTED

CITRATE;CALCIUM; CHOLINE BITARTRATE;CHROMIUM;COLECALCIFEROL;COPPER;DEANOL;DOCOSAHEXAENOIC ACID;ELECTROLYTES NOS;FOLIC ACID;GAMMA-AMINOBUTYRIC ACID;HUPERZIA S				
CALCIUM;VITAMIN D NOS	500 mg	QD	Y-M: 20[redacted] / 527	NOT REPORTED
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted] / 527	NOT REPORTED
RIVASTIGMINE HYDROGEN TARTRATE	6 mg	BID	Y-M: 20[redacted] / 709	NOT REPORTED
DOCUSATE SODIUM;SENNOSIDE A+B	8.6-50 mg	BID	Y-M: 20[redacted] / 714	NOT REPORTED
OXYCODONE	5 mg	OTHER: Q4H	Y-M: 20[redacted] / 714	NOT REPORTED
TRAMADOL	50 mg	QID	Y-M: 20[redacted] / 714	NOT REPORTED

Event #1: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	MECHANICAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 523
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 523): Albumin: 44 [33 - 48] G/L; Alkaline Phosphatase: 99 [35 - 115] U/L; Basophils: 0.03 [0 - 0.1] 10^9/L; Bilirubin: 15 [2 - 26] UMOL/L; Blood: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Blood Urea Nitrogen: 7.1 [2.9 - 8.9] MMOL/L; Calcium: 2.47 [2.12 - 2.62] MMOL/L; Chloride: 106 [99 - 109] MMOL/L; Creatinine: 57 [44 - 88] UMOL/L; Eosinophils/Leukocytes: 0 [1 - 4] %; Ery. Mean Corpuscular HGB Concentration: 323 [320 - 355] G/L; Ery. Mean Corpuscular Hemoglobin: 29.8 [27 - 34] PG; Erythrocytes: 3.9 [3.7 - 5.1] 10^12/L; Glucose: NEG [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Glucose: 6.4 [3.6 - 5.5] MMOL/L; Hematocrit: 0.36 [0.34 - 0.46] FRACTION OF 1; Hemoglobin: 117 [113 - 155] G/L; Ketones: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Leukocytes: 15.2 [3.8 - 11] 10^9/L; Lymphocytes: 0.86 [1 - 3.9] 10^9/L; Lymphocytes/Leukocytes: 5.6 [20 - 44] %; Monocytes: 0.89 [0 - 0.8] 10^9/L; Monocytes/Leukocytes: 5.8 [2 - 9] %; Neutrophils: 13.37 [1.9 - 7.4] 10^9/L; Platelets: 174 [150 - 400] 10^9/L; Potassium: 4.1 [3.5 - 4.9] MMOL/L; Protein: 72 [63 - 82] G/L; Prothrombin Time: 13 [12 - 14] SEC; Sodium: 138 [135 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	523

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 RELATED
Other Cause of Event	POOR BALANCE DUE TO PD
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	CLOSED DISPLACED FRACTURE OF LEFT FEMORAL NECK
Preferred Term	転位骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 523
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 523): Albumin: 44 [33 - 48] G/L; Alkaline Phosphatase: 99 [35 - 115] U/L; Basophils: 0.03 [0 - 0.1] 10^9/L; Bilirubin: 15 [2 - 26] UMOL/L; Blood: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Blood Urea Nitrogen: 7.1 [2.9 - 8.9] MMOL/L; Calcium: 2.47 [2.12 - 2.62] MMOL/L; Chloride: 106 [99 - 109] MMOL/L; Creatinine: 57 [44 - 88] UMOL/L; Eosinophils/Leukocytes: 0 [1 - 4] %; Ery. Mean Corpuscular HGB Concentration: 323 [320 - 355] G/L; Ery. Mean Corpuscular Hemoglobin: 29.8 [27 - 34] PG; Erythrocytes: 3.9 [3.7 - 5.1] 10^12/L; Glucose: NEG [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Glucose: 6.4 [3.6 - 5.5] MMOL/L; Hematocrit: 0.36 [0.34 - 0.46] FRACTION OF 1; Hemoglobin: 117 [113 - 155] G/L; Ketones: TRACE [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Leukocytes: 15.2 [3.8 - 11] 10^9/L; Lymphocytes: 0.86 [1 - 3.9] 10^9/L; Lymphocytes/Leukocytes: 5.6 [20 - 44] %; Monocytes: 0.89 [0 - 0.8] 10^9/L; Monocytes/Leukocytes: 5.8 [2 - 9] %; Neutrophils: 13.37 [1.9 - 7.4] 10^9/L; Platelets: 174 [150 - 400] 10^9/L; Potassium: 4.1 [3.5 - 4.9] MMOL/L; Protein: 72 [63 - 82] G/L; Prothrombin Time: 13 [12 - 14] SEC; Sodium: 138 [135 - 145] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	525
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	NOT RELATED

[redacted] **Infusion Set**	
Other Cause of Event	MECHANICAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	MECHANICAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 700
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	700
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	PARKINSON'S DISEASE PROGRESSION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #4: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	CLOSED FRACTURE OF NECK OF RIGHT FEMUR
Preferred Term	大腿骨頚部骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 700
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	714

Duration of AE	15 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	OSTEOPENIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #5: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 708
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of 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]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に左大腿頚部の閉鎖転位骨折及び機械的転倒を発現した。

Event 1 及び 2 の臨床経過：

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

投与 523 日目，被験者は左大腿頚部の閉鎖転位骨折及び機械的転倒を発現した。投与 523 日目，機械的転倒は消失した。投与 525 日目，左大腿頚部の閉鎖転位骨折は消失した。

投与 523 日目，被験者は自宅の玄関の階段から誤って機械的転倒し，左臀部を痛めたため救急診療部に来院した。救急診療部で行われた X 線検査により左大腿頚部の閉鎖転位骨折が認められ，被験者は入院した。投与 525 日目，整形外科医にかかり，完全股関節形成術が予定され，同日完了した。被験者は必要に応じて経口鎮痛剤が投与された。投与 527 日目，被験者は退院した。

被験者に MIRALAX，CELEBREX，オキシコドン，及びアセトアミノフェンが投与された。

Causality for ABBV-951 (Open Label)

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1) Fracture displacement (10053206) (Fracture displacement (10053206)) [v.24.1] [10053206]

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

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

Dechallenge: Not Applicable

2) Fall (10016173) (Fall (10016173)) [v.24.1] [10016173]

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 CLOSED DISPLACED FRATURE OF LEFT FEMORAL NECK

- Investigator: Mechanical fall

- AbbVie: More likely a related to current mechanical fall in an elderly female with history of osteopenia.

Event of MECHANICAL FALL

- Investigator: Poor balance due to PD (Parkinson's disease)

- AbbVie: More likely related to missing the front step on the home stairs, age, and Parkinson disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALBUMIN:** 4.4 G/DL (normal 3.3 to 4.8)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 99 U/L (normal 35 to 115)

[redacted] **20[redacted] BASOPHILS ABS:** 0.03 K/UL (normal 0.00 to 0.10)

[redacted] **20[redacted] BLOOD UREA NITROGEN:** 20 mg/dL (normal 8 to 25)

[redacted] **20[redacted] BLOOD URINE:** Trace, no reference range

[redacted] **20[redacted] CALCIUM:** 9.9 mg/dL (normal 8.5 to 10.5)

[redacted] **20[redacted] CHLORIDE:** 106 MMOL/L (normal 99 to 109)

[redacted] **20[redacted] CREATININE:** 0.64 mg/dL (normal 0.50 to 1.00)

[redacted] **20[redacted] EOSINOPHILS:** 0.00%

[redacted] **20[redacted] GLUCOSE:** 116 mg/dL (normal 65 to 99)

[redacted] 20[redacted] **HEMATOCRIT:** 36.2% (normal 34.0 to 46.0)

[redacted] 20[redacted] **HEMOGLOBIN:** 11.7 G/DL (normal 11.3 to 15.5)

[redacted] 20[redacted] **LYMPHOCYTES:** 5.60%

[redacted] 20[redacted] **LYMPHOCYTES ABS:** 0.86 K/UL (normal 1.00 to 3.90)

[redacted] 20[redacted] **MCH:** 29.8 PG (normal 27.0 to 34.0)

[redacted] 20[redacted] **MCHC:** 32.3 G/DL (normal 32.0 to 35.5)

[redacted] 20[redacted] **MONOCYTES:** 5.80%

[redacted] 20[redacted] **MONOCYTES ABS:** 0.89 K/UL (normal 0.00 to 0.80)

[redacted] 20[redacted] **NEUTROPHILS ABS:** 13.37 K/UL (normal 1.90 to 7.40)

[redacted] 20[redacted] **PLATELET COUNT:** 174 K/UL (normal 150 to 400)

[redacted] 20[redacted] **POTASSIUM:** 4.1 MMOL/L (normal 3.5 to 4.9)

[redacted] 20[redacted] **PROTHROMBIN TIME:** 13.2 SEC (normal 11.7 to 14.4)

[redacted] 20[redacted] **RBC:** 3.93 mU/L (normal 3.70 to 5.10)

[redacted] 20[redacted] **SODIUM:** 138 MMOL/L (normal 135 to 145)

[redacted] 20[redacted] **TOTAL BILIRUBIN:** 0.9 mg/dL (normal 0.1 to 1.5)

[redacted] 20[redacted] **TOTAL PROTEIN:** 7.2 G/DL (normal 6.3 to 8.2)

[redacted] 20[redacted] **URINE GLUCOSE:** Negative, no reference range

[redacted] 20[redacted] **URINE KETONES:** Trace, no reference range

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 5.23 K/UL (normal 3.8 to 11)

[redacted] 20[redacted] **X-RAY:** CLOSED DISPLACED FRACTURE OF LEFT FEMORAL NECK.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に機械的転倒及び右大腿骨頚部の閉鎖骨折を発現した。

Event 3 及び 4 の臨床経過：

関連する病歴は，骨減少症，パーキンソン病，閉経，及び飲酒者（1 日 2 杯未満）であった。

投与 700 日目，被験者は機械的転倒及び右大腿骨頚部の閉鎖骨折を発現した。投与 700 日目，機械的転倒は消失した。投与 714 日目，右大腿骨頚部の閉鎖骨折は消失した。

投与 710 日目，被験者は機械的転倒後に姿勢不安定及び右股関節痛のため，緊急治療室に来院した。X 線検査を実施した結果，右大腿骨頚部の閉鎖骨折が認められた。被験者は外科医にかかり，経口鎮痛剤の投与が開始された。

投与 714 日目，被験者は入院し，右股関節全置換術が実施された。投与 715 日目，被験者は退院した。

被験者にオキシコドン，センナエキス，ドクサートナトリウム，及びトラマドールが投与された。

Causality for ABBV-951 (Open Label)

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1) Fall (10016173) (Fall (10016173)) [v.24.1] [10016173]

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

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

Dechallenge: Not Applicable

2) Fracture of unspecified part of neck of femur, closed (10017236) (Femoral neck fracture (10016450)) [v.24.1] [10017236]

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 MECHANICAL FALL

- **Investigator:** Parkinson's disease progression.

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

Event of CLOSED FRACTURE OF NECK OF RIGHT FEMUR

- **Investigator:** Osteopenia.

- **AbbVie:** More likely related to the concurrent event of fall and history of osteopenia

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] X-RAY:** Closed fracture of the neck of the right femur.

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 M15-741 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	0.26	0.27	0.24	60	0.11	[redacted] / 381
ABBV-951	0.26	0.27	0.24	60	0.11	[redacted] / 581
ABBV-951	0.27	0.28	0.26	60	0.11	[redacted] / 644
ABBV-951	0.28	0.29	0.26	60	0.11	[redacted] / 735

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	635.19		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 9	[redacted] / 18
M15-741 /ABBV-951	986.93		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	963.03		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 21	[redacted] / 27
M15-741 /ABBV-951	950.73		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 29	[redacted] / 39
M15-741 /ABBV-951	980.10		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 41	[redacted] / 91
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 92	
M15-741 /ABBV-951	1002.47		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 93	
M15-741 /ABBV-951	1052.16		SC / CONTINUOUS	[redacted] / 93	[redacted] / 93
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted] / 94	[redacted] / 180
M15-741 /ABBV-951	1043.45		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1032.86		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1024.5		SC / CONTINUOUS	[redacted] / 183	[redacted] / 271

M15-741 /ABBV-951	1059.16	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	1088.01	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
ABBV-951	532.74	SC / CONTINUOUS	[redacted]20[redacted] / 381	[redacted]20[redacted] / 381
ABBV-951	1065.48	SC / CONTINUOUS	[redacted]20[redacted] / 382	[redacted]20[redacted] / 632
ABBV-951	1072.99	SC / CONTINUOUS	[redacted]20[redacted] / 633	[redacted]20[redacted] / 633
ABBV-951	1092.62	SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 635
ABBV-951	1106.46	SC / CONTINUOUS	[redacted]20[redacted] / 636	[redacted]20[redacted] / 732
ABBV-951	1097.23	SC / CONTINUOUS	[redacted]20[redacted] / 733	[redacted]20[redacted] / 734

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] / -363
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309
CARBIDOPA MONOHYDRATE;LEVODOPA	200.000 mg	QID	Y-M: 20[redacted] / -275
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]	NOT REPORTED
ONDANSETRON	4 mg	OTHER: Q8HOURS	Y-M: 20[redacted]	NOT REPORTED
MACROGOL 3350	17 OTHER: GRAM	QD	Y-M: 20[redacted]	NOT REPORTED
OMEPRAZOLE	40 mg	QD	Y-M: 20[redacted]	NOT REPORTED
PROPRANOLOL	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
MIRABEGRON	50 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CICLOSPORIN	1 gtt	PRN	Y-M: 20[redacted] / -309	NOT REPORTED
MELATONIN	5 mg	QD	Y-M: 20[redacted] / -133	NOT REPORTED
SERTRALINE	50 mg	QD	Y-M: 20[redacted] / -121	NOT REPORTED

HYDROCHLORIDE

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	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	42
Duration of AE	5 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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PATIENT HAS A HISTORY OF LOW SODIUM
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
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 を投与中に，ナトリウム低値を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，ナトリウム濃度の低下，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，うつ病，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 38 日目，被験者はナトリウム低値を発現した。投与 42 日目，ナトリウム低値は消失した。

投与 37 日目，被験者は定期的な臨床血液検査を受けた。投与 39 日目，被験者は疲労，錯乱，及びナトリウム低値が認められたため入院した。治験責任医師によると，被験者にはナトリウム低値の病歴があった。対症療法として輸液療法を開始した。被験者は，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:

RASAGILINE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
CARBIDOPA/LEVODOPA IMMEDIATE RELEASE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
CARBIDOPA/ LEVODOPA IMMEDIATE RELEASE 25/100 for PARKINSON'S 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.24.1] [10041274]

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 LOW SODIUM

- Investigator: Not Applicable

- AbbVie: More likely related to history of low sodium, 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
股関節部骨折	X			X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 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]
SEASONAL ALLERGIES	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	0.33	0.35	0.32	60	0.15	[redacted]20[redacted] / 366
ABBV-951	0.33	0.35	0.32	60	0.15	[redacted]20[redacted] / 536
ABBV-951	0.30	0.32	0.34		0.00	[redacted]20[redacted] / 703

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	480.83		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951	781.35		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951	448.04		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	109.28		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951	5.46		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	404.33		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	1213.00		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 26
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	

M15-741 /ABBV-951	945.27		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 43
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 55
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 54	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951	1131.04		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951	1218.47		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 61	

M15-741 /ABBV-951	152.99		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 85
M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 92
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	907.02		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 94	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 95	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 97
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 98	
M15-741 /ABBV-951	1374.87		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 99	
M15-741 /ABBV-951	1408.51		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 100	
M15-741 /ABBV-951	5.46		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 101	
M15-741 /ABBV-951	645.26		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 103	
M15-741 /ABBV-951	1278.57		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951	1207.54		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 105
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 106	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 106	[redacted]20[redacted] / 107
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 108	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 109	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 111
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 111	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 112	
M15-741 /ABBV-951	628.36		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 113	
M15-741 /ABBV-951	655.68		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 117
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 115	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118

M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 119
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 119 [redacted]20[redacted] / 121
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 120
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 121
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 122
M15-741 /ABBV-951	1245.79		SC / CONTINUOUS	[redacted]20[redacted] / 122 [redacted]20[redacted] / 122
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 123
M15-741 /ABBV-951	1234.86		SC / CONTINUOUS	[redacted]20[redacted] / 123 [redacted]20[redacted] / 123
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 124 [redacted]20[redacted] / 124
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 125
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 125 [redacted]20[redacted] / 126
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 127 [redacted]20[redacted] / 127
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 128
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 128 [redacted]20[redacted] / 128
M15-741 /ABBV-951	1223.93		SC / CONTINUOUS	[redacted]20[redacted] / 129 [redacted]20[redacted] / 129
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 130 [redacted]20[redacted] / 130
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 131 [redacted]20[redacted] / 131
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 132 [redacted]20[redacted] / 132
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 133 [redacted]20[redacted] / 134
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 135
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 135 [redacted]20[redacted] / 135
M15-741 /ABBV-951	81.96		SC / CONTINUOUS	[redacted]20[redacted] / 136 [redacted]20[redacted] / 136
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 137 [redacted]20[redacted] / 138
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 138
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 139
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 139 [redacted]20[redacted] / 139
M15-741 /ABBV-951	71.03		SC / CONTINUOUS	[redacted]20[redacted] / 140 [redacted]20[redacted] / 140
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 141 [redacted]20[redacted] / 141
M15-741 /ABBV-951	1278.57		SC / CONTINUOUS	[redacted]20[redacted] / 142 [redacted]20[redacted] / 142
M15-741 /ABBV-951	1316.82		SC / CONTINUOUS	[redacted]20[redacted] / 143 [redacted]20[redacted] / 143
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 144
M15-741 /ABBV-951	1300.43		SC / CONTINUOUS	[redacted]20[redacted] / 144 [redacted]20[redacted] / 144
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 145 [redacted]20[redacted] / 145
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 146
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 146 [redacted]20[redacted] / 146
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 147 [redacted]20[redacted] / 147
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 148

M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 148	[redacted]20[redacted] / 148
M15-741 /ABBV-951	1152.90		SC / CONTINUOUS	[redacted]20[redacted] / 149	[redacted]20[redacted] / 149
M15-741 /ABBV-951	76.49		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
M15-741 /ABBV-951	371.55		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	710.32		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 157	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 158
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 159	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 159	[redacted]20[redacted] / 159
M15-741 /ABBV-951	1191.15		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 161	
M15-741 /ABBV-951	300.52		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 162	
M15-741 /ABBV-951	1213.00		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 163	
M15-741 /ABBV-951	1240.32		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 166
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 166	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 167	
M15-741 /ABBV-951	1196.61		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 169	
M15-741 /ABBV-951	622.89		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 170	
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 171	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 172	
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173
M15-741 /ABBV-951	1251.25		SC / CONTINUOUS	[redacted]20[redacted] / 174	[redacted]20[redacted] / 174
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 175	[redacted]20[redacted] / 175
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 176	[redacted]20[redacted] / 176
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 177	[redacted]20[redacted] / 177
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 178	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178

M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	1049.08		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	256.80		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 184	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
M15-741 /ABBV-951	1191.15		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951	1267.64		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 187	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 188
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 188	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 189	
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted]20[redacted] / 189	[redacted]20[redacted] / 189
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 190	
M15-741 /ABBV-951	1305.89		SC / CONTINUOUS	[redacted]20[redacted] / 190	[redacted]20[redacted] / 190
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 191	[redacted]20[redacted] / 191
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 192	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 192	[redacted]20[redacted] / 192
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 195
M15-741 /ABBV-951	1016.30		SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 199
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 202
M15-741 /ABBV-951	1300.09		SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
M15-741 /ABBV-951	1313.92		SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 207
M15-741 /ABBV-951	1223.93		SC / CONTINUOUS	[redacted]20[redacted] / 208	[redacted]20[redacted] / 208
M15-741 /ABBV-951	240.41		SC / CONTINUOUS	[redacted]20[redacted] / 209	[redacted]20[redacted] / 209
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 210	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 210	[redacted]20[redacted] / 210
M15-741 /ABBV-951	1174.76		SC / CONTINUOUS	[redacted]20[redacted] / 211	[redacted]20[redacted] / 211
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 213	

M15-741 /ABBV-951	125.50		SC / CONTINUOUS	[redacted]20[redacted] / 213	[redacted]20[redacted] / 213
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 214	
M15-741 /ABBV-951	1416.37		SC / CONTINUOUS	[redacted]20[redacted] / 214	[redacted]20[redacted] / 214
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 215	
M15-741 /ABBV-951	1302.82		SC / CONTINUOUS	[redacted]20[redacted] / 215	[redacted]20[redacted] / 215
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 216	
M15-741 /ABBV-951	902.41		SC / CONTINUOUS	[redacted]20[redacted] / 216	[redacted]20[redacted] / 216
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 217	[redacted]20[redacted] / 219
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 219	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 220	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 220	[redacted]20[redacted] / 220
M15-741 /ABBV-951	1410.39		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 222	
M15-741 /ABBV-951	1404.41		SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 222
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 223	
M15-741 /ABBV-951	1368.56		SC / CONTINUOUS	[redacted]20[redacted] / 223	[redacted]20[redacted] / 223
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 224	
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 225	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 225	[redacted]20[redacted] / 226
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 226	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 227	
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 227	[redacted]20[redacted] / 227
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 228	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 228	[redacted]20[redacted] / 229
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 229	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 230	
M15-741 /ABBV-951	1308.79		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
M15-741 /ABBV-951	1344.65		SC / CONTINUOUS	[redacted]20[redacted] / 232	[redacted]20[redacted] / 232
ABBV-951	619.82		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 448
ABBV-951	1056.43		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951	675.31		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 450
ABBV-951	0		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951	957.90		SC / CONTINUOUS	[redacted]20[redacted] / 701	[redacted]20[redacted] / 701

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]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272
BACITRACIN;NEOMYCIN SULFATE;POLYMYXIN B SULFATE	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted] / 42
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]-[redacted] / 154

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]	NOT REPORTED
ASCORBIC ACID	1000 mg	QD	Y-M: 19[redacted]	NOT REPORTED
FEXOFENADINE	180 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
FLUNISOLIDE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ARMODAFINIL	75 mg	QD	Y-M: 20[redacted]-[redacted] / -272	NOT REPORTED
AZELASTINE	1 OTHER: SPRAY	PRN	Y-M: 20[redacted]-[redacted] / 154	NOT REPORTED
HYDROCODONE BITARTRATE;PARACETAMOL	5/325 mg	TID	Y-M: 20[redacted]-[redacted] / 505	Y-M: 20[redacted]-[redacted] / 511
CEFALEXIN	500 mg	TID	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 730
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted]-[redacted] / 723	Y-M: 20[redacted]-[redacted] / 730
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted]-[redacted] / 798	Y-M: 20[redacted]-[redacted] / 808
BACITRACIN	500 OTHER: UNITS/GRAM	BID	Y-M: 20[redacted]-[redacted] / 798	Y-M: 20[redacted]-[redacted] / 828

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] / 505

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	505
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 #2: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	FRACTURED HIP
Preferred Term	股関節部骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 505
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	566
Duration of AE	62 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	SUBJECT TRIPPED

Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	ABDOMEN INFUSION SITE ERYTHEMA GRADE 5
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 534
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	538
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 #4: 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] / 713
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	730
Duration of AE	18 DAYS
Severity	SEVERE

Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT REPORTED
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	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

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

Event Description	CELLULITIS ON ABDOMEN AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 784
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	791
Duration of AE	8 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 795

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	PROBABLE
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	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Generated: [redacted] 20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に股関節部骨折を発現した。

Event 2 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 505 日目，被験者は股関節部骨折を発現した。

投与 505 日目，被験者は仕事場で滑り股関節を骨折し，入院した。投与 507 日目，被験者に骨折整復手術を実施した。手術は成功した。大腿骨頭にピンを留置した。

Causality for ABBV-951 (Open Label)

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1) Fractured hip (10017287) (Hip fracture (020100)) [v.23.1] [10017287]

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of FRACTURED HIP

- Investigator: Subject tripped

- AbbVie: More likely related to traumatic injury from tripping in an advanced aged patient with a history of Parkinson's disease and daytime somnolence.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 6[redacted] KG

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に，投与 713 日目及び投与 795 日目に注入部位の蜂巣炎を発現した。

Event 4 及び 6 の臨床経過：

関連する病歴は，パーキンソン病，非喫煙者，及び禁酒者であった。

投与 713 日目，被験者は注入部位の蜂巣炎を発現した。投与 730 日目，注入部位の蜂巣炎は消失した。投与 795 日目，被験者は注入部位の蜂巣炎を発現した。

治験責任医師によると，投与から約 23 ヵ月後，被験者は左腹部に皮膚感染が発現し，緊急治療室に来院するよう指導された。被験者に 2 種類の抗生物質が処方された。投与 730 日目，被験者は皮膚科医に評価された。

投与 784 日目，被験者は腹部の注入部位に非重篤な蜂巣炎を発現した。
治験責任医師によると，本事象のため治験薬の投与が中止された。
被験者にドキシサイクリン，バシトラシン，BACTRIM，及びセファレキシンが投与された。

The patient's past medications include:

CARBIDOPA/LEVODOPA IMMEDIATE RELEASE 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.24.1] [10065455]

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

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

Dechallenge: Not Applicable

2) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.1] [10065455]

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Event of CELLULITIS AT INFUSION SITE

- **Investigator:** Not applicable

- **AbbVie:** Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 14[redacted] Pounds

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
胃腸炎	X			
体重減少				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	WHITE

Medical History	Onset Year
CHRONIC STREP THROAT	NOT REPORTED
DAYTIME SLEEPINESS	NOT REPORTED
FOCAL WEAKNESS	NOT REPORTED
HALLUCINATIONS	NOT REPORTED
MOUTH SORES	NOT REPORTED
NEUROPATHY	NOT REPORTED
SLOWING COGNITIVE IMPAIRMENT	NOT REPORTED
WEAKNESS	NOT REPORTED
CHRONIC STREP THROAT	19[redacted]
CHRONIC LEFT SHOULDER DISLOCATION	19[redacted]
DROOLING	19[redacted]
ANXIETY	19[redacted]
DEPRESSION	19[redacted]
MILD APATHY	19[redacted]
EARLY SATIETY	20[redacted]
URINARY URGENCY	20[redacted]
MIGRAINES	20[redacted]
LEFT HAND TREMOR	20[redacted]
LOSS OF SMELL	20[redacted]
CONSTIPATION	20[redacted]
BRAIN FOG	20[redacted]
RAPID EYE MOVEMENT SLEEP BEHAVIOR DISORDER (RBD OR REM)	20[redacted]

SHORT-TERM MEMORY LOSS	20[redacted]
CHOKING (OCCASIONAL)	20[redacted]
COUGHING WHEN EATING (OCCASIONAL)	20[redacted]
DIZZINESS	20[redacted]
LIGHTHEADEDNESS	20[redacted]
FATIGUE	20[redacted]
MASKING OF FACE	20[redacted]
MILD HYPOPHOMIA	20[redacted]
LUMP ON LEFT NECK	20[redacted]
NON-HODGKIN'S (B-CELL) LYMPHOMA	20[redacted]
NUMBNESS IN FINGERS	20[redacted]
SOLID TUMOR IN NASOPHARYNX	20[redacted]
LACK OF IMPULSE CONTROL WITH INTERNET USE FOR SEXUAL DESIRES	20[redacted]
DYSPHAGIA	20[redacted]
LEFT CARPAL TUNNEL SYNDROME	20[redacted]

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

Prior Procedures	Procedure Year
TONSILS REMOVED	19[redacted]
SHOULDER SURGERY	19[redacted]
SOLID TUMOR IN NASOPHARYNX	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.29	0.32	0.26	120	0.24	[redacted]20[redacted] / 366
ABBV-951	0.38	0.41	0.35	120	0.30	[redacted]20[redacted] / 436
ABBV-951	0.50	0.56	0.44	120	0.30	[redacted]20[redacted] / 485
ABBV-951	0.56	0.58	0.54	120	0.30	[redacted]20[redacted] / 534
ABBV-951	0.50	0.52	0.48	120	0.30	[redacted]20[redacted] / 618
ABBV-951	0.50	0.52	0.48	120	0.11	[redacted]20[redacted] / 703

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	245.88		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	792.28		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	798.42		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	922.90		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	915.04		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	899.34		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	988.13		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	1012.20		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 11
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	1029.96		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 19
M15-741 /ABBV-951	1034.40		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1021.08		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21

M15-741 /ABBV-951	1043.28		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 27
M15-741 /ABBV-951	986.76		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1114.14		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 32
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1124.04		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	559.54		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 36
M15-741 /ABBV-951	990.35		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951	747.71		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	807.13		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1158.70		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1109.19		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1114.14		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1158.70		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 46
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	1148.80		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 50
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	1148.80		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951	1178.51		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 55	

M15-741 /ABBV-951	1138.90		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 58
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1005.20		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	1163.66		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1138.90		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	1221.71		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951	928.88		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	655.68		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951	1120.12		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 69
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 70	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 72	
M15-741 /ABBV-951	1218.47		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 74	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 76	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 78
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 79	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79

M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 80
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted]20[redacted] / 81	[redacted]20[redacted] / 81
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 82	
M15-741 /ABBV-951	1234.86		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 84	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	934.34		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 89	
M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	1092.8		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 92	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 98
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 95	
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 99	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 99
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 101
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 104	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 105	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 107
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 108	
M15-741 /ABBV-951	1267.64		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 109	[redacted]20[redacted] / 109
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 110	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 110	[redacted]20[redacted] / 110
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 111	[redacted]20[redacted] / 111
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 112	[redacted]20[redacted] / 112
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 114	[redacted]20[redacted] / 114
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 115	[redacted]20[redacted] / 115

M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 116	
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 116	[redacted]20[redacted] / 117
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 117	
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 119	
M15-741 /ABBV-951	1240.32		SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 121	
M15-741 /ABBV-951	1273.11		SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 121
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 122	[redacted]20[redacted] / 124
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 125	
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 125	[redacted]20[redacted] / 125
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 126	
M15-741 /ABBV-951	628.36		SC / CONTINUOUS	[redacted]20[redacted] / 126	[redacted]20[redacted] / 126
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 127	[redacted]20[redacted] / 127
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 128	
M15-741 /ABBV-951	1141.97		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 130
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 131	[redacted]20[redacted] / 134
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 135	[redacted]20[redacted] / 135
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 136	[redacted]20[redacted] / 136
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 137	[redacted]20[redacted] / 137
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 138	[redacted]20[redacted] / 138
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 139	[redacted]20[redacted] / 139
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 140	[redacted]20[redacted] / 140
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 141	
M15-741 /ABBV-951	1202.08		SC / CONTINUOUS	[redacted]20[redacted] / 141	[redacted]20[redacted] / 141
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 142	[redacted]20[redacted] / 150
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 151	[redacted]20[redacted] / 151
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 152	[redacted]20[redacted] / 152
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 153	
M15-741 /ABBV-951	1256.72		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 160
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 159	

M15-741 /ABBV-951	1174.76		SC / CONTINUOUS	[redacted] / 161	[redacted] / 161
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 162	[redacted] / 165
M15-741 /ABBV-951	1038.16		SC / CONTINUOUS	[redacted] / 166	[redacted] / 166
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 167	[redacted] / 167
M15-741 /ABBV-951	546.4		SC / CONTINUOUS	[redacted] / 168	[redacted] / 168
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 169	[redacted] / 170
M15-741 /ABBV-951	683		SC / CONTINUOUS	[redacted] / 171	[redacted] / 171
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 172	[redacted] / 172
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 173	[redacted] / 173
M15-741 /ABBV-951	409.8		SC / CONTINUOUS	[redacted] / 174	[redacted] / 174
M15-741 /ABBV-951	109.28		SC / CONTINUOUS	[redacted] / 180	[redacted] / 180
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 183	[redacted] / 183
M15-741 /ABBV-951	1289.50		SC / CONTINUOUS	[redacted] / 184	[redacted] / 184
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 185	[redacted] / 272
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1294.96		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 274	[redacted] / 274
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 275	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 275	[redacted] / 275
ABBV-951	611.96		SC / CONTINUOUS	[redacted] / 366	[redacted] / 366
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 367	[redacted] / 367
ABBV-951		40.98	SC / ONCE	[redacted] / 368	
ABBV-951	1294.96		SC / CONTINUOUS	[redacted] / 368	[redacted] / 368
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 369	[redacted] / 430
ABBV-951		40.98	SC / ONCE	[redacted] / 431	
ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 431	[redacted] / 431
ABBV-951		40.98	SC / ONCE	[redacted] / 432	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 432	[redacted] / 432
ABBV-951		40.98	SC / ONCE	[redacted] / 433	
ABBV-951	1207.54		SC / CONTINUOUS	[redacted] / 433	[redacted] / 433
ABBV-951		81.96	SC / ONCE	[redacted] / 434	
ABBV-951	1284.04		SC / CONTINUOUS	[redacted] / 434	[redacted] / 434
ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 435	[redacted] / 531
ABBV-951		51.22	SC / ONCE	[redacted] / 530	
ABBV-951		51.22	SC / ONCE	[redacted] / 532	

ABBV-951	1747.11		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 533	
ABBV-951	2247.07		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 700
ABBV-951	2124.13		SC / CONTINUOUS	[redacted]20[redacted] / 701	[redacted]20[redacted] / 701
ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 702	[redacted]20[redacted] / 702
ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 859
ABBV-951	1988.89		SC / CONTINUOUS	[redacted]20[redacted] / 860	[redacted]20[redacted] / 860
ABBV-951	2130.96		SC / CONTINUOUS	[redacted]20[redacted] / 861	[redacted]20[redacted] / 874
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 875	
ABBV-951	2042.17		SC / CONTINUOUS	[redacted]20[redacted] / 875	[redacted]20[redacted] / 875
ABBV-951	2104.32		SC / CONTINUOUS	[redacted]20[redacted] / 876	[redacted]20[redacted] / 876

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PAROXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 19[redacted]
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	250, 250, 65 mg	PRN	Y-M: 20[redacted]
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]
HYDROCORTISONE	1 OTHER: DOSE	PRN	Y-M: 20[redacted]-[redacted] / 23
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted] / 66
BACITRACIN;NEOMYCIN;POLYMYXIN B	SMALL AMOUNT mg	PRN	Y-M: 20[redacted]-[redacted] / 117

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PAROXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 19[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	250, 250, 65 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
HYDROCORTISONE	1 OTHER: DOSE	PRN	Y-M: 20[redacted]-[redacted] / 23	NOT REPORTED
BACITRACIN;NEOMYCIN;POLYMYXIN B	SMALL AMOUNT mg	PRN	Y-M: 20[redacted]-[redacted] / 117	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 487	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 515	NOT REPORTED
HYDROMORPHONE	240 OTHER: MG/ML	PRN	Y-M: 20[redacted]-[redacted] / 547	Y-M: 20[redacted]-[redacted] / 548

HYDROCHLORIDE				
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]-[redacted] / 784	ONGOING

Event #1: Serious Adverse Event

Event Description	GASTROENTERITIS
Preferred Term	胃腸炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 547
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 547): Basophils: 0.06 [0 - 0.2] 10^9/L; Eosinophils: 0.19 [0 - 0.8] 10^9/L; Ery. Mean Corpuscular HGB Concentration: 346 [300 - 370] G/L; Ery. Mean Corpuscular Hemoglobin: 29.9 [26 - 36] PG; Erythrocytes: 5.7 [4.3 - 6.1] 10^12/L; Hematocrit: 0.49 [0.4 - 0.54] FRACTION OF 1; Hemoglobin: 171 [140 - 180] G/L; Leukocytes: 11.8 [3.5 - 11.5] 10^9/L; Lymphocytes: 1.35 [0.6 - 5.2] 10^9/L; Monocytes: 0.88 [0 - 1] 10^9/L; NPTST041-MCV: 87 [80 - 120] FL; Neutrophils: 9.24 [2 - 8] 10^9/L; Platelets: 233 [150 - 400] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	548
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT 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	PI DETERMINED THAT THE PATIENT WAS ADMITTED FOR GASTROENTERITIS BASED ON LAB, IMAGING AND ADMISSIONS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	DELUSIONS
Preferred Term	妄想
AE Onset Date / Rx Day	[redacted]20[redacted] / 617
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

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

Event #3: Event of Interest - Weight Loss

Event Description	WEIGHT LOSS
Preferred Term	体重減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は米国の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に胃腸炎を発現した。

Event 1 の臨床経過：

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

投与 547 日目，被験者は胃腸炎を発現した。投与 548 日目，胃腸炎は消失した。

被験者は背部及び脇腹全体に鋭い痛みを発現した（日時不明）。被験者は緊急治療室に来院した。投与 547 日目，被験者は入院した。嘔吐及び悪心の症状が認められた。投与 548 日目，被験者は退院した。

治験責任医師によると，被験者のリスク因子は胃腸炎を引き起こしやすい体質であった。

被験者にヒドロモルフォンが投与された。

Causality for ABBV-951 (Open Label)

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1) Gastroenteritis (10017888) (Gastroenteritis (10017888)) [v.24.1] [10017888]

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 GASTROENTERITIS

- Investigator: PI determined that the patient was admitted for gastroenteritis based on lab, imaging and admissions.

- AbbVie: More likely related to commonly occurring incidental event in the general population. Event recovered within one day and study drug was ongoing at the time of event recovery.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] PHYSICAL EXAMINATION:** CONSTITUTIONAL: WELL DEVELOPED, NON-TOXIC APPEARENCE, NO ACUTE DISTRESS HENT: NORMOCEPHALIC, ATRAUMATIC, BILATERAL EXTERNAL EARS NORMAL, NO PHARYNGEAL ERYTHMEA, SWELLING OF EXUDE, NOSE NORMAL. EYES: PERRL, EOMI, CONJUCTIVA NORMAL, NO DISCHARGE. NECK: NORMAL RANGE OF MOTION, NO TENDERNESS, NO STRIDOR, NO MENINGISMUS. CARDIOVASCULAR: NORMAL HEART RATE, NORMAL RHYTHM. THORAX AND LUNGS: NO RESPIRATORY DISTRESS. NO CHEST WALL TENDERNESS. CTABL, NO WHEEZES RALES OR RHONCHI. ABDOMEN: BOWEL SOUNDS NORMAL. SOFT, NON-DISTENDED. MILD DIFFUSE TENDERNESS WITHOUT RIGIDITY, ROEBOUND OR GUARDING. NO MASSES. NO PULSATILE MASSES. NO PERITONEAL SIGNS. SKIN: WARM, DRY, NO LESIONS OR RASHES. BACK: NO FOCAL BONY TENDERNESS, NO CVA TENDERNESS. ETREMITIES: INTACT DIATAL PULSES. NO CYANOSIS OR ERYTHEMA. NO DEMA. MUSCULOSKELETAL: NO TENDERNESS TO PALPATION OR MAJOR DEFORMITIES NOTED. NEUROLOGIC: ALERT AND ORIENTED X3, NORMAL MOTOR FUNCTION, NORMALSENSATION., NO FOCAL DEFICITS NOTED. PSYCHIATRIC: ALERT, NORMAL, MOOD NORMAL

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

Weight Decreased: Day 1 weight 18[redacted] lbs. Weight at time of event 17[redacted] lbs. Weight loss occurred over a period of 3 months. Change in diet or mobility level with pump/infusion therapy reported as the patient noted experiencing more physical activity during this time via boxing and walking. The patient made some lifestyle changes. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced previous episode of cognitive decline and temporal episodes of activity increase/more active since treatment began, and dyskinesia and depression worsening since treatment began. No additional conditions or circumstances reported.

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
反射減弱				X
注入部位蜂巣炎	X			X
変形性関節症	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ANXIETY	19[redacted]
INSOMNIA	19[redacted]
DEPRESSION	19[redacted]
GASTROESOPHAGEAL REFLUX	19[redacted]
HYPERTENSION	20[redacted]
POST-MENOPAUSAL	20[redacted]
OSTEOARTHRITIS	20[redacted]
MENINGIOMA, RIGHT FRONTAL	20[redacted]
PARKINSON'S DISEASE	20[redacted]
CERVICAL SPONDYLOSIS	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
ALLERGY - MOLD	20[redacted]
ALLERGY - POLLEN	20[redacted]
CONSTIPATION	20[redacted]
PSORIASIS (ON RIGHT ELBOW)	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
DEEP BRAIN STIMULATOR, GLOBUS PALLIDUS INTERNA (DBS GPI) IMPLANT	20[redacted]
DEEP BRAIN STIMULATOR, GLOBUS PALLIDUS INTERNA (DBS GPI), EXPLANT	20[redacted]
DEEP BRAIN STIMULATOR, SUBTHALAMIC NUCLEUS (DBS STN), IMPLANT	20[redacted]
IMPULSE GENERATOR (IPG) PLACEMENT	20[redacted]
RIGHT KNEE ARTHROPLASTY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	10 CIGARETTE	5	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.38	0.40	0.36	60	0.11	[redacted]20[redacted] / 365
ABBV-951	0.38	0.40	0.36	60	0.11	[redacted]20[redacted] / 533

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	832.06		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1815.41		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1790.82		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	1657.98		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 6	

M15-741 /ABBV-951	1595.48		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1554.16		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	1519.50		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	1423.54		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1425.25		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	1346.70		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951	1309.14		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 19
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1394.17		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1469.81		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 27
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1485.35		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 40
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1500.72		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1532.99		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1492.18		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 89
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 90	
M15-741 /ABBV-951	1544.43		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	1568.85		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	1566.46		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 180

M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 181
M15-741 /ABBV-951	1570.21		SC / CONTINUOUS	[redacted]20[redacted] / 181 [redacted]20[redacted] / 181
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 182
M15-741 /ABBV-951	1560.31		SC / CONTINUOUS	[redacted]20[redacted] / 182 [redacted]20[redacted] / 182
M15-741 /ABBV-951	1570.55		SC / CONTINUOUS	[redacted]20[redacted] / 183 [redacted]20[redacted] / 183
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 184 [redacted]20[redacted] / 271
M15-741 /ABBV-951	1587.97		SC / CONTINUOUS	[redacted]20[redacted] / 272 [redacted]20[redacted] / 272
M15-741 /ABBV-951	1553.31		SC / CONTINUOUS	[redacted]20[redacted] / 273 [redacted]20[redacted] / 273
M15-741 /ABBV-951	1573.97		SC / CONTINUOUS	[redacted]20[redacted] / 274 [redacted]20[redacted] / 274
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 275 [redacted]20[redacted] / 362
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 363
M15-741 /ABBV-951	1593.26		SC / CONTINUOUS	[redacted]20[redacted] / 363 [redacted]20[redacted] / 363
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 364
M15-741 /ABBV-951	1530.60		SC / CONTINUOUS	[redacted]20[redacted] / 364 [redacted]20[redacted] / 364
ABBV-951	486.63		SC / CONTINUOUS	[redacted]20[redacted] / 365 [redacted]20[redacted] / 365
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 366 [redacted]20[redacted] / 450
ABBV-951	1588.65		SC / CONTINUOUS	[redacted]20[redacted] / 451 [redacted]20[redacted] / 451
ABBV-951	1523.09		SC / CONTINUOUS	[redacted]20[redacted] / 452 [redacted]20[redacted] / 452
ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 453 [redacted]20[redacted] / 530
ABBV-951	772.13		SC / CONTINUOUS	[redacted]20[redacted] / 531 [redacted]20[redacted] / 531
ABBV-951	1600.61		SC / CONTINUOUS	[redacted]20[redacted] / 532 [redacted]20[redacted] / 532

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
TRAZODONE HYDROCHLORIDE	50 mg	PRN	Y-M: 20[redacted]-[redacted]
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]
CLONAZEPAM	1 mg	PRN	Y-M: 20[redacted]-[redacted]
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]-[redacted]
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted]
LACTOBACILLUS ACIDOPHILUS	50000 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
COLECALCIFEROL	1000 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
CALCIUM ASCORBATE	1000 mg	PRN	Y-M: 20[redacted]-[redacted]
ISTRADEFYLLINE	42.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -75
ESCITALOPRAM OXALATE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -41
OXYCODONE	5 mg	PRN	Y-M: 20[redacted]-[redacted] / -36
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted]-[redacted] / -32

FOLIC ACID	400 OTHER: MCG	QD	Y-M: 20[redacted] / -30
PRAMIPEXOLE	0.375 mg	BID	Y-M: 20[redacted] / -6
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted] / 1
CANNABIS SATIVA	10 mg	QD	Y-M: 20[redacted] / 53
IBUPROFEN	600 mg	PRN	Y-M: 20[redacted] / 64
CALCIUM	200 mg	BID	Y-M: 20[redacted] / 171
COLECALCIFEROL	600 IU	BID	Y-M: 20[redacted] / 171
PYRIDOXINE HYDROCHLORIDE	25 ug	OTHER: QOD	Y-M: 20[redacted] / 197

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
TRAZODONE HYDROCHLORIDE	50 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CLONAZEPAM	1 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
OMEPRAZOLE	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
LACTOBACILLUS ACIDOPHILUS	50000 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
COLECALCIFEROL	1000 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
CALCIUM ASCORBATE	1000 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
ESCITALOPRAM OXALATE	20 mg	QD	Y-M: 20[redacted] / -41	NOT REPORTED
OXYCODONE	5 mg	PRN	Y-M: 20[redacted] / -36	NOT REPORTED
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / -32	NOT REPORTED
FOLIC ACID	400 OTHER: MCG	QD	Y-M: 20[redacted] / -30	NOT REPORTED
CANNABIS SATIVA	10 mg	QD	Y-M: 20[redacted] / 53	NOT REPORTED
IBUPROFEN	600 mg	PRN	Y-M: 20[redacted] / 64	NOT REPORTED
CALCIUM	200 mg	BID	Y-M: 20[redacted] / 171	NOT REPORTED
COLECALCIFEROL	600 IU	BID	Y-M: 20[redacted] / 171	NOT REPORTED
PYRIDOXINE HYDROCHLORIDE	25 ug	OTHER: QOD	Y-M: 20[redacted] / 197	NOT REPORTED
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 397	Y-M: 20[redacted] / 411
GABAPENTIN	100 mg	TID	Y-M: 20[redacted] / 397	Y-M: 20[redacted] / 520
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 430	Y-M: 20[redacted] / 433
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435

SENNOSIDE A+B	17.2 mg	BID	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435
VANCOMYCIN HYDROCHLORIDE	1.25 g	OTHER: EVERY 12 HOURS	Y-M: 20[redacted] / 433	Y-M: 20[redacted] / 435
ENOXAPARIN SODIUM	40 mg	OTHER: ONCE	Y-M: 20[redacted] / 434	Y-M: 20[redacted] / 434
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted] / 434	Y-M: 20[redacted] / 435
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted] / 436	NOT REPORTED
MUPIROCIN	1/2 OTHER: TUBE	BID	Y-M: 20[redacted] / 474	Y-M: 20[redacted] / 478
BUPIVACAINE	10 mL	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
BUPIVACAINE	50 mL	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: CONTINUOUS	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
CEFAZOLIN SODIUM	2 g	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
CELECOXIB	200 mg	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
CELECOXIB	400 mg	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
CLONIDINE HYDROCHLORIDE	50 OTHER: MCG	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
KETOROLAC TROMETHAMINE	30 mg	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
POVIDONE-IODINE	30 mL	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
TRAMADOL HYDROCHLORIDE	25 mg	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
TRANEXAMIC ACID	1137 mg	OTHER: ONCE	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 479
OXYCODONE HYDROCHLORIDE	15 mg	PRN	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 480
OXYCODONE HYDROCHLORIDE	5 mg	PRN	Y-M: 20[redacted] / 480	NOT REPORTED
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / 480	Y-M: 20[redacted] / 481
LIDOCAINE	1 OTHER: PATCH	OTHER: EVERY 12 HOURS	Y-M: 20[redacted] / 480	Y-M: 20[redacted] / 481
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 480	Y-M: 20[redacted] / 520
MACROGOL 3350	17 g	QD	Y-M: 20[redacted] / 481	NOT REPORTED
NAPROXEN	500 mg	OTHER: EVERY 12 HOURS	Y-M: 20[redacted] / 481	NOT REPORTED
ACETYLSALICYLIC	81 mg	OTHER: EVERY 12	Y-M: 20[redacted] / 481	Y-M: 20[redacted] / 520

ACID		HOURS		
CEFALEXIN	500 mg	BID	Y-M: 20[redacted] / 533	NOT REPORTED

Event #1: Event of Interest - Polyneuropathy

Event Description	HYPOREFLEXIVITY OF KNEES AND ANKLES
Preferred Term	反射減弱
AE Onset Date / Rx Day	[redacted] / 365
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	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 Infections

Event Description	CELLULITIS AT INFUSION SITE, RIGHT UPPER THIGH
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted] / 393
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	429
Duration of AE	37 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 - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE, RIGHT FLANK
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 430
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	433
Duration of AE	4 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	ABDOMINAL WALL CELLULITIS, RIGHT FLANK, AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 433

Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 433): Leukocytes: 12.4 [4 - 9.5] 10^9/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PROBABLY RELATED TO THE CANNULA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #5: Serious Adverse Event

Event Description	WORSENING RIGHT HIP OSTEOARTHRITIS
Preferred Term	変形性関節症
AE Onset Date / Rx Day	[redacted]20[redacted] / 479
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	DISEASE PROGRESSION OF OSTEOARTHRITIS

Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE, LEFT LOWER ABDOMEN
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 533
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に右脇腹の腹壁部に注入部位蜂巣炎を発現した。

Event 4 の臨床経過：

関連する病歴は，パーキンソン病，元喫煙者（1 日 10 本を 5 年間），及び現飲酒者（1 日 2 杯未満）であった。

投与 433 日目，被験者は右脇腹の腹壁部に注入部位蜂巣炎を発現した。

被験者は本事象発現前の投与から約 13 ヵ月後に右大腿部上部，投与から約 14 ヵ月後に右脇腹にそれぞれ非重篤の注入部位蜂巣炎を発現した。

投与 433 日目，被験者は右側腹部の注入部位に発赤，熱感，浮腫，及び疼痛の増強が 3 日間発現したため救急診療部にかかった。また，わずかに出血を伴った化膿部の排膿が認められた。被験者によると，発熱，悪寒，胸痛，息切れ，悪心，又は嘔吐は認められなかった。検査の結果，中心に硬化した部位が認められ，ベッドにて行った超音波検査で液状ポケットが確認された。切開及びドレナージが実施され，膿の顕著な排出はなかったが，小胞形成を認めたためパッキングを行った。臨床検査を実施し，抗生物質の静脈内投与を開始した。同日，抗生物質の静脈内投与を継続し精密な管理を行うために，被験者は入院した。蜂巣炎のモニタリングを行い，入院中に改善が認められた。投与 435 日目，被験者は退院し，経口の抗生物質の投与及びパッキングの交換が行われた。

被験者に VANCOCIN 及び BACTRIM が投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.1] [10065455]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of ABDOMINAL WALL CELLULITIS, RIGHT FLANK, AT INFUSION SITE

- Investigator: Probably related to the cannula

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ULTRASOUND OF ABDOMEN:** Fluid pocket revealed

[redacted] **20[redacted] WHITE BLOOD CELLS:** 12.4 X10**3/MCL (normal 4.0 to 9.5)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に，右股関節の変形性関節症の悪化を発現した。

Event 5 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，及び右膝関節形成術であった。

投与 479 日目，被験者は右股関節の変形性関節症の悪化を発現した。

非外科的な管理が奏効しなかった後，投与 479 日目，被験者に右股関節の完全股関節形成術が実施された。被験者は経過観察及び術後の標準的な院内滞在のため入院した。投与 480 日目，被験者の報告では，疼痛の管理は良好であり，歩行器具により歩き回ることができた。被験者によると，悪心，嘔吐，息切れ，又はその他の問題は認められなかった。投与 481 日目，医学的に安定と判断され，被験者は退院した。

被験者にクロナゼパム，クロニジン，ケトロラク，乳酸リンゲル液，LIDODERM，オキシコドン，トラマドール，セレコキシブ，トラネキサム酸，アセトアミノフェン，ナプロキセン，アスピリン腸溶錠，及びセファゾリンが投与された。

Causality for ABBV-951 (Open Label)

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1) Osteoarthritis aggravated (10031162) (Osteoarthritis (10031161)) [v.24.1] [10031162]

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING RIGHT HIP OSTEOARTHRITIS

- **Investigator:** Disease progression of osteoarthritis

- **AbbVie:** Event was likely a consequence to Osteoarthritis in this Elderly aged patient with a history of Right Knee Arthroplasty.

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
注入部位丘疹				X
パーキンソン病	X	X	X	
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 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]
BILATERAL CATARACTS	20[redacted]
CELIAC -NON TROPICAL SPRUE	20[redacted]
WALKING PNEUMONIA	20[redacted]
RESTLESS LEG SYNDROME	20[redacted]
LEFT BUNDLE BRANCH BLOCK	20[redacted]
EPIRETINAL MEMBRANE	20[redacted]
MACULAR DEGENERATION BOTH EYES	20[redacted]
POLYMYALGIA RHEUMATICA	20[redacted]
OSTEOARTHRITIS	20[redacted]
CARPAL TUNNEL SYNDROME LEFT HAND	20[redacted]
URINARY TRACT INFECTION	20[redacted]
ADRENAL INSUFICIENCY	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	0.57	0.68	0.48	60	0.15	[redacted]20[redacted] / 367
ABBV-951	0.55	0.64	0.46	60	0.15	[redacted]20[redacted] / 457
ABBV-951	0.55	0.66	0.46		0.15	[redacted]20[redacted] / 535

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	669.34		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 5

M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1105.77		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1056.77		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 12
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1234.52		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1066.33		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1055.57		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 19
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1128.31		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1111.75		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	1220.17		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 29
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1166.05		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1171.00		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 40
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1036.79		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1070.77		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1058.99		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	928.53		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 184
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 185	
M15-741 /ABBV-951	1193.54		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951	1225.98		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 186

M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 266
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 267	
M15-741 /ABBV-951	507.12		SC / CONTINUOUS	[redacted]20[redacted] / 267	[redacted]20[redacted] / 267
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 268	
M15-741 /ABBV-951	680.26		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
ABBV-951	1749.33		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 539
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 540	
ABBV-951	2314.00		SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 540
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 541	[redacted]20[redacted] / 542
ABBV-951	1795.60		SC / CONTINUOUS	[redacted]20[redacted] / 543	[redacted]20[redacted] / 543
ABBV-951	291.12		SC / CONTINUOUS	[redacted]20[redacted] / 544	[redacted]20[redacted] / 544

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]
ASCORBIC ACID;TOCOPHERYL ACETATE	1 OTHER: TABLET	QD	Y-M: 20[redacted]
PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]
GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted] / 66
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted] / 289
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 289
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 289
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted] / 289

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
GABAPENTIN	100 mg	OTHER: EVERY MORNING	Y-M: 20[redacted]	Y-M: 20[redacted] / 597
LEVOTHYROXINE	100 OTHER: MCG	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 597
COLECALCIFEROL	2000 IU	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 597
ASCORBIC ACID;TOCOPHERYL ACETATE	1 OTHER: TABLET	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 597

PREDNISOLONE	5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 597
GABAPENTIN	400 mg	OTHER: EVERY NIGHT	Y-M: 20[redacted] / 66	Y-M: 20[redacted] / 597
FLUDROCORTISONE	0.3 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
FOLIC ACID	1 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
PYRIDOXINE HYDROCHLORIDE	100 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
SOLIFENACIN	10 mg	QD	Y-M: 20[redacted] / 289	Y-M: 20[redacted] / 597
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 597
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 519	Y-M: 20[redacted] / 526
HYDROMORPHONE	1 mg	OTHER: 1 DOSE PER HOUR FOR PAIN	Y-M: 20[redacted] / 598	ONGOING
PHENOBARBITAL	100 OTHER: MG/ML	OTHER: EVERY 3 HOURS AS NEEDED	Y-M: 20[redacted] / 598	ONGOING

Event #1: 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	
AE Stopped Rx Day	535
Duration of AE	169 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship 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	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	
AE Stopped Rx Day	535
Duration of AE	169 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship 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	LEFT ABDOMINAL WALL CELLULITIS AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 372
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	164 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

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

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF THE LEFT LOWER ABDOMINAL WALL AT INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	17 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	END STAGE PARKINSON'S DISEASE
Preferred Term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 598
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	600
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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	PROGRESSION OF HER PARKINSON'S TO DEATH
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に死亡に至った終末期のパーキンソン病を発現した。

Event 5 の臨床経過：

関連する病歴は，アジソン病，橋本甲状腺炎，非熱帯性セリアックスプルー，左脚ブロック，リウマチ性多発筋痛，変形性関節症，副腎不全，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 598 日目，被験者は終末期のパーキンソン病を発現した。投与 600 日目，被験者は死亡した。死因は終末期のパーキンソン病と報告された。剖検は実施されなかった。

投与 597 日目，被験者は長椅子に座ったまま反応がなくなり始めた。また，被験者は水，食事及び薬を拒否するようになった。治験責任医師によると，これは非常に時間をかけて進行したものと，被験者の家族が報告したとのことであった。投与 598 日目，被験者は家族により緊急治療室に連れてこられ，譫妄，食欲不振，新たに認められた寝たきりの状態，及び新たに認められた失禁を伴っていた。被験者の家族は臨床検査及び診断検査を拒否し，被験者をホスピ

スへ移すことを決めた。投与 600 日目，被験者は死亡した。被験者は，治験の医学専門家の承認を得て，死亡時に治験薬投与中であった。
治験責任医師によると，本事象と関連するリスク因子はパーキンソン病であった。
被験者にヒドロモルフォン及びフェノバルビタールが投与された。

Causality for ABBV-951 (Open Label)

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1) End stage Parkinson's disease (10076917) (Parkinson's disease (10061536)) [v.24.0] [10076917]

Csality 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 END STAGE PARKINSON'S DISEASE

- Investigator: PROGRESSION OF HER PARKINSON'S TO DEATH

- AbbVie: More likely related to the progression of pre existing Parkinson disease in an elderly subject with multiple comorbidities.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BMI:** 17.98 kg/m2

[redacted] **20[redacted] BODY WEIGHT:** 4[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
冠動脈疾患	X			
注入部位紅斑				X

Treatment Group	Age at M15-741 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]
ALLERGIES	20[redacted]
LEFT HIP OSTEOARTHRITIS	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	0.21	0.23	0.19		0.11	[redacted]20[redacted] / 363
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 371
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 532
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 691
ABBV-951	0.22	0.25	0.19	60	0.15	[redacted]20[redacted] / 868

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	375.65		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 5
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	815.16		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	912.82		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 12
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	946.63		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13

M15-741 /ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	889.26		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	849.65		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 18
M15-741 /ABBV-951	848.96		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	950.05		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	846.23		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	935.36		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 25
M15-741 /ABBV-951	934.85		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	749.59		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 41
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	914.19		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	877.65		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 82
M15-741 /ABBV-951	894.73		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 84	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 180
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	868.09		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	834.62		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 270
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 271	
M15-741 /ABBV-951	825.57		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 272	
M15-741 /ABBV-951	895.07		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 362
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 361	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted]20[redacted] / 362	

ABBV-951	394.43		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 529
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 530	
ABBV-951	918.46		SC / CONTINUOUS	[redacted]20[redacted] / 530	[redacted]20[redacted] / 530
ABBV-951	929.05		SC / CONTINUOUS	[redacted]20[redacted] / 531	[redacted]20[redacted] / 531
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 532	
ABBV-951	862.11		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 613
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 614	
ABBV-951	911.63		SC / CONTINUOUS	[redacted]20[redacted] / 614	[redacted]20[redacted] / 614
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 615	
ABBV-951	920.00		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 688
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 689	
ABBV-951	924.09		SC / CONTINUOUS	[redacted]20[redacted] / 689	[redacted]20[redacted] / 689
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 690	
ABBV-951	901.73		SC / CONTINUOUS	[redacted]20[redacted] / 690	[redacted]20[redacted] / 690
ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 691	[redacted]20[redacted] / 779
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 780	
ABBV-951	828.30		SC / CONTINUOUS	[redacted]20[redacted] / 780	[redacted]20[redacted] / 780
ABBV-951	866.21		SC / CONTINUOUS	[redacted]20[redacted] / 781	[redacted]20[redacted] / 781
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 782	[redacted]20[redacted] / 865
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 866	
ABBV-951	966.61		SC / CONTINUOUS	[redacted]20[redacted] / 866	[redacted]20[redacted] / 866
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 867	
ABBV-951	865.19		SC / CONTINUOUS	[redacted]20[redacted] / 867	[redacted]20[redacted] / 867

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]
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]-[redacted]
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]-[redacted]
LOSARTAN	25 mg	QD	Y-M: 20[redacted]-[redacted] / -150
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted]-[redacted] / -150
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] / -35
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted] / -35
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / -35
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted] / -35
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted] / -35
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / -35
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted] / 327
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted] / 331
LISINOPRIL	15 mg	BID	Y-M: 20[redacted] / 331
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 331
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 331
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted] / 338
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 339
FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352

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]	NOT REPORTED
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
INSULIN DEGLUDEC	12 OTHER: UNITS	QD	Y-M: 20[redacted]	NOT REPORTED
LOSARTAN	25 mg	QD	Y-M: 20[redacted] / -150	NOT REPORTED
PARACETAMOL	500-1000 mg	PRN	Y-M: 20[redacted] / -150	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted] / -113	NOT REPORTED
ASTAXANTHIN	4 mg	QD	Y-M: 20[redacted] / -35	NOT REPORTED
COLECALCIFEROL	5000 IU	QD	Y-M: 20[redacted] / -35	NOT REPORTED
CURCUMA LONGA	400 mg	BID	Y-M: 20[redacted] / -35	NOT REPORTED
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted] / -35	NOT REPORTED
MAGNESIUM OXIDE	400 mg	QD	Y-M: 20[redacted] / -35	NOT REPORTED
MELATONIN	300 OTHER: MCG	OTHER: QHS	Y-M: 20[redacted] / -35	NOT REPORTED
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / -35	NOT REPORTED
METOPROLOL TARTRATE	50 mg	QD	Y-M: 20[redacted] / 327	NOT REPORTED
DOCUSATE SODIUM;SENNOSIDE A+B	100 mg	BID	Y-M: 20[redacted] / 331	NOT REPORTED

LISINOPRIL	15 mg	BID	Y-M: 20[redacted] / 331	NOT REPORTED
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 331	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 331	NOT REPORTED
LIDOCAINE	1-2 OTHER: PATCHES	QD	Y-M: 20[redacted] / 338	NOT REPORTED
CLOPIDOGREL BISULFATE	75 mg	QD	Y-M: 20[redacted] / 339	NOT REPORTED
FLUTICASONE PROPIONATE	2 OTHER: SPRAYS	QD	Y-M: 20[redacted] / 345	NOT REPORTED
POTASSIUM CHLORIDE	10 mEq	QD	Y-M: 20[redacted] / 352	NOT REPORTED
BETAMETHASONE	6 mg	OTHER: ONCE	Y-M: 20[redacted] / 377	Y-M: 20[redacted] / 377
LIDOCAINE	1 mL	OTHER: ONCE	Y-M: 20[redacted] / 377	Y-M: 20[redacted] / 377
SULFAMETHOXAZOLE;TRIMETHOPRIM	800-160 mg	BID	Y-M: 20[redacted] / 580	Y-M: 20[redacted] / 586

Event #1: 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	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	HOSPITALIZATION OR PROLONGED HOSPITALIZATION,

IMPORTANT MEDICAL OR SURGICAL INTERVENTION, LIFE THREATENING

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] / 579
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11
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 を投与中に心内膜下心筋梗塞，冠動脈疾患，心停止，及び低ナトリウム血症を発現した。

Event 1 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，頸動脈狭窄症，脳血管発作，高血圧，パーキンソン病，全般性不安障害，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。また，被験者の父親に糖尿病，高血圧，及び冠動脈疾患の病歴が，母親に脳卒中の病歴があった。

投与 1 日目から 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の治験薬の調整を必要とした。投与 5 週時に，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，被験者は心内膜下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。投与 336 日目，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，救急診療部に来院した。被験者によると，症状は 1 週間ほど継続しており，2 種類の薬剤（ロスバスタチン及びヒドロクロロチアジド）を新たに服用し始めた辺りから症状が出たことに気が付いたとのことであった。被験者はこれまでヒドロクロロチアジドを不定期に使用していたと述べた。被験者は嘔吐をしたと述べ，「古い血液」のようだと言われたと報告した。被験者は最近旅行に行ったことはなく，病気の人と接触したこともなかった。被験者は妻と 2 階建ての自宅に住み，大きな問題もなく階段を使っていた。被験者によると，経口摂取も少なかったとのことであった。被験者はインスリン注入ポンプでグルコース値を管理していた。また，Sinemet（CD/LD）でも注入ポンプを使用した経験があり，現在治験に参加している。被験者は低ナトリウム血症及び脱水のため入院した。被験者は横紋筋融解症（非重篤）とも診断された。また，被験者は頚部痛及び嘔吐のエピソードを発現した。初回採血時のトロポニンは陰性であったが，その後の採血では上昇した（心内膜下心筋梗塞）。

被験者は他院へ移送され，低ナトリウム血症，心内膜下心筋梗塞，及び上部消化管出血の疑いのため集中治療室に入院した。被験者に衰弱，便秘，悪心，嘔吐，及び不安が認められた。発熱，悪寒，咳嗽，息切れ，及び下痢は認められなかった。トロポニンは投与 327 日目の遅くまで上昇した。投与 328 日目，被験者は心臓カテーテル処置を受け，びまん性の糖尿病性心疾患が発見された。投与 335 日目，横紋筋融解症（非重篤）は消失した。投与 336 日目，被験者は 3 ヵ所の冠動脈バイパス移植を受けた。夕方，被験者に迷走神経反射が認められ，心停止を引き起こした。心肺機能蘇生を受けた結果，被験者は自発循環が回復し，その後再挿管され，最終的には抜管された。当初はラシックスが必要であった。両側性の胸腔チューブが挿管され，その後抜管された。集中治療室に滞在している期間を通して血圧は不安定であった。数日間利尿剤を休薬した後，フロセミドの静脈内投与に移行し，その後経口投与に切り替えた。酸素の補給は徐々に中止した。手術前の体重は約 12[redacted] ポンドであり，退院時は 14[redacted] ポンドであった。経口ラシックス 20 mg 1 日 2 回を 7 日間，及び塩化カリウム 10 mEq を毎日投与し，カリウム値

を 4.3 の高値に維持した状態で，室内での酸素飽和濃度が 97%となり被験者は退院した。クレアチニンは術後の最高値が 1.19 であり，安定して推移した。
　被験者にフロセミド，リシノプリル，メトプロロール酒石酸塩，5%デキストロースを含む乳酸リンゲル液，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
心房細動	X			
冠動脈疾患	X			
転倒				X
注入部位紅斑				X
肺塞栓症	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
ANXIETY	NOT REPORTED
GASTRIC REFLUX	19[redacted]
HYPERCHOLESTEROLEMIA	19[redacted]
NISSEN FUNDOPLICATION	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]
RIGHT SHOULDER PAIN	20[redacted]
HEARTBURN	20[redacted]
LEFT SHOULDER PAIN	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	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 365
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 382
ABBV-951	0.70	0.71	0.68	60	0.19	[redacted]20[redacted] / 395
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 421
ABBV-951	0.70	0.71	0.68	0	0.00	[redacted]20[redacted] / 435
ABBV-951	0.7	0.71	0.68	0	0.00	[redacted]20[redacted] / 449
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 463
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 477
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted]20[redacted] / 491

ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 505
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 523
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 535
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 571
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 589
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 596
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 624
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 640
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 653
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 667
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 680
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 695
ABBV-951	0.69	0.71	0.67	0	0.00	[redacted] / 710
ABBV-951	0.69	0.71	0.68	0	0.00	[redacted] / 723
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 736
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 752
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 766
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 780
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 788
ABBV-951	0.68	0.69	0.66	0	0.00	[redacted] / 820

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	1506.01		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 2	[redacted] / 5
M15-741 /ABBV-951	2560.22		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		0	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	2506.43		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 8	[redacted] / 12
M15-741 /ABBV-951	2559.03		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2597.10		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 15	[redacted] / 20
M15-741 /ABBV-951		0	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951	2591.98		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	2627.15		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22

M15-741 /ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 26
M15-741 /ABBV-951	2688.45		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951	2699.89		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 33
M15-741 /ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951	2693.23		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951	2685.89		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 40
M15-741 /ABBV-951	2705.02		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951	2688.28		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 61
M15-741 /ABBV-951	2733.02		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951	2659.60		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 89
M15-741 /ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 90	
M15-741 /ABBV-951	2608.71		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951		0	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	2796.88		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 180
M15-741 /ABBV-951	2754.19		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951	2721.75		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	2786.64		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 267
M15-741 /ABBV-951	2772.29		SC / CONTINUOUS	[redacted]20[redacted] / 268	[redacted]20[redacted] / 268
M15-741 /ABBV-951	2783.22		SC / CONTINUOUS	[redacted]20[redacted] / 269	[redacted]20[redacted] / 269
M15-741 /ABBV-951	2786.64		SC / CONTINUOUS	[redacted]20[redacted] / 270	[redacted]20[redacted] / 362
M15-741 /ABBV-951	2780.15		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
M15-741 /ABBV-951	2716.97		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	1553.82		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	2868.6		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 532
ABBV-951	2779.46		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	2771.27		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 534
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 621
ABBV-951	2782.71		SC / CONTINUOUS	[redacted]20[redacted] / 622	[redacted]20[redacted] / 622
ABBV-951	2740.19		SC / CONTINUOUS	[redacted]20[redacted] / 623	[redacted]20[redacted] / 623
ABBV-951	2745.66		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 707
ABBV-951	2654.13		SC / CONTINUOUS	[redacted]20[redacted] / 708	[redacted]20[redacted] / 708
ABBV-951	2608.37		SC / CONTINUOUS	[redacted]20[redacted] / 709	[redacted]20[redacted] / 709

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]
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted] / 191
AMIODARONE	200 mg	QD	Y-M: 20[redacted] / 263
VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted] / 327

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]	NOT REPORTED
ROPINIROLE	1 mg	TID	Y-M: 20[redacted]	NOT REPORTED
ROSUVASTATIN	10 mg	OTHER: QHS	Y-M: 20[redacted]	NOT REPORTED
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CITALOPRAM	40 mg	OTHER: QAM	Y-M: 20[redacted]	NOT REPORTED
MAGNESIUM CARBONATE	1 OTHER: TBSP	OTHER: QHS	Y-M: 20[redacted]	NOT REPORTED
CALCIUM CARBONATE	1 OTHER: TAB	PRN	Y-M: 20[redacted]	NOT REPORTED
MIRABEGRON	25 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CURCUMA LONGA	500 mg	BID	Y-M: 20[redacted]	NOT REPORTED
PYRIDOSTIGMINE	60 mg	TID	Y-M: 20[redacted]	NOT REPORTED
MELATONIN	3 mg	OTHER: QHS	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted] / 191	NOT REPORTED
AMIODARONE	200 mg	QD	Y-M: 20[redacted] / 263	NOT REPORTED

VITAMIN B12 NOS	1000 MCG OTHER: MCG	OTHER: MONTHLY	Y-M: 20[redacted] / 327	NOT REPORTED
CLINDAMYCIN	300 mg	BID	Y-M: 20[redacted] / 441	NOT REPORTED
TOZINAMERAN	1 SHOT PFIZER mL	OTHER: ONCE	Y-M: 20[redacted] / 441	Y-M: 20[redacted] / 441
TOZINAMERAN	1 mg	OTHER: ONCE	Y-M: 20[redacted] / 463	Y-M: 20[redacted] / 463

Event #1: 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	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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 FACTORS, FAMILY HISTORY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: 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	

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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, NEW DIAGNOSIS OF CORONARY ARTERY DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: 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	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	SUBJECT HAS A HISTORY OF ATRIAL FIBRILLATION, PER LAST AE, NEW SINCE SIGNING CONSENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	ERYTHEMA TO INFUSION SITE LEFT LOWER ABDOMEN
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 441
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 577
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	577
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]:09:11
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 を投与中に冠動脈疾患，尿路感染，及び心房細動を発現した。

Event 1 及び 2 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 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の治験薬の調整を必要とした。投与 5 週時に，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に来院した。投与 192 日目，被験者に心臓カテーテル手術を実施し，ステントを 2 本留置した。投与 195 日目，被験者は尿路感染を発現し，入院が延長となった。被験者に精神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。心房細動は無症候性であり，入院中の心臓モニタリングで当該リズムを記録した。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ることを指摘した。

被験者にアミオダロン，メトプロロール，クロピドグレル硫酸塩，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 を投与中に肺塞栓症を発現した。

Event 3 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。

本事象発現前の投与から約 6 ヵ月後に，被験者は尿路感染のために入院期間を延長した。投与から約 6 ヵ月後の入院中に，被験者に心房細動（間欠性）と評価された心リズム異常が記録された。

投与から約 10 ヵ月後，被験者は胸痛及び最近の病歴である心房細動のため入院した。被験者は胸部 CT スキャンにより肺塞栓症と診断された。大静脈フィルターが留置され，心臓専門医は抗凝血剤の投与に反対する決断をした。投与 334 日目，被験者は退院した。

治験責任医師によると，関連するリスク因子は心房細動であった。

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:** 101/57 mmHg

[redacted] **20[redacted] BLOOD PRESSURE - SCREENING:** 128/88 mmHg

[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
転倒				X
手骨折				X
腎結石症	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
ALLERGIES (SEASONAL)	19[redacted]
CONSTIPATION	19[redacted]
DEVIATED SEPTUM	19[redacted]
DEPRESSION	19[redacted]
MUSCULOSKELETAL PAIN	20[redacted]
HYPERTENSION	20[redacted]
CORONARY ARTERY DISEASE	20[redacted]
SLEEP DISORDER	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
HYPOTHYROIDISM	20[redacted]
LEFT EYE CATARACT	20[redacted]
FALL	20[redacted]
KIDNEY STONES	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
IRRITABILITY	20[redacted]
GLAUCOMA	20[redacted]
NAUSEA	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	0.67	0.68	0.0	0	0.00	[redacted] / 375
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 388
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 402
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 414
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 428
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 443
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 472
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 484
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 500
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 514
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 542
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 556
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 572
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 597
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 612
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 626
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 640

ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 649
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 668
ABBV-951	0.67	0.68	0.0	0	0.00	[redacted] / 696
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 703
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 724
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 738
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 752
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 766
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 778
ABBV-951	0.69	0.0	0.0	0	0.00	[redacted] / 792
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 802
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 815
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 829
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 838
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 857
ABBV-951	0.69	0.70	0.68	0	0.00	[redacted] / 871

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	1602.31		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	2786.64		SC / CONTINUOUS	[redacted] / 2	[redacted] / 5
M15-741 /ABBV-951	1395.71		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	2527.95		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	2581.74		SC / CONTINUOUS	[redacted] / 8	[redacted] / 12
M15-741 /ABBV-951	2563.81		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2619.30		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951	2552.71		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	2608.20		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted] / 22	[redacted] / 26
M15-741 /ABBV-951	2612.98		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951	2670.87		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted] / 29	[redacted] / 40
M15-741 /ABBV-951	2659.60		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951	2670.87		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	2704.68		SC / CONTINUOUS	[redacted] / 43	[redacted] / 89

M15-741 /ABBV-951	2676.50	SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	2677.01	SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	2745.66	SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 194
M15-741 /ABBV-951	2700.75	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
M15-741 /ABBV-951	2716.97	SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 287
M15-741 /ABBV-951	2600.86	SC / CONTINUOUS	[redacted]20[redacted] / 288	[redacted]20[redacted] / 288
M15-741 /ABBV-951	2751.80	SC / CONTINUOUS	[redacted]20[redacted] / 289	[redacted]20[redacted] / 289
M15-741 /ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 290	[redacted]20[redacted] / 371
M15-741 /ABBV-951	2713.55	SC / CONTINUOUS	[redacted]20[redacted] / 372	[redacted]20[redacted] / 372
M15-741 /ABBV-951	2670.87	SC / CONTINUOUS	[redacted]20[redacted] / 373	[redacted]20[redacted] / 373
ABBV-951	1292.74	SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 540
ABBV-951	2654.13	SC / CONTINUOUS	[redacted]20[redacted] / 541	[redacted]20[redacted] / 541
ABBV-951	2745.66	SC / CONTINUOUS	[redacted]20[redacted] / 542	[redacted]20[redacted] / 623
ABBV-951	2719.02	SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 624
ABBV-951	2751.29	SC / CONTINUOUS	[redacted]20[redacted] / 625	[redacted]20[redacted] / 625
ABBV-951	2745.66	SC / CONTINUOUS	[redacted]20[redacted] / 626	[redacted]20[redacted] / 693
ABBV-951	2675.31	SC / CONTINUOUS	[redacted]20[redacted] / 694	[redacted]20[redacted] / 694
ABBV-951	2707.24	SC / CONTINUOUS	[redacted]20[redacted] / 695	[redacted]20[redacted] / 695
ABBV-951	2745.66	SC / CONTINUOUS	[redacted]20[redacted] / 696	[redacted]20[redacted] / 701
ABBV-951	2728.07	SC / CONTINUOUS	[redacted]20[redacted] / 702	[redacted]20[redacted] / 702
ABBV-951	1486.20	SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 703
ABBV-951	2786.64	SC / CONTINUOUS	[redacted]20[redacted] / 704	[redacted]20[redacted] / 789
ABBV-951	2789.71	SC / CONTINUOUS	[redacted]20[redacted] / 790	[redacted]20[redacted] / 790
ABBV-951	1553.48	SC / CONTINUOUS	[redacted]20[redacted] / 791	[redacted]20[redacted] / 791
ABBV-951	2812.59	SC / CONTINUOUS	[redacted]20[redacted] / 792	[redacted]20[redacted] / 792
ABBV-951	2827.62	SC / CONTINUOUS	[redacted]20[redacted] / 793	[redacted]20[redacted] / 868
ABBV-951	2729.43	SC / CONTINUOUS	[redacted]20[redacted] / 869	[redacted]20[redacted] / 869
ABBV-951	2598.81	SC / CONTINUOUS	[redacted]20[redacted] / 870	[redacted]20[redacted] / 870

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]
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]
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted]
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted]-[redacted] / -237
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted]-[redacted] / -105
NIFEDIPINE	30 mg	QD	Y-M: 20[redacted]-[redacted] / 20
LATANOPROST	0.005% 1 DROP EACH EYE gtt	QD	Y-M: 20[redacted]-[redacted] / 157
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted]-[redacted] / 318
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	BID	Y-M: 20[redacted]-[redacted] / 374
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted]-[redacted] / 374

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]	NOT REPORTED
VITAMINS NOS	1 OTHER: TAB	QD	Y-M: 19[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	81 mg	QD	Y-M: 20[redacted]	NOT REPORTED
IBUPROFEN	200 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CITALOPRAM	40 mg	QD	Y-M: 20[redacted]	NOT REPORTED
LEVOTHYROXINE	50 ug	OTHER: QAM	Y-M: 20[redacted]	NOT REPORTED
VITAMIN D NOS	4000 IU	QD	Y-M: 20[redacted]	NOT REPORTED
SENNA ALEXANDRINA	6-8 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
DRONABINOL	1000 mg	QD	Y-M: 20[redacted]	NOT REPORTED
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
MELATONIN	5 mg	OTHER: QHS	Y-M: 20[redacted]-[redacted]	NOT REPORTED
LISINOPRIL	40 mg	OTHER: QAM	Y-M: 20[redacted]-[redacted] / -237	NOT REPORTED
EZETIMIBE	10 mg	OTHER: QAM	Y-M: 20[redacted]-[redacted] / -105	NOT REPORTED
NIFEDIPINE	30 mg	QD	Y-M: 20[redacted]-[redacted] / 20	NOT REPORTED

LATANOPROST	0.005% 1 DROP EACH EYE gtt	QD	Y-M: 20[redacted] / 157	NOT REPORTED
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	BID	Y-M: 20[redacted] / 374	NOT REPORTED
DOXYCYCLINE	100 mg	BID	Y-M: 20[redacted] / 374	NOT REPORTED
AMLODIPINE	5MG mg	QD	Y-M: 20[redacted] / 499	NOT REPORTED
TOZINAMERAN	1 SHOT mL	OTHER: ONCE	Y-M: 20[redacted] / 499	NOT REPORTED
HYDROCHLOROTHIAZIDE	12.5 mg	QD	Y-M: 20[redacted] / 667	NOT REPORTED

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] / 552
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	552
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	RIGHT HAND 5TH METACARPAL NECK FRACTURE
Preferred Term	手骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 552
Age at AE Onset	6[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	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	KIDNEY STONE
Preferred Term	腎結石症
AE Onset Date / Rx Day	[redacted]20[redacted] / 773
Age at AE Onset	6[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 775): NPTST015-COMPLETE BLOOD COUNT: WITHIN N [12 - 15] mg/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	MEDICAL HISTORY OF KIDNEY STONES
Discontinued Study Drug Due to the Event	NO

SAE Criteria HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に，腎結石を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，腎結石，右側の逆行性腎盂尿管造影を伴う膀胱尿道鏡検査，及び現飲酒者（1 日 2 杯未満）であった。

投与 773 日目，被験者は腎結石を発現した。

本事象の発現前，投与から約 4 年 9 ヵ月前，被験者は腎結石に伴う脇腹痛を発現した。

投与 773 日目，被験者は右脇腹痛を伴い入院した。入院は水分補給及び疼痛の管理のためであった。被験者は腎結石と診断された。結石は通過し，疼痛は緩和された。投与 775 日目，被験者は退院した。

The patient's past medications include:

PFIZER COVID-19 VACCINE for PREVENTATIVE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Kidney stone (10023436) (Nephrolithiasis (10029148)) [v.24.1] [10023436]

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 KIDNEY STONE

- **Investigator:** Medical history of kidney stones

- **AbbVie:** More likely related to medical history of kidney stones

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT ABDOMEN:** Stones at right urterovesicular junction.

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
注入部位内出血				X
注入部位蜂巣炎	X	X		X
注入部位紅斑				X
注入部位結節				X
注入部位異常感覚				X
注入部位腫脹				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
ARRYTHMIA-AFIB	19[redacted]
HYPERTENSION	19[redacted]
GLASSES- READING	20[redacted]
LBP (LOWER BACK PAIN)	20[redacted]
CONSTIPATION- OCCASIONALLY	20[redacted]
DEPRESSION	20[redacted]
BPH (BENIGN PROSTATIC HYPERPLASIA	20[redacted]
KERATOSIS	20[redacted]
MILD CATARACTS	20[redacted]
BLADDER INCONTINENCE	20[redacted]
GYRAL PETECHIAL HEMORRHAGE	20[redacted]
CONCUSSION	20[redacted]
NOSE BLEEDS FREQUENT	20[redacted]

Indication Disease History, Diagnosis and/or Symptoms	Onset Year
LEVODOPA INDUCED DYSKINESIA	NOT REPORTED

PARKINSON'S DISEASE	20[redacted]
PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

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

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.48	0.46	0.50	60	0.19	[redacted]20[redacted] / 367
ABBV-951	0.48	0.46	0.50	60	0.19	[redacted]20[redacted] / 537
ABBV-951	0.48	0.46	0.50	60	0.19	[redacted]20[redacted] / 563

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	625.45		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 5
M15-741 /ABBV-951	1335.43		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1318.53		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 9
M15-741 /ABBV-951	1377.95		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 12

M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1584.90		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1551.60		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 16	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 19	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	1666.00		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	1670.95		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 22	[redacted] / 28
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 23	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 24	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 25	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 26	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 29	
M15-741 /ABBV-951	1713.98		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 30	
M15-741 /ABBV-951	1649.44		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 31	
M15-741 /ABBV-951	1692.47		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 32	
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 32	[redacted] / 40
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 33	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 34	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 35	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 36	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted] / 37	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 39	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 40	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 41	

M15-741 /ABBV-951	1663.78		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1678.13		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1685.30		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 45
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1699.64		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	1706.81		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951	1685.30		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	1745.23		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 58
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 54	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 89
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 64	

M15-741 /ABBV-951		32.44	SC / ONCE	20 / 65	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 66	
M15-741 /ABBV-951		97.32	SC / ONCE	20 / 67	
M15-741 /ABBV-951		97.32	SC / ONCE	20 / 68	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 69	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 70	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 71	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 72	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 73	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 74	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 79	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 80	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 82	
M15-741 /ABBV-951		97.32	SC / ONCE	20 / 83	
M15-741 /ABBV-951		97.32	SC / ONCE	20 / 84	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 85	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 86	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 87	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 88	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 89	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 90	
M15-741 /ABBV-951	1740.11		SC / CONTINUOUS	20 / 90	20 / 90
M15-741 /ABBV-951	1732.77		SC / CONTINUOUS	20 / 91	20 / 91
M15-741 /ABBV-951	1710.74		SC / CONTINUOUS	20 / 92	20 / 92
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 93	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	20 / 93	20 / 182
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 94	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 95	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 96	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 97	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 98	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 100	
M15-741 /ABBV-951		64.88	SC / ONCE	20 / 101	
M15-741 /ABBV-951		129.77	SC / ONCE	20 / 102	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 105	
M15-741 /ABBV-951		32.44	SC / ONCE	20 / 106	
M15-741 /ABBV-951		97.32	SC / ONCE	20 / 107	

M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 108
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 111
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 113
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 114
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 115
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 116
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 117
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 118
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 119
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 120
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 121
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 122
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 123
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 124
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 126
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 127
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 128
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 130
M15-741 /ABBV-951	162.21	SC / ONCE	[redacted]20[redacted] / 131
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 132
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 134
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 135
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 136
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 137
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 138
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 139
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 140
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 142
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 143
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 144
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 146
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 148
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 149
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 151
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 152
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 153
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 154

M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 155	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 156	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 157	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 158	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 159	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 160	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 162	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 163	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 164	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 165	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 166	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 167	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 168	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 169	
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 170	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 171	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 172	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 173	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 174	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 177	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 178	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 179	
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 180	
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 183	
M15-741 /ABBV-951	1681.37		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 184	
M15-741 /ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 185	
M15-741 /ABBV-951	1757.52		SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 185
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 186	
M15-741 /ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 186	[redacted]20[redacted] / 275
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 187	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 188	
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 189	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 190	

M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 191
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 192
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 193
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 194
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 195
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 196
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 197
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 198
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 199
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 200
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 201
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 202
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 203
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 204
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 205
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 206
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 207
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 208
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 209
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 210
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 211
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 212
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 213
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 214
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 215
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 216
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 217
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 218
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 219
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 220
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 221
M15-741 /ABBV-951	129.77	SC / ONCE	[redacted]20[redacted] / 222
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 223
M15-741 /ABBV-951	32.44	SC / ONCE	[redacted]20[redacted] / 224
M15-741 /ABBV-951	64.88	SC / ONCE	[redacted]20[redacted] / 225
M15-741 /ABBV-951	97.32	SC / ONCE	[redacted]20[redacted] / 226
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ABBV-951	32.44	SC / ONCE	[redacted] / 516
ABBV-951	97.32	SC / ONCE	[redacted] / 517
ABBV-951	97.32	SC / ONCE	[redacted] / 518
ABBV-951	64.88	SC / ONCE	[redacted] / 519
ABBV-951	64.88	SC / ONCE	[redacted] / 520
ABBV-951	64.88	SC / ONCE	[redacted] / 521
ABBV-951	162.21	SC / ONCE	[redacted] / 522
ABBV-951	32.44	SC / ONCE	[redacted] / 523
ABBV-951	97.32	SC / ONCE	[redacted] / 524
ABBV-951	32.44	SC / ONCE	[redacted] / 525
ABBV-951	64.88	SC / ONCE	[redacted] / 526
ABBV-951	97.32	SC / ONCE	[redacted] / 527
ABBV-951	64.88	SC / ONCE	[redacted] / 528
ABBV-951	97.32	SC / ONCE	[redacted] / 529
ABBV-951	97.32	SC / ONCE	[redacted] / 530
ABBV-951	32.44	SC / ONCE	[redacted] / 531

ABBV-951		64.88	SC / ONCE	[redacted] / 532	
ABBV-951	1934.25		SC / CONTINUOUS	[redacted] / 532	[redacted] / 532
ABBV-951		97.32	SC / ONCE	[redacted] / 533	
ABBV-951	1909.66		SC / CONTINUOUS	[redacted] / 533	[redacted] / 533
ABBV-951		64.88	SC / ONCE	[redacted] / 534	
ABBV-951	1950.64		SC / CONTINUOUS	[redacted] / 534	[redacted] / 534
ABBV-951		97.32	SC / ONCE	[redacted] / 535	
ABBV-951	1917.86		SC / CONTINUOUS	[redacted] / 535	[redacted] / 535
ABBV-951		64.88	SC / ONCE	[redacted] / 536	
ABBV-951	1926.06		SC / CONTINUOUS	[redacted] / 536	[redacted] / 536
ABBV-951		97.32	SC / ONCE	[redacted] / 537	
ABBV-951	1958.84		SC / CONTINUOUS	[redacted] / 537	[redacted] / 537
ABBV-951		64.88	SC / ONCE	[redacted] / 538	
ABBV-951	1967.04		SC / CONTINUOUS	[redacted] / 538	[redacted] / 562
ABBV-951		32.44	SC / ONCE	[redacted] / 539	
ABBV-951		97.32	SC / ONCE	[redacted] / 540	
ABBV-951		129.77	SC / ONCE	[redacted] / 541	
ABBV-951		64.88	SC / ONCE	[redacted] / 542	
ABBV-951		97.32	SC / ONCE	[redacted] / 543	
ABBV-951		64.88	SC / ONCE	[redacted] / 544	
ABBV-951		64.88	SC / ONCE	[redacted] / 545	
ABBV-951		129.77	SC / ONCE	[redacted] / 546	
ABBV-951		129.77	SC / ONCE	[redacted] / 547	
ABBV-951		97.32	SC / ONCE	[redacted] / 548	
ABBV-951		97.32	SC / ONCE	[redacted] / 550	
ABBV-951		64.88	SC / ONCE	[redacted] / 551	
ABBV-951		64.88	SC / ONCE	[redacted] / 552	
ABBV-951		32.44	SC / ONCE	[redacted] / 555	
ABBV-951		64.88	SC / ONCE	[redacted] / 557	
ABBV-951		129.77	SC / ONCE	[redacted] / 558	
ABBV-951		129.77	SC / ONCE	[redacted] / 559	
ABBV-951		129.77	SC / ONCE	[redacted] / 560	
ABBV-951		129.77	SC / ONCE	[redacted] / 561	
ABBV-951		97.32	SC / ONCE	[redacted] / 562	

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LOSARTAN	100 mg	QD	Y-M: 20[redacted]
SERTRALINE	100 mg	QD	Y-M: 20[redacted]
SELEGILINE	5.000 mg	BID	Y-M: 20[redacted] / -150
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 109
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 110
PRAMIPEXOLE	0.500 mg	TID	Y-M: 20[redacted] / 278
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: 20[redacted] / 299
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TAB	BID	Y-M: 20[redacted] / 360

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
SERTRALINE	100 mg	QD	Y-M: 20[redacted]	ONGOING
AMLODIPINE	10 mg	QD	Y-M: 20[redacted] / -7	ONGOING
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 109	ONGOING
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 110	ONGOING
HYDROCHLOROTHIAZIDE	25 mg	BID	Y-M: 20[redacted] / 299	Y-M: 20[redacted] / 557
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 368	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 390	NOT REPORTED
DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID	1 OTHER: DOSE	OTHER: ONCE	Y-M: 20[redacted] / 408	Y-M: 20[redacted] / 408
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / 529	Y-M: 20[redacted] / 557
SULFAMETHOXAZOLE;TRIMETHOPRIM	1 OTHER: TABLET	BID	Y-M: 20[redacted] / 550	Y-M: 20[redacted] / 552
HYDROCODONE;PARACETAMOL	650 mg	OTHER: Q4H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
MACROGOL 3350	17 g	QD	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
ONDANSETRON	4 mg	OTHER: Q6H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 553
SODIUM CHLORIDE	1000 mL	OTHER: ONCE	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 555
CEFAZOLIN	2 g	OTHER: Q8H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 557

VANCOMYCIN	1750 mg	OTHER: Q24H	Y-M: 20[redacted] / 552	Y-M: 20[redacted] / 557
GLUCOSE	500 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
SODIUM CHLORIDE	250 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
SODIUM CHLORIDE	500 mL	OTHER: Q8H	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 557
CYANOCOBALAMIN	1000 OTHER: MCG	QD	Y-M: 20[redacted] / 557	ONGOING
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 557	Y-M: 20[redacted] / 567
METOPROLOL	25 mg	QD	Y-M: 20[redacted] / 558	Y-M: 20[redacted] / 559
HYDROCHLOROTHIAZIDE	25 mg	QD	Y-M: 20[redacted] / 559	ONGOING

Event #1: 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] / 406
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	408
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	RAISED NODULE AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 406
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	408
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 #3: 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] / 406
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	408
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 #4: 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] / 418
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	431
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 #5: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SMALL NODULE AT INFUSION SITE
Preferred Term	注入部位結節
AE Onset Date / Rx Day	[redacted]20[redacted] / 418
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	431
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 #6: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	TINGLING DURING INFUSION AT THE INFUSION SITE AFTER GIVING EXTRA DOSE
Preferred Term	注入部位異常感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 418
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	431
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 #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT INFUSION SITE
Preferred Term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]

Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	440
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	RED AT THE INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	440
Duration of AE	3 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO

SAE Criteria	NONE

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

Event Description	SLIGHTLY SWOLLEN AT INFUSION SITE
Preferred Term	注入部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 438
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	440
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 #10: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT THE INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 527
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 551): Alanine Aminotransferase: 4 [7 - 52] U/L; Aspartate Aminotransferase: 18 [13 - 39] U/L; Calcium: 2.32 [2.12 - 2.62] MMOL/L; Chloride: 92 [98 - 108] MMOL/L; Creatinine: 85 [53 - 106] UMOL/L; Erythrocytes: 3.9 [4.2 - 5.5] 10^12/L; Glucose: 7.5 [3.9 - 5.5] MMOL/L; Hematocrit: 0.37 [0.4 - 0.54] FRACTION OF 1; Hemoglobin: 128 [134 - 170] G/L; Leukocytes: 9.6 [3.6 - 10.6] 10^9/L; NPTST008-BUN: 26 [5 - 20] MG/DL; Potassium: 3.6 [3.5 - 5.5] MMOL/L; Sodium: 127 [135 - 145] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 551): BLOOD BLOOD CULTURE: NEGATIVE-SHOWED NO GROWTH; [redacted]20[redacted] (RX

DAY 554): WOUND WOUND CULTURE: POSITIVE-STAPH AUREAS

AE Stopped Rx Day	563
Duration of AE	37 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	YES
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に注入部位蜂巣炎を発現した。

Event 14 の臨床経過：

関連する病歴は，高血圧，パーキンソン病，非喫煙者，及び非飲酒者であった。

投与 549 日目，被験者は注入部位蜂巣炎を発現した。投与 563 日目，注入部位蜂巣炎は消失した。

治験責任医師によると，被験者は過去に膿及び血液の排出とともに，注入部位に非重篤な感染症，発赤，及び結節の出現を発現したことがあった。

投与 547 日目，被験者は注入ポンプの位置を変更した。投与 549 日目，被験者は体調がすぐれなかった。被験者は昼寝をし，2 時間後に気分が悪くなったため注入ポンプを確認した。被験者は変更前の注入部位が赤くなっていることに気が付いた。夕方までに，被験者は 100.4°Fの低グレードの発熱を発現した。被験者は疼きと嗜眠を認め，やや混乱していた。投与 550 日目，変更前の注入部位は悪化しているようだった。腹部は赤く，圧痛があった。発熱及び悪寒が 48 時間続き，医師により Bactrim の投与が開始された。その後，被験者の変更前の注入部位から黄

色がかかった膿が出現し，発疹が広がり始めた。被験者は緊急治療室に行くよう指示された。変更後の部位での注入は順調であった。

投与 551 日目，被験者は腹壁の蜂巣炎，悪寒の症状，及び腹部の発赤のため入院した。悪心，嘔吐，下痢，又は便秘は認められなかった。被験者に抗生物質が投与された。投与 555 日目，創傷パッキングが除去され，化膿物の残留物を培養物とともに検査に送った。創傷部位を生理食塩水で清潔になるまで洗浄した。創傷部位に小さなドレーン（wick）を入れ，再度包帯を巻いた。投与 557 日目，被験者は退院した。

本事象により被験者は治験を中止した。

被験者にジフテリア・破傷風混合ワクチン，セファレキシン，デキストロース 5%，ポリエチレングリコール，オンダンセトロン，アセトアミノフェン / ヒドロコドン配合剤，塩化ナトリウム，バンコマイシン，セファゾリン，及び BACTRIM DS が投与された。

The patient's past medications include:

BACTRIM DS for INFECTION ([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.24.0] [10065455]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS AT THE INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BLOOD CULTURE:** Negative - no growth

[redacted] **20[redacted] BUN:** 26 mg/dL (normal 5 to 20)

[redacted] **20[redacted] CALCIUM:** 9.3 mg/dL (normal 8.5 to 10.5)

[redacted] **20[redacted] CREATININE:** 0.96 mg/dL (normal 0.6 to 1.2)

[redacted] **20[redacted] GLUCOSE:** 136 mg/dL (normal 70 to 99)

[redacted] **20[redacted] HEMATOCRIT:** 37.2% (normal 40 to 54)

[redacted] **20[redacted] HEMOGLOBIN:** 12.8 G/DL (normal 13.4 to 17)

[redacted] **20[redacted] POTASSIUM:** 3.6 MMOL/L (norm 3.5 to 5.5)

[redacted] **20[redacted] RED BLOOD CELLS:** 3.93 X10**3/MM**3 (normal 4.18 to 5.51)

[redacted] **20[redacted] SODIUM:** 127 MMOL/L (normal 135 to 145)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 9.6 X10**9/L (normal 3.6 to 10.6)

[redacted] **20[redacted] WOUND CULTURE:** Positive staph Aureas

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			X
頭蓋内出血	X			X
上腕骨骨折	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
MENOPAUSE	19[redacted]
OSTEOPOROSIS	20[redacted]
PARKINSON'S DISEASE	20[redacted]
HYPOGLYCEMIA	20[redacted]
AMNESIA	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
REM SLEEP BEHAVIOR DISORDER	20[redacted]
VITAMIN B-12 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
DBS	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	10	19[redacted]

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.28	0.24	60	0.11	[redacted] / 364
ABBV-951	0.27	0.28	0.24	60	0.11	[redacted] / 517
ABBV-951	0.27	0.28	0.24	60	0.19	[redacted] / 552
ABBV-951	0.27	0.28	0.24	60	0.19	[redacted] / 620
ABBV-951	0.27	0.28	0.24	60	0.24	[redacted] / 651
ABBV-951	0.27	0.28	0.24	60	0.24	[redacted] / 679
ABBV-951	0.27	0.28	0.24	60	0.24	[redacted] / 714

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	594.72		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 9	[redacted] / 17
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951	1080.84		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	1149.14		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	1179.88		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
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M15-741 /ABBV-951	961.32		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 34	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 37	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
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M15-741 /ABBV-951	1046.69		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
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M15-741 /ABBV-951	1111.92		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 45	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 48	
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M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 50	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 51	
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M15-741 /ABBV-951	1255.01		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
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M15-741 /ABBV-951	1109.87		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
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M15-741 /ABBV-951	903.26		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
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M15-741 /ABBV-951	1024.5		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1042.42		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 64	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 65	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 66	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 67	
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 68	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 72	
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M15-741 /ABBV-951	1004.86		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 76	
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M15-741 /ABBV-951	999.74		SC / CONTINUOUS	[redacted]20[redacted] / 77	[redacted]20[redacted] / 77
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 82	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 185	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 195	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 198	
M15-741 /ABBV-951	858.01		SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
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M15-741 /ABBV-951	857.16		SC / CONTINUOUS	[redacted] / 211	[redacted] / 211
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 212	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 213	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 215	
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M15-741 /ABBV-951	846.06		SC / CONTINUOUS	[redacted] / 217	[redacted] / 217
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 220	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 221	
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M15-741 /ABBV-951	862.28		SC / CONTINUOUS	[redacted] / 222	[redacted] / 222
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 224	
M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 224	[redacted]20[redacted] / 224
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 225	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 226	
M15-741 /ABBV-951	852.89		SC / CONTINUOUS	[redacted]20[redacted] / 226	[redacted]20[redacted] / 226
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 227	
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M15-741 /ABBV-951	911.29		SC / CONTINUOUS	[redacted]20[redacted] / 230	[redacted]20[redacted] / 230
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M15-741 /ABBV-951	912.65		SC / CONTINUOUS	[redacted]20[redacted] / 231	[redacted]20[redacted] / 231
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 234	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 235	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 236	
M15-741 /ABBV-951	908.04		SC / CONTINUOUS	[redacted]20[redacted] / 236	[redacted]20[redacted] / 236
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 237	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 245	
M15-741 /ABBV-951	884.82		SC / CONTINUOUS	[redacted]20[redacted] / 245	[redacted]20[redacted] / 245
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 247	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 250	
M15-741 /ABBV-951	858.87		SC / CONTINUOUS	[redacted]20[redacted] / 250	[redacted]20[redacted] / 250
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M15-741 /ABBV-951	895.24		SC / CONTINUOUS	[redacted]20[redacted] / 254	[redacted]20[redacted] / 254
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 256	
M15-741 /ABBV-951	886.53		SC / CONTINUOUS	[redacted]20[redacted] / 256	[redacted]20[redacted] / 256
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 259	
M15-741 /ABBV-951	893.87		SC / CONTINUOUS	[redacted]20[redacted] / 259	[redacted]20[redacted] / 259
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 260	
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M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 327	
M15-741 /ABBV-951	881.07		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
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M15-741 /ABBV-951	880.04		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 330	
M15-741 /ABBV-951	881.07		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 331	
M15-741 /ABBV-951	859.55		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
M15-741 /ABBV-951	852.38		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 333	
M15-741 /ABBV-951	897.46		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 334	
M15-741 /ABBV-951	885.16		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 335	
M15-741 /ABBV-951	859.55		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 336	
M15-741 /ABBV-951	893.36		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 337	
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 343	
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M15-741 /ABBV-951	915.90		SC / CONTINUOUS	[redacted]20[redacted] / 345	[redacted]20[redacted] / 345
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M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 350	
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M15-741 /ABBV-951	872.87		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 354	
M15-741 /ABBV-951	893.36		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
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M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 356	
M15-741 /ABBV-951	881.07		SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
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M15-741 /ABBV-951	866.72		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 358	
M15-741 /ABBV-951	886.19		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 359	

M15-741 /ABBV-951	894.38		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 360	
M15-741 /ABBV-951	872.87		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 361	
M15-741 /ABBV-951	887.21		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
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M15-741 /ABBV-951	992.74		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
M15-741 /ABBV-951	973.27		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 367	
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 371	
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ABBV-951	1061.38		SC / CONTINUOUS	[redacted]20[redacted] / 372	[redacted]20[redacted] / 372
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ABBV-951	1083.06		SC / CONTINUOUS	[redacted]20[redacted] / 375	[redacted]20[redacted] / 375
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 379	
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ABBV-951	1052.67		SC / CONTINUOUS	[redacted]20[redacted] / 380	[redacted]20[redacted] / 380
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 381	

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ABBV-951	1101.50		SC / CONTINUOUS	[redacted]20[redacted] / 395	[redacted]20[redacted] / 395
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ABBV-951	1073.33		SC / CONTINUOUS	[redacted]20[redacted] / 403	[redacted]20[redacted] / 403
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ABBV-951	1130.87		SC / CONTINUOUS	[redacted]20[redacted] / 619	[redacted]20[redacted] / 619
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ABBV-951	1127.80		SC / CONTINUOUS	[redacted]20[redacted] / 621	[redacted]20[redacted] / 621
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ABBV-951	1127.29		SC / CONTINUOUS	[redacted]20[redacted] / 626	[redacted]20[redacted] / 626
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ABBV-951	1125.41		SC / CONTINUOUS	[redacted]20[redacted] / 629	[redacted]20[redacted] / 629
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ABBV-951	1135.31		SC / CONTINUOUS	[redacted]20[redacted] / 631	[redacted]20[redacted] / 631
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ABBV-951	1093.65		SC / CONTINUOUS	[redacted]20[redacted] / 639	[redacted]20[redacted] / 639
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ABBV-951	1120.80		SC / CONTINUOUS	[redacted]20[redacted] / 643	[redacted]20[redacted] / 643
ABBV-951	1121.99		SC / CONTINUOUS	[redacted]20[redacted] / 644	[redacted]20[redacted] / 644
ABBV-951	1118.24		SC / CONTINUOUS	[redacted]20[redacted] / 645	[redacted]20[redacted] / 645
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ABBV-951	1124.21		SC / CONTINUOUS	[redacted]20[redacted] / 648	[redacted]20[redacted] / 648
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ABBV-951	1129.85		SC / CONTINUOUS	[redacted]20[redacted] / 651	[redacted]20[redacted] / 651
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ABBV-951	1127.63		SC / CONTINUOUS	[redacted]20[redacted] / 657	[redacted]20[redacted] / 657
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ABBV-951	1123.53		SC / CONTINUOUS	[redacted] / 671	[redacted] / 671
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ABBV-951	1128.14		SC / CONTINUOUS	[redacted]20[redacted] / 685	[redacted]20[redacted] / 685
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ABBV-951	1144.19		SC / CONTINUOUS	[redacted]20[redacted] / 687	[redacted]20[redacted] / 687
ABBV-951	1124.21		SC / CONTINUOUS	[redacted]20[redacted] / 688	[redacted]20[redacted] / 688
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 689	
ABBV-951	1100.14		SC / CONTINUOUS	[redacted]20[redacted] / 689	[redacted]20[redacted] / 689
ABBV-951	1131.21		SC / CONTINUOUS	[redacted]20[redacted] / 690	[redacted]20[redacted] / 690
ABBV-951	1118.92		SC / CONTINUOUS	[redacted]20[redacted] / 691	[redacted]20[redacted] / 691
ABBV-951	1088.36		SC / CONTINUOUS	[redacted]20[redacted] / 692	[redacted]20[redacted] / 692
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ABBV-951	1120.97		SC / CONTINUOUS	[redacted]20[redacted] / 694	[redacted]20[redacted] / 694
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ABBV-951	1122.51		SC / CONTINUOUS	[redacted]20[redacted] / 696	[redacted]20[redacted] / 696
ABBV-951	1130.19		SC / CONTINUOUS	[redacted]20[redacted] / 697	[redacted]20[redacted] / 697
ABBV-951	1138.21		SC / CONTINUOUS	[redacted]20[redacted] / 698	[redacted]20[redacted] / 698
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ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 702	
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ABBV-951	1086.31		SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 703
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 713	
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ABBV-951	1127.46		SC / CONTINUOUS	[redacted]20[redacted] / 714	[redacted]20[redacted] / 714
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 715	
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ABBV-951	1125.41		SC / CONTINUOUS	[redacted]20[redacted] / 740	[redacted]20[redacted] / 740
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ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 743	
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 744	
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ABBV-951	1115.85		SC / CONTINUOUS	[redacted]20[redacted] / 748	[redacted]20[redacted] / 748
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ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 754	
ABBV-951	1128.48		SC / CONTINUOUS	[redacted]20[redacted] / 754	[redacted]20[redacted] / 754
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 755	
ABBV-951	1122.16		SC / CONTINUOUS	[redacted]20[redacted] / 755	[redacted]20[redacted] / 755
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 756	
ABBV-951	1071.11		SC / CONTINUOUS	[redacted]20[redacted] / 756	[redacted]20[redacted] / 756
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 757	
ABBV-951	1121.31		SC / CONTINUOUS	[redacted]20[redacted] / 757	[redacted]20[redacted] / 757
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 758	
ABBV-951	1084.43		SC / CONTINUOUS	[redacted]20[redacted] / 758	[redacted]20[redacted] / 758
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 759	
ABBV-951	1123.87		SC / CONTINUOUS	[redacted]20[redacted] / 759	[redacted]20[redacted] / 759
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 760	
ABBV-951	1087.67		SC / CONTINUOUS	[redacted]20[redacted] / 760	[redacted]20[redacted] / 760
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 761	
ABBV-951	1090.92		SC / CONTINUOUS	[redacted]20[redacted] / 761	[redacted]20[redacted] / 761
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 762	
ABBV-951	1132.24		SC / CONTINUOUS	[redacted]20[redacted] / 762	[redacted]20[redacted] / 762
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 763	
ABBV-951	1095.36		SC / CONTINUOUS	[redacted]20[redacted] / 763	[redacted]20[redacted] / 763
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 764	
ABBV-951	1090.40		SC / CONTINUOUS	[redacted]20[redacted] / 764	[redacted]20[redacted] / 764
ABBV-951	1077.43		SC / CONTINUOUS	[redacted]20[redacted] / 765	[redacted]20[redacted] / 765
ABBV-951	1132.41		SC / CONTINUOUS	[redacted]20[redacted] / 766	[redacted]20[redacted] / 766
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 767	
ABBV-951	1103.72		SC / CONTINUOUS	[redacted]20[redacted] / 767	[redacted]20[redacted] / 767
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 768	
ABBV-951	1130.02		SC / CONTINUOUS	[redacted]20[redacted] / 768	[redacted]20[redacted] / 768
ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 769	
ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 769	[redacted]20[redacted] / 769

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / -154
ESCITALOPRAM OXALATE	10 mg	QD	Y-M: 20[redacted] / -51
ALPRAZOLAM	0.25 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
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / -154	NOT REPORTED
ESCITALOPRAM OXALATE	10 mg	QD	Y-M: 20[redacted] / -51	NOT REPORTED
ALPRAZOLAM	0.25 mg	PRN	Y-M: 20[redacted] / -15	NOT REPORTED

Event #1: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	FALL W/ SEQUALAE
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	618
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 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 RELATED TO IMBALANCE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	INTRACRANIAL HEMORRHAGE
Preferred Term	頭蓋内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 618
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	IMBALANCE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 663
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	663
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 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 DUE TO INSTABILITY, FALL WAS UNINTENTIONAL. SUBJECT REPORTED NO DIZZINESS OR FREEZING PRECEDING FALL.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Event #4: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	LEFT HUMERUS FRACTURE
Preferred Term	上腕骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 663
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	664
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT 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	SUBJECT FELL AND FRACTURED HER LEFT HUMERUS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に後遺症を伴う転倒及び頭蓋内出血を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，骨粗鬆症，パーキンソン病，低血糖，レム睡眠行動障害，ビタミン B12 欠乏症，及び飲酒者（1 日 2 杯未満）であった。

投与 618 日目，被験者は後遺症を伴う転倒及び頭蓋内出血を発現した。投与 618 日目，後遺症を伴う転倒及び頭蓋内出血は消失した。

投与 618 日目，被験者は救急診療部に来院し，自宅で転倒し頭を打ち付けたと報告した。同日，被験者は脳 CT スキャンにより頭蓋内出血が確認され，精密検査のため入院した。

治験責任医師によると，被験者のリスク因子は平衡失調であった。

Causality for ABBV-951 (Open Label)

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1) Fall (10016173) (Fall (10016173)) [v.24.0] [10016173]

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

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

Dechallenge: Not Applicable

2) Intracranial hemorrhage (10022763) (Haemorrhage intracranial (10018985)) [v.24.0] [10022763]

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 W/ SEQUALAE

- Investigator: Fall related to imbalance

- AbbVie: More likely related to age, reported imbalance with underlying Parkinson disease, confounded by history of vitamin B12 deficiency and hypoglycemia.

Event of INTRACRANIAL HEMORRHAGE

- Investigator: Imbalance

- AbbVie: More likely related to trauma from current fall and hitting head in an elderly subject with Parkinson disease.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に，転落事故及び左上腕骨骨折を発現した。

Event 3 及び 4 の臨床経過：

関連する病歴は，元喫煙者（1 日 1 本を 10 年間），閉経，骨粗鬆症，パーキンソン病，健忘，ビタミン B12 欠乏症，及び飲酒者（1 日 2 杯未満）であった。

投与 663 日目，被験者は転落事故及び左上腕骨骨折を発現した。投与 663 日目，転落事故は消失した。投与 664 日目，左上腕骨骨折は消失した。

投与 663 日目，被験者は転落事故による左上腕骨骨折のため入院した。投与 664 日目，被験者に上腕骨骨折に対する外科手術を実施した。投与 666 日目，被験者は退院した。

Causality for ABBV-951 (Open Label)

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1) Fall (10016173) (Fall (10016173)) [v.24.1] [10016173]

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

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

Dechallenge: Not Applicable

2) Fracture of humerus (10017127) (Humerus fracture (10020462)) [v.24.1] [10017127]

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 ACCIDENTAL FALL

- Investigator: Fall due to instability, fall was unintentional. Subject reported no dizziness or freezing preceding fall.

- AbbVie: More likely related to reported instability and history of Parkinson's disease and advanced age

Event of LEFT HUMERUS FRACTURE

- Investigator: subject fell and fractured her left humerus

- AbbVie: More likely related to reported fall in a postmenopausal women with osteoporosis and advanced age

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] X-RAY OF LEFT HUMERUS: Fracture of left humerus

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			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

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

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

Prior Procedures	Procedure Year
POLYPECTOMY SINUS	19[redacted]
CAESAREAN	19[redacted]
CAESAREAN	19[redacted]
HYSTERECTOMY	19[redacted]

APPENDECTOMY	20[redacted]
CHOLECYSTECTOMY	20[redacted]
CATARACT RESECTION, RIGHT EYE	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.52	0.59	0.46		0.19	[redacted]20[redacted] / 365
ABBV-951	0.52	0.6	0.46	60	0.19	[redacted]20[redacted] / 534
ABBV-951	0.5	0.61	0.46	60	0.19	[redacted]20[redacted] / 555
ABBV-951	0.52	0.61	0.46		0.19	[redacted]20[redacted] / 697
ABBV-951	0.61	0.63	0.49		0.19	[redacted]20[redacted] / 794

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	518.39		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	1128.14		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 13
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1231.61		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 15	

M15-741 /ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951	1238.62		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 18	
M15-741 /ABBV-951	1366.17		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 19	[redacted] / 26
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	1308.45		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951	476.39		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951	1291.04		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted] / 39	
M15-741 /ABBV-951	1335.94		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	1065.48		SC / CONTINUOUS	[redacted] / 40	[redacted] / 93
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted] / 94	
M15-741 /ABBV-951	1307.94		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 95	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 95	[redacted] / 180
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 181	
M15-741 /ABBV-951	1626.56		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted] / 182	
M15-741 /ABBV-951	1553.31		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 183	[redacted] / 270
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1674.54		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 272	
M15-741 /ABBV-951	1739.60		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1711.42		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 274	[redacted] / 362
M15-741 /ABBV-951		194.65	SC / ONCE	[redacted] / 363	
M15-741 /ABBV-951	2062.66		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 364	
M15-741 /ABBV-951	2243.99		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	861.26		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365
ABBV-951	2130.96		SC / CONTINUOUS	[redacted] / 366	[redacted] / 446

ABBV-951	2346.10		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		194.65	SC / ONCE	[redacted]	
ABBV-951	2405.86		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		227.09	SC / ONCE	[redacted]	
ABBV-951	2317.07		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	2417.82		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		162.21	SC / ONCE	[redacted]	
ABBV-951	2343.54		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		129.77	SC / ONCE	[redacted]	
ABBV-951	2346.10		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	2448.55		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	2458.8		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		129.77	SC / ONCE	[redacted]	
ABBV-951	2452.82		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		194.65	SC / ONCE	[redacted]	
ABBV-951	2292.31		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	2499.78		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		129.77	SC / ONCE	[redacted]	
ABBV-951		227.09	SC / ONCE	[redacted]	
ABBV-951	2441.38		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951	2049		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		194.65	SC / ONCE	[redacted]	
ABBV-951	2297.27		SC / CONTINUOUS	[redacted]	[redacted]
ABBV-951		162.21	SC / ONCE	[redacted]	
ABBV-951	2332.95		SC / CONTINUOUS	[redacted]	[redacted]

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted]
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83

DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41
PRAMIPEXOLE	0.500 mg	BID	Y-M: 20[redacted] / 12
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 40
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / 40
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 183
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 275
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 275
GLYCERYL TRINITRATE	0.2 mg	OTHER: PER 24 HRS, CONTINUOUS	Y-M: 20[redacted] / 321
ISOSORBIDE DINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 321
MIDODRINE	2.5 mg	BID	Y-M: 20[redacted] / 321

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]	NOT REPORTED
FOLIC ACID	5 mg	QD	Y-M: 20[redacted]	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted]	NOT REPORTED
SENNOSIDE A+B	17 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
NICOTINAMIDE	1 OTHER: CAPS	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 393
VITAMIN D NOS	10000 IU	OTHER: ONCE A WEEK	Y-M: 20[redacted] / -244	NOT REPORTED
DABIGATRAN ETEXILATE MESILATE	110 mg	BID	Y-M: 20[redacted] / -123	Y-M: 20[redacted] / 589
AMIODARONE	100 mg	QD	Y-M: 20[redacted] / -83	NOT REPORTED
DIGOXIN	0.125 mg	QD	Y-M: 20[redacted] / -83	NOT REPORTED
DEXLANSOPRAZOLE	60 mg	QD	Y-M: 20[redacted] / -41	NOT REPORTED
TRAZODONE	25 mg	QD	Y-M: 20[redacted] / 40	NOT REPORTED
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 697
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 183	NOT REPORTED
PREGABALIN	50 mg	BID	Y-M: 20[redacted] / 275	NOT REPORTED
PREGABALIN	25 mg	QD	Y-M: 20[redacted] / 275	Y-M: 20[redacted] / 697
GLYCERYL TRINITRATE	0.2 mg	OTHER: PER 24 HRS, CONTINUOUS	Y-M: 20[redacted] / 321	NOT REPORTED
ISOSORBIDE DINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 321	NOT REPORTED
MIDODRINE	2.5 mg	BID	Y-M: 20[redacted] / 321	NOT REPORTED

CYCLOBENZAPRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 365	NOT REPORTED
NICOTINAMIDE	1 OTHER: CAPS	OTHER: EVERY 2 DAYS	Y-M: 20[redacted] / 393	NOT REPORTED
SODIUM PHOSPHATE DIBASIC;SODIUM PHOSPHATE MONOBASIC	1 OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 428	NOT REPORTED
DOCUSATE SODIUM	2 OTHER: CAPS	PRN	Y-M: 20[redacted] / 450	NOT REPORTED
APIXABAN	5 mg	BID	Y-M: 20[redacted] / 590	NOT REPORTED
PARACETAMOL	1 g	TID	Y-M: 20[redacted] / 697	NOT REPORTED
BISACODYL	1 OTHER: SUPPOSITORY	PRN	Y-M: 20[redacted] / 766	NOT REPORTED

Event #1: 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	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
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	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

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 を投与中に原因不明の胸痛を発現した。

Event 1 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 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の治験薬の調整を必要とした。投与 5 週時に，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。

被験者は過去に胸部痛を 15 日間発現していた。被験者は緊急治療室に来院するよう指導された。投与 318 日目，被験者は緊急治療室に来院し，不安定狭心症の診断に基づいて入院した。投与 320 日目，緊急冠動脈造影が実施され，結果は正常であった。投与 321 日目，被験者は退院した。

被験者に NITRO-DUR が投与された。

The patient's past medications include:

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

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

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

Causality for ABBV-951 (Open Label)

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

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

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

Dechallenge: No

Alternative Etiology for ABBV-951 (Open Label)

Event of CHEST PAIN OF UNDETERMINED ETIOLOGY

- Investigator:

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

Relevant Laboratory & Other Diagnostic Tests

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

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
転倒				X
幻覚	X			X
注入部位蜂巣炎				X
精神病性障害	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
ORTHOSTATIC HYPOTENSION	19[redacted]
DEPRESSION	19[redacted]
SURGICALLY STERILE	19[redacted]
UTERINE DESCENT	19[redacted]
HALLUCINATIONS	19[redacted]
ANXIETY	20[redacted]
CONSTIPATION	20[redacted]
GASTROINTESTINAL REFLUX	20[redacted]
DEPRESSION	20[redacted]
INSOMNIA	20[redacted]
CARPAL TUNNEL SYNDROME	20[redacted]

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

Prior Procedures	Procedure Year
TUBAL LIGATION	19[redacted]
HYSTERECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	3 CIGARETTE	0	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	0.53	0.57	0.46	60	0.30	[redacted] / 368
ABBV-951	0.52	0.57	0.46	60	0.24	[redacted] / 528
ABBV-951	0.5	0.56	0.46	60	0.24	[redacted] / 547
ABBV-951	0.5	0.5	0.46	240	0.11	[redacted] / 561
ABBV-951	0.5	0.5	0.43	240	0.11	[redacted] / 709

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		206.60	SC / ONCE	[redacted] / 5	
M15-741 /ABBV-951	767.00		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		262.95	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1077.09		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		75.13	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 8	[redacted] / 12
M15-741 /ABBV-951		131.47	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1534.87		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951	1399.80		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 15	[redacted] / 19
M15-741 /ABBV-951		131.47	SC / ONCE	[redacted] / 20	
M15-741 /ABBV-951	1481.25		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 21	

M15-741 /ABBV-951	1455.30		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 22	
M15-741 /ABBV-951	1611.53		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	1721.16		SC / CONTINUOUS	[redacted] / 23	[redacted] / 26
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951	1563.21		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	1453.76		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 29	
M15-741 /ABBV-951	1472.03		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted] / 30	[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951	1368.04		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1297.52		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 43	[redacted] / 89
M15-741 /ABBV-951		245.88	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	1495.77		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 91	
M15-741 /ABBV-951	1572.26		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted] / 92	
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 92	[redacted] / 178
M15-741 /ABBV-951	1723.20		SC / CONTINUOUS	[redacted] / 179	[redacted] / 179
M15-741 /ABBV-951		163.92	SC / ONCE	[redacted] / 180	
M15-741 /ABBV-951	1857.76		SC / CONTINUOUS	[redacted] / 180	[redacted] / 180
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted] / 181	
M15-741 /ABBV-951	1885.08		SC / CONTINUOUS	[redacted] / 181	[redacted] / 270
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1961.91		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951		327.84	SC / ONCE	[redacted] / 272	
M15-741 /ABBV-951	2012.45		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	2114.73		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted] / 274	[redacted] / 364
M15-741 /ABBV-951		245.88	SC / ONCE	[redacted] / 365	
M15-741 /ABBV-951	2099.20		SC / CONTINUOUS	[redacted] / 365	[redacted] / 365
M15-741 /ABBV-951		286.86	SC / ONCE	[redacted] / 366	
M15-741 /ABBV-951	2057.70		SC / CONTINUOUS	[redacted] / 366	[redacted] / 366

M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 367
M15-741 /ABBV-951	2124.13		SC / CONTINUOUS	[redacted]20[redacted] / 367 [redacted]20[redacted] / 367
ABBV-951	1176.46		SC / CONTINUOUS	[redacted]20[redacted] / 368 [redacted]20[redacted] / 368
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 369 [redacted]20[redacted] / 447
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 448
ABBV-951	2189.35		SC / CONTINUOUS	[redacted]20[redacted] / 448 [redacted]20[redacted] / 448
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 449
ABBV-951	2144.96		SC / CONTINUOUS	[redacted]20[redacted] / 449 [redacted]20[redacted] / 449
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 450 [redacted]20[redacted] / 525
ABBV-951	2162.89		SC / CONTINUOUS	[redacted]20[redacted] / 526 [redacted]20[redacted] / 526
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 527
ABBV-951	1719.45		SC / CONTINUOUS	[redacted]20[redacted] / 527 [redacted]20[redacted] / 527
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 528
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 528 [redacted]20[redacted] / 615
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 616
ABBV-951	1988.72		SC / CONTINUOUS	[redacted]20[redacted] / 616 [redacted]20[redacted] / 616
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 617
ABBV-951	1990.94		SC / CONTINUOUS	[redacted]20[redacted] / 617 [redacted]20[redacted] / 617
ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 618 [redacted]20[redacted] / 706
ABBV-951	2001.19		SC / CONTINUOUS	[redacted]20[redacted] / 707 [redacted]20[redacted] / 707
ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 708 [redacted]20[redacted] / 708
ABBV-951	2001.19		SC / CONTINUOUS	[redacted]20[redacted] / 709 [redacted]20[redacted] / 709

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]
OXAZEPAM	15 mg	PRN	Y-M: 20[redacted]
TRAZODONE	100 mg	QD	Y-M: 20[redacted]
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]
NICOTINAMIDE	1 OTHER: 1 CO	QD	Y-M: 20[redacted] / -11
PRAMIPEXOLE	0.250 mg	QD	Y-M: 20[redacted] / 7
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 43
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / 121
DONEPEZIL HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 256
MELATONIN	10 mg	QD	Y-M: 20[redacted] / 298
OXAZEPAM	15 mg	QD	Y-M: 20[redacted] / 320

MIDODRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 340
MIDODRINE HYDROCHLORIDE	7,5 mg	QD	Y-M: 20[redacted] / 340

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]	NOT REPORTED
OXAZEPAM	15 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
TRAZODONE	100 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 567
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 520
LORAZEPAM	0.5 mg	PRN	Y-M: 20[redacted] / 43	NOT REPORTED
SERTRALINE	100 mg	QD	Y-M: 20[redacted] / 121	NOT REPORTED
DONEPEZIL HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 256	NOT REPORTED
MELATONIN	10 mg	QD	Y-M: 20[redacted] / 298	NOT REPORTED
OXAZEPAM	15 mg	QD	Y-M: 20[redacted] / 320	Y-M: 20[redacted] / 476
MIDODRINE HYDROCHLORIDE	10 mg	QD	Y-M: 20[redacted] / 340	Y-M: 20[redacted] / 566
MIDODRINE HYDROCHLORIDE	7,5 mg	QD	Y-M: 20[redacted] / 340	Y-M: 20[redacted] / 566
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 398	NOT REPORTED
OXAZEPAM	7,5 mg	QD	Y-M: 20[redacted] / 476	Y-M: 20[redacted] / 478
QUETIAPINE FUMARATE	6,25 mg	QD	Y-M: 20[redacted] / 476	Y-M: 20[redacted] / 478
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 479	NOT REPORTED
QUETIAPINE FUMARATE	12.5 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 529
OXAZEPAM	22.5 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 566
CALCIUM CARBONATE;COLECALCIFEROL	500MG/800UI OTHER: SEE DOSE	QD	Y-M: 20[redacted] / 491	NOT REPORTED
DOCUSATE SODIUM	100 mg	PRN	Y-M: 20[redacted] / 493	NOT REPORTED
SENNOSIDE A+B	8,6 mg	PRN	Y-M: 20[redacted] / 493	NOT REPORTED
MACROGOL 3350	17 g	PRN	Y-M: 20[redacted] / 499	NOT REPORTED
DALTEPARIN	5000 IU	QD	Y-M: 20[redacted] / 521	Y-M: 20[redacted] / 582
QUETIAPINE FUMARATE	25 mg	QD	Y-M: 20[redacted] / 529	Y-M: 20[redacted] / 578
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 546	NOT REPORTED
BISACODYL	10 mg	QD	Y-M: 20[redacted] / 553	Y-M: 20[redacted] / 554

SODIUM CHLORIDE	1 g	BID	Y-M: 20[redacted] / 554	NOT REPORTED
FOSFOMYCIN	3 g	QD	Y-M: 20[redacted] / 556	Y-M: 20[redacted] / 556
CEFADROXIL	1 g	BID	Y-M: 20[redacted] / 564	Y-M: 20[redacted] / 570
MIDODRINE	10 mg	TID	Y-M: 20[redacted] / 567	NOT REPORTED
OXAZEPAM	15 mg	QD	Y-M: 20[redacted] / 567	NOT REPORTED
QUETIAPINE FUMARATE	75 mg	QD	Y-M: 20[redacted] / 567	Y-M: 20[redacted] / 578
QUETIAPINE FUMARATE	125 mg	QD	Y-M: 20[redacted] / 579	Y-M: 20[redacted] / 706
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 645	NOT REPORTED
QUETIAPINE FUMARATE	150 mg	QD	Y-M: 20[redacted] / 707	NOT REPORTED
CIPROFLOXACIN	1 g	QD	Y-M: 20[redacted] / 707	Y-M: 20[redacted] / 709
NICOTINAMIDE	1 OTHER: CO	OTHER: THREE TIMES A WEEK	Y-M: 20[redacted] / 729	NOT REPORTED

Event #1: Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 381
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	567
Duration of AE	187 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 398
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	398
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 #3: Event of Interest - Falls and Associated Injuries

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 399
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	399
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 #4: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 545
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 546): Creatinine: 74 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Leukocytes: OVER 20 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST004-BACTERIA: 3 + [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted]20[redacted] (RX DAY 547): Hemoglobin: 112 [117 - 161] G/L; Leukocytes: 5.4 [4.5 - 11] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 546): URINE CULTURE: POSITIVE-E. COLI NO SYMPTOMS

AE Stopped Rx Day	567
Duration of AE	23 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 RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #5: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	PSYCHOTIC STATE
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 545
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 546): Creatinine: 74 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Leukocytes: OVER 20 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST004-BACTERIA: 3 + [NOT REPORTED - NOT REPORTED] UNKNOWN; [redacted]20[redacted] (RX DAY 547): Hemoglobin: 112 [117 - 161] G/L; Leukocytes: 5.4 [4.5 - 11] 10^9/L

Microbiology

[redacted]20[redacted] (RX DAY 546): URINE CULTURE: POSITIVE-E. COLI NO SYMPTOMS

AE Stopped Rx Day	567
Duration of AE	23 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 RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	OLD INFUSION SITE CELLULITIS (RIGHT SIDE OF ABDOMEN)
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 563
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	570
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	NOT APPLICABLE

[redacted] **Infusion Set**	
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #7: Event of Interest - Hallucinations/Psychosis

Event Description	INCREASED HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 635
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に幻覚の増強及び精神病性障害を発現

した。

Event 4 及び 5 の臨床経過：

関連する病歴は，うつ病，幻覚，不安，パーキンソン病，不眠症，元喫煙者（1 日 3 本），及び元飲酒者（1 日 2 杯未満）であった。

投与 545 日目，被験者は幻覚の増強及び精神病性障害を発現した。投与 567 日目，幻覚の増強及び精神病状態は消失した。

投与 545 日目，被験者は精神病要素を伴う幻覚の増強のため緊急治療室に来院した。投与 546 日目，担当の神経科医が精密検査のため被験者を入院させることを決めた。クエチアピンフマル酸塩の用量が調整された（詳細は不明）。入院中，注入ポンプの注入速度を変更した。幻覚の増強及び精神病性障害は退院時に消失したと考えられた。投与 567 日目，被験者は退院した。

治験責任医師によると，うつ病，不安，幻覚の病歴以外のリスク因子は，過去に発現した不安の増強（非重篤），軽度の認知機能障害（非重篤），軽度のパニック発作（非重篤），及び幻覚の増強（非重篤）であった。

The patient's past medications include:

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

Causality for ABBV-951 (Open Label)

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1) Hallucinations aggravated (10019078) (Hallucination (10019063)) [v.24.0] [10019078]

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

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

Dechallenge: Not Applicable

2) Psychotic state (10037259) (Psychotic disorder (10061920)) [v.24.0] [10037259]

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 INCREASED HALLUCINATIONS

- Investigator: Not applicable.

- AbbVie: Not applicable

Event of PSYCHOTIC STATE

- Investigator: Not applicable.

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** CUTANEOUS THICKENING OF 4MM WITH MODERATE EDEMA. NO LIQUID COLLECTION. AUGMENTATION OF TISSUE VASCULARIZATION. NO FOREIGN BODY. PROBABLE INFECTIOUS PROCESS

[redacted] **20[redacted] CREATININE:** 74 UM/L

[redacted] **20[redacted] HEMOGLOBIN:** 112 G/L

[redacted] **20[redacted] URINE BACTERIA:** 3+

[redacted] **20[redacted] URINE CULTURE:** positive E.coli, no symptoms

[redacted] **20[redacted] URINE WBC:** over 20

[redacted] **20[redacted] WBC:** 5.4 X10**3/MM**3

[redacted] **20[redacted] WEIGHT:** 10[redacted] Pounds

[redacted] **20[redacted] X-RAY CHEST:** 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
肩甲骨骨折	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	ASIAN

Medical History	Onset Year
CEREBRAL INFARCTION	19[redacted]
CERVICAL SPINE SURGERY	20[redacted]
CATARACT SURGERY(BOTH EYES)	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	1 CIGARETTE	37	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.45	0.49	0.36	120	0.24	[redacted]20[redacted] / 364
ABBV-951	0.52	0.56	0.45	120	0.24	[redacted]20[redacted] / 478
ABBV-951	0.52	0.56	0.45	120	0.24	[redacted]20[redacted] / 534
ABBV-951	0.49	0.52	0.46	120	0.24	[redacted]20[redacted] / 572
ABBV-951	0.47	0.49	0.44	120	0.19	[redacted]20[redacted] / 583
ABBV-951	0.46	0.48	0.44	90	0.15	[redacted]20[redacted] / 622
ABBV-951	0.46	0.48	0.44	90	0.15	[redacted]20[redacted] / 686
ABBV-951	0.47	0.49	0.45	90	0.15	[redacted]20[redacted] / 713
ABBV-951	0.48	0.50	0.46	90	0.15	[redacted]20[redacted] / 749
ABBV-951	0.50	0.52	0.46	90	0.15	[redacted]20[redacted] / 861

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	796.03		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	2219.06		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 3	

M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 4
M15-741 /ABBV-951	2254.75		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	2078.02		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 11
M15-741 /ABBV-951	2155.71		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1557.75		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1597.02		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1781.77		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 20
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1871.76		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1841.36		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	1826.17		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 26
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1898.74		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1851.44		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	1869.20		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 40
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1953.55		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1862.54		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	2125.83		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 89
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 90	
M15-741 /ABBV-951	2004.26		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	1819.17		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 92	

M15-741 /ABBV-951	2165.79		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	2294.88		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 180
M15-741 /ABBV-951	1829.92		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	1552.45		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	1692.98		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 270
M15-741 /ABBV-951	1691.27		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951	1657.98		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 361
M15-741 /ABBV-951	1647.73		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
M15-741 /ABBV-951	1607.26		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
ABBV-951	937.41		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 445
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 446	
ABBV-951	1821.04		SC / CONTINUOUS	[redacted]20[redacted] / 446	[redacted]20[redacted] / 447
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 448	
ABBV-951	1851.61		SC / CONTINUOUS	[redacted]20[redacted] / 448	[redacted]20[redacted] / 448
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 449	
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 531
ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 532	
ABBV-951	2024.07		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 533	
ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 614
ABBV-951	1851.78		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951	1827.87		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 683
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 684	
ABBV-951	1819.17		SC / CONTINUOUS	[redacted]20[redacted] / 684	[redacted]20[redacted] / 684
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 685	
ABBV-951	1795.26		SC / CONTINUOUS	[redacted]20[redacted] / 685	[redacted]20[redacted] / 685
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 686	[redacted]20[redacted] / 858
ABBV-951	1895.66		SC / CONTINUOUS	[redacted]20[redacted] / 859	[redacted]20[redacted] / 859
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 860	
ABBV-951	1918.54		SC / CONTINUOUS	[redacted]20[redacted] / 860	[redacted]20[redacted] / 860

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]
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]-[redacted]
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]-[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]-[redacted]
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]-[redacted]
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]-[redacted]
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]-[redacted]
SILODOSIN	4 mg	BID	Y-M: 20[redacted]-[redacted]
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]-[redacted]
PRAMIPEXOLE	1.500 mg	QD	Y-M: 20[redacted]-[redacted]
DIMETICONE	40 mg	TID	Y-M: 20[redacted]-[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]-[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted]-[redacted] / -344
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted]-[redacted] / -331
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted]-[redacted] / -191
CANDESARTAN	2 mg	BID	Y-M: 20[redacted]-[redacted] / -153
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted]-[redacted] / -65
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted]-[redacted] / 44
CAMPHOR;ENOXOLONE;LEVOMENTHOL;METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER:	PRN	Y-M: 20[redacted]-[redacted] / 51

	APPROPRIATE AMOUNT		
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190

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
ESOMEPRAZOLE MAGNESIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
BENZBROMARONE	50 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 749
RIVAROXABAN	15 mg	QD	Y-M: 20[redacted]	NOT REPORTED
GALANTAMINE HYDROBROMIDE	8 mg	BID	Y-M: 20[redacted]	Y-M: 20[redacted] / 449
LOXOPROFEN	100 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
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]	NOT REPORTED
FLUNITRAZEPAM	2 mg	QD	Y-M: 20[redacted]	NOT REPORTED
SENNOSIDE A+B	36 mg	QD	Y-M: 20[redacted]	NOT REPORTED
BISOPROLOL FUMARATE	1.25 mg	BID	Y-M: 20[redacted]	NOT REPORTED
SILODOSIN	4 mg	BID	Y-M: 20[redacted]	NOT REPORTED
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	APPROPRIATE AMOUNT OTHER: APPLICATION	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 534
DIMETICONE	40 mg	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 446
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA	2.5 g	TID	Y-M: 20[redacted]	Y-M: 20[redacted] / 449

SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK				
SOLIFENACIN SUCCINATE	5 mg	QD	Y-M: 20[redacted] / -331	NOT REPORTED
EPINASTINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / -191	NOT REPORTED
CANDESARTAN	2 mg	BID	Y-M: 20[redacted] / -153	NOT REPORTED
ZOLPIDEM	2.5 mg	QD	Y-M: 20[redacted] / -65	NOT REPORTED
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted] / 44	NOT REPORTED
CAMPHOR;ENOXOLONE;LEVOMENTHOL; METHYL SALICYLATE	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	PRN	Y-M: 20[redacted] / 51	NOT REPORTED
PITAVASTATIN	1 mg	QD	Y-M: 20[redacted] / 135	NOT REPORTED
RUPATADINE FUMARATE	10 mg	QD	Y-M: 20[redacted] / 136	Y-M: 20[redacted] / 446
FLURBIPROFEN	40 mg	QD	Y-M: 20[redacted] / 190	NOT REPORTED
PARACETAMOL	200 mg	TID	Y-M: 20[redacted] / 436	Y-M: 20[redacted] / 439
PRANOPROFEN	APPROPRIATE AMOUNT OTHER: APPROPRIATE AMOUNT	BID	Y-M: 20[redacted] / 457	Y-M: 20[redacted] / 478

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] / 436
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	436
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

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

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

Event Description	RIGHT SCAPULA FRACTURE
Preferred Term	肩甲骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 436
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	460
Duration of AE	25 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ACCIDENTAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に右肩甲骨骨折を発現した。

Event 2 の臨床経過：

関連する病歴は，心房細動，高血圧，パーキンソン病，パーキンソン病による衝動制御障害，パーキンソン病による頻尿，元喫煙者（1 日 1 本を 37 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 436 日目，被験者は右肩甲骨骨折を発現した。

投与 436 日目，被験者は自宅で入浴中に転倒し，右肩甲骨が陥没したため，救急車により病院へ搬送された。検査の結果，被験者は右肩甲骨骨折と診断された。被験者の関節可動域が正常であったため，吊り包帯による保存療法が実施され，被験者は帰宅した。

投与 439 日目，被験者は右肩甲骨の動きが限られており，安静にする必要があると訴えた。同日，右肩甲骨の安静及びリハビリテーションのため，被験者は入院した。投与 460 日目，被験者は退院した。投与 460 日目，右肩甲骨骨折は消失した。

被験者にアセトアミノフェンが投与された。

Causality for ABBV-951 (Open Label)

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1) Scapula fracture (10039579) (Scapula fracture (10039579)) [v.23.1] [10039579]

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 RIGHT SCAPULA FRACTURE

- Investigator: Accidental fall.

- AbbVie: More likely related to reported accidental fall in an advanced age subject with Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CT:** Right scapula fracture

[redacted] **20[redacted] X-RAY:** Right scapula 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
窒息	X	X	X	
誤嚥	X	X	X	
注入部位皮膚炎				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	ASIAN

Medical History	Onset Year
DUODENAL ULCER	19[redacted]
ECTOPIC PREGNANCY	19[redacted]
HULLUCINATION	19[redacted]
RIGHT HAND FRECTURE	19[redacted]
SCHIZOPHRENIA	19[redacted]
HEPATIC STEATOSIS	20[redacted]
INSOMNIA	20[redacted]
RIGHT TROCHANTERIC FEMORAL FRACTURE	20[redacted]
MISSING TOOTH	20[redacted]
LEFT FEMUR FRACTURE	20[redacted]
LOW BACK PAIN	20[redacted]
OVARIAN CYSTOMA	20[redacted]
UTERINE MYOMA	20[redacted]
OSTEOPOROSIS	20[redacted]

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

PARKINSON'S DISEASE DIAGNOSIS	20[redacted]

Prior Procedures	Procedure Year
UNILATERAL OVARIECTOMY	19[redacted]
TOTAL HIP ARTHROPLASTY	20[redacted]
TOTAL HIP ARTHROPLASTY	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	MORE THAN 4 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.40	0.28	60	0.11	[redacted]20[redacted] / 366
ABBV-951	0.32	0.37	0.26	60	0.11	[redacted]20[redacted] / 478
ABBV-951	0.30	0.34	0.24	60	0.11	[redacted]20[redacted] / 506
ABBV-951	0.30	0.34	0.24	60	0.11	[redacted]20[redacted] / 534
ABBV-951	0.30	0.32	0.22	60	0.11	[redacted]20[redacted] / 591

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	833.26		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1482.11		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1488.94		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 5

M15-741 /ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1651.49		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 14
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1740.11		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 16	
M15-741 /ABBV-951	1710.06		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 19
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1473.57		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1765.55		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 24
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 25	
M15-741 /ABBV-951	1901.98		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1837.78		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1918.03		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 29
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1772.38		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1689.05		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1801.24		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 34	

M15-741 /ABBV-951	1791.67		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951	1784.33		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951	1805.85		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 38
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	1789.28		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1550.75		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1793.55		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1793.55		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	1672.83		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1883.71		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	1985.65		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	2002.04		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	1969.25		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951	1961.06		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951	1992.99		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1999.31		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	2003.92		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 53	

M15-741 /ABBV-951	1927.76		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 54	
M15-741 /ABBV-951	1993.84		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951	1952.86		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	2027.99		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1967.04		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1986.16		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1936.98		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951	1954.23		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1978.30		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 64	
M15-741 /ABBV-951	1971.13		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 65	
M15-741 /ABBV-951	1871.42		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 68	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 69
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 70	
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 70	[redacted]20[redacted] / 70
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	1754.79		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 72
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 72	
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M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 83	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 86	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 93	
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M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 115
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M15-741 /ABBV-951	1469.13		SC / CONTINUOUS	[redacted]20[redacted] / 130 [redacted]20[redacted] / 130
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ABBV-951	1353.70		SC / CONTINUOUS	[redacted]20[redacted] / 385	[redacted]20[redacted] / 385
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 386	
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 387	
ABBV-951	1558.60		SC / CONTINUOUS	[redacted]20[redacted] / 387	[redacted]20[redacted] / 387
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 388	
ABBV-951	1617.68		SC / CONTINUOUS	[redacted]20[redacted] / 388	[redacted]20[redacted] / 388
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 389	

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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 390	
ABBV-951	1520.35		SC / CONTINUOUS	[redacted]20[redacted] / 390	[redacted]20[redacted] / 390
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 391	
ABBV-951	1550.41		SC / CONTINUOUS	[redacted]20[redacted] / 391	[redacted]20[redacted] / 391
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 392	
ABBV-951	1632.02		SC / CONTINUOUS	[redacted]20[redacted] / 392	[redacted]20[redacted] / 392
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 393	
ABBV-951	1557.58		SC / CONTINUOUS	[redacted]20[redacted] / 393	[redacted]20[redacted] / 393
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 394	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 395	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 396	
ABBV-951	1538.11		SC / CONTINUOUS	[redacted]20[redacted] / 396	[redacted]20[redacted] / 396
ABBV-951		93.91	SC / ONCE	[redacted]20[redacted] / 397	
ABBV-951	1538.79		SC / CONTINUOUS	[redacted]20[redacted] / 397	[redacted]20[redacted] / 397
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 398	[redacted]20[redacted] / 399
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 401	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 408	
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ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 409	

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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 413	
ABBV-951	1529.92		SC / CONTINUOUS	[redacted]20[redacted] / 413	[redacted]20[redacted] / 413
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 414	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 415	
ABBV-951	1582.85		SC / CONTINUOUS	[redacted]20[redacted] / 415	[redacted]20[redacted] / 415
ABBV-951	1410.73		SC / CONTINUOUS	[redacted]20[redacted] / 416	[redacted]20[redacted] / 416
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 422	
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 423	
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ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 462	[redacted] / 462
ABBV-951		75.13	SC / ONCE	[redacted] / 463	
ABBV-951	1402.88		SC / CONTINUOUS	[redacted] / 463	[redacted] / 463
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ABBV-951	1343.11		SC / CONTINUOUS	[redacted] / 465	[redacted] / 465
ABBV-951		18.78	SC / ONCE	[redacted] / 466	
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ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 467	[redacted] / 467
ABBV-951		56.34	SC / ONCE	[redacted] / 468	

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ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 469	[redacted]20[redacted] / 469
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 470	
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ABBV-951	1157.00		SC / CONTINUOUS	[redacted]20[redacted] / 471	[redacted]20[redacted] / 471
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ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 473	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 474	
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ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 492	
ABBV-951	1287.11		SC / CONTINUOUS	[redacted]20[redacted] / 492	[redacted]20[redacted] / 492
ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 493	[redacted]20[redacted] / 494
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 495	
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ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 496	[redacted]20[redacted] / 498
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 499	
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ABBV-951	1065.48		SC / CONTINUOUS	[redacted]20[redacted] / 506	[redacted]20[redacted] / 506
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 507	
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ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 508	
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ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 509	[redacted]20[redacted] / 515
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ABBV-951	1281.64		SC / CONTINUOUS	[redacted]20[redacted] / 528	[redacted]20[redacted] / 528
ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 529	
ABBV-951	1293.60		SC / CONTINUOUS	[redacted]20[redacted] / 529	[redacted]20[redacted] / 529
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 530	[redacted]20[redacted] / 530
ABBV-951	1242.37		SC / CONTINUOUS	[redacted]20[redacted] / 531	[redacted]20[redacted] / 531
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 532	
ABBV-951	1302.13		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 533	
ABBV-951	1285.74		SC / CONTINUOUS	[redacted]20[redacted] / 533	[redacted]20[redacted] / 533
ABBV-951	1241.01		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 534
ABBV-951	1229.4		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 536	
ABBV-951	1269.35		SC / CONTINUOUS	[redacted]20[redacted] / 536	[redacted]20[redacted] / 536
ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 537	[redacted]20[redacted] / 538
ABBV-951	987.95		SC / CONTINUOUS	[redacted]20[redacted] / 539	[redacted]20[redacted] / 539
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 541
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 542	[redacted]20[redacted] / 542
ABBV-951	122.94		SC / CONTINUOUS	[redacted]20[redacted] / 543	[redacted]20[redacted] / 543
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 544	[redacted]20[redacted] / 544
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 545	
ABBV-951	1215.74		SC / CONTINUOUS	[redacted]20[redacted] / 545	[redacted]20[redacted] / 545
ABBV-951	983.52		SC / CONTINUOUS	[redacted]20[redacted] / 546	[redacted]20[redacted] / 555
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 555	
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 556	
ABBV-951	1257.74		SC / CONTINUOUS	[redacted]20[redacted] / 556	[redacted]20[redacted] / 556
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 557	
ABBV-951	1290.87		SC / CONTINUOUS	[redacted]20[redacted] / 557	[redacted]20[redacted] / 557
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 558	
ABBV-951	1348.24		SC / CONTINUOUS	[redacted]20[redacted] / 558	[redacted]20[redacted] / 558
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 559	
ABBV-951	1230.42		SC / CONTINUOUS	[redacted]20[redacted] / 559	[redacted]20[redacted] / 559
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 560	

ABBV-951	1210.61		SC / CONTINUOUS	[redacted] / 560	[redacted] / 560
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 561	[redacted] / 564
ABBV-951		37.56	SC / ONCE	[redacted] / 565	
ABBV-951	1217.44		SC / CONTINUOUS	[redacted] / 565	[redacted] / 565
ABBV-951		18.78	SC / ONCE	[redacted] / 566	
ABBV-951	1209.93		SC / CONTINUOUS	[redacted] / 566	[redacted] / 566
ABBV-951		75.13	SC / ONCE	[redacted] / 567	
ABBV-951	1215.74		SC / CONTINUOUS	[redacted] / 567	[redacted] / 567
ABBV-951		93.91	SC / ONCE	[redacted] / 568	
ABBV-951	1199.68		SC / CONTINUOUS	[redacted] / 568	[redacted] / 568
ABBV-951		93.91	SC / ONCE	[redacted] / 569	
ABBV-951	1208.91		SC / CONTINUOUS	[redacted] / 569	[redacted] / 569
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 570	[redacted] / 570
ABBV-951		18.78	SC / ONCE	[redacted] / 571	
ABBV-951	1294.28		SC / CONTINUOUS	[redacted] / 571	[redacted] / 571
ABBV-951	1314.09		SC / CONTINUOUS	[redacted] / 572	[redacted] / 572
ABBV-951		18.78	SC / ONCE	[redacted] / 573	
ABBV-951	1348.92		SC / CONTINUOUS	[redacted] / 573	[redacted] / 573
ABBV-951		56.34	SC / ONCE	[redacted] / 574	
ABBV-951	1173.05		SC / CONTINUOUS	[redacted] / 574	[redacted] / 574
ABBV-951		37.56	SC / ONCE	[redacted] / 575	
ABBV-951	1286.77		SC / CONTINUOUS	[redacted] / 575	[redacted] / 575
ABBV-951	1265.25		SC / CONTINUOUS	[redacted] / 576	[redacted] / 576
ABBV-951		56.34	SC / ONCE	[redacted] / 577	
ABBV-951	1291.89		SC / CONTINUOUS	[redacted] / 577	[redacted] / 577
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 578	[redacted] / 578
ABBV-951	1355.75		SC / CONTINUOUS	[redacted] / 579	[redacted] / 579
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 580	[redacted] / 583
ABBV-951		56.34	SC / ONCE	[redacted] / 584	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 584	[redacted] / 584
ABBV-951		18.78	SC / ONCE	[redacted] / 585	
ABBV-951	1174.07		SC / CONTINUOUS	[redacted] / 585	[redacted] / 585
ABBV-951		18.78	SC / ONCE	[redacted] / 586	
ABBV-951	1223.59		SC / CONTINUOUS	[redacted] / 586	[redacted] / 586
ABBV-951	1217.44		SC / CONTINUOUS	[redacted] / 587	[redacted] / 587
ABBV-951		112.69	SC / ONCE	[redacted] / 588	
ABBV-951	1259.45		SC / CONTINUOUS	[redacted] / 588	[redacted] / 588

ABBV-951		37.56	SC / ONCE	[redacted]20[redacted] / 589	
ABBV-951	1387.51		SC / CONTINUOUS	[redacted]20[redacted] / 589	[redacted]20[redacted] / 589
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 590	
ABBV-951	1379.66		SC / CONTINUOUS	[redacted]20[redacted] / 590	[redacted]20[redacted] / 590
ABBV-951	1161.1		SC / CONTINUOUS	[redacted]20[redacted] / 591	[redacted]20[redacted] / 591
ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 592	[redacted]20[redacted] / 594
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 595	
ABBV-951	1142.31		SC / CONTINUOUS	[redacted]20[redacted] / 595	[redacted]20[redacted] / 595
ABBV-951		75.13	SC / ONCE	[redacted]20[redacted] / 596	
ABBV-951	1196.95		SC / CONTINUOUS	[redacted]20[redacted] / 596	[redacted]20[redacted] / 596
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 597	
ABBV-951	1194.90		SC / CONTINUOUS	[redacted]20[redacted] / 597	[redacted]20[redacted] / 597
ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 598	
ABBV-951	1212.32		SC / CONTINUOUS	[redacted]20[redacted] / 598	[redacted]20[redacted] / 598
ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 599	
ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 599	[redacted]20[redacted] / 599
ABBV-951	930.58		SC / CONTINUOUS	[redacted]20[redacted] / 600	[redacted]20[redacted] / 600

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RAMELTEON	8 mg	QD	Y-M: 20[redacted]-[redacted]
MOSAPRIDE	5 mg	TID	Y-M: 20[redacted]-[redacted]
ESFLURBIPROFEN;MENTHA SPP. OIL	1 OTHER: SHEET	PRN	Y-M: 20[redacted]
ELDECALCITOL	0.75 mg	QD	Y-M: 20[redacted]-[redacted]
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / 1
CARBOCISTEINE	500 mg	TID	Y-M: 20[redacted]-[redacted] / 30
PARAFFIN	0.5 g	PRN	Y-M: 20[redacted]-[redacted] / 65
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]-[redacted] / 91
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	BID	Y-M: 20[redacted]-[redacted] / 128
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	250 mL	BID	Y-M: 20[redacted]-[redacted] / 247
ZONISAMIDE	25.000 mg	QD	Y-M: 20[redacted]-[redacted] / 304
RIVASTIGMINE	9 mg	QD	Y-M: 20[redacted]-[redacted] / 332

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
RAMELTEON	8 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ESFLURBIPROFEN;MENTHA SPP. OIL	1 OTHER: SHEET	PRN	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ELDECALCITOL	0.75 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 607
ETIZOLAM	0.5 mg	QD	Y-M: 20[redacted] / 1	Y-M: 20[redacted] / 607
CARBOCISTEINE	500 mg	TID	Y-M: 20[redacted] / 30	Y-M: 20[redacted] / 607
PARAFFIN	0.5 g	PRN	Y-M: 20[redacted] / 65	Y-M: 20[redacted] / 607
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted] / 91	Y-M: 20[redacted] / 607
ANGELICA ACUTILOBA ROOT;ATRACTYLODES LANCEA RHIZOME;BUPLEURUM FALCATUM ROOT;CNIDIUM OFFICINALE RHIZOME;GLYCYRRHIZA SPP. ROOT;PORIA COCOS SCLEROTIUM;UNCARIA SPP. HOOK	2.5 g	BID	Y-M: 20[redacted] / 128	Y-M: 20[redacted] / 607
CARBOHYDRATES NOS;FATTY ACIDS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	250 mL	BID	Y-M: 20[redacted] / 247	Y-M: 20[redacted] / 607
RIVASTIGMINE	9 mg	QD	Y-M: 20[redacted] / 332	Y-M: 20[redacted] / 607
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	1 OTHER: CAPSULE	BID	Y-M: 20[redacted] / 395	Y-M: 20[redacted] / 478
MOSAPRIDE CITRATE	5 mg	QD	Y-M: 20[redacted] / 395	Y-M: 20[redacted] / 607
QUETIAPINE	25 mg	QD	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 607
BENFOTIAMINE;CYANOCOBALAMIN;PYRIDOXINE HYDROCHLORIDE	2 OTHER: CAPSULES	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 562
BETAMETHASONE VALERATE	0.5 g	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 607

GENTAMICIN SULFATE	0.5 g	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 607
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 517	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 538	NOT REPORTED
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0.5 g	QD	Y-M: 20[redacted] / 592	Y-M: 20[redacted] / 607

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

Event Description	DERMATITIS(INFUSION SITE)
Preferred Term	注入部位皮膚炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 492
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	608
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: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	SUFFOCATION
Preferred Term	窒息
AE Onset Date / Rx Day	[redacted]20[redacted] / 608
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	608
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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ASPIRATION ACCIDENTALLY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Event #3: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	DUE TO ASPIRATION
Preferred Term	誤嚥
AE Onset Date / Rx Day	[redacted]20[redacted] / 608
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	608
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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	ASPIRATION ACCIDENTALLY
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

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 を投与中に誤嚥による死亡に至ったグレード 5 の窒息を発現した。

Event 2 及び 3 の臨床経過：

関連する病歴は，十二指腸潰瘍，パーキンソン病，統合失調症，不眠症，非喫煙者，及び元飲酒者（1 日 4 杯超）であった。

投与 608 日目，被験者は誤嚥による窒息を発現した。投与 608 日目，被験者は死亡した。死因は誤嚥による窒息と報告された。剖検が実施されたかは不明であった。

投与 608 日目の朝，被験者の介護者は 3 時間離れて戻ってきたとき，被験者がベッドの脇にあるごみ箱に頭を突っ込んで死んでいるのを発見した。

The patient's past medications include:

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

Causality for ABBV-951 (Open Label)

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1) Suffocation (10042443) (Asphyxia (10003497)) [v.24.0] [10042443]

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

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

Dechallenge: Not Applicable

2) Aspiration (10003504) (Aspiration (10003504)) [v.24.0] [10003504]

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 SUFFOCATION DUE TO ASPIRATION

- Investigator: aspiration accidentally

- AbbVie: More likely related to accidental aspiration (per PI) in an elderly patient with a history of Parkinson's disease.

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
COVID-19	X			
注入部位硬結				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	4[redacted]	MALE	ASIAN

Medical History	Onset Year
IDIOPATHIC HYPERTENSION	20[redacted]
FRACTURE(LEFT HAND)	20[redacted]
LARGE INTESTINE POLYP	20[redacted]
RECTAL CANCER	20[redacted]
RENAL CYST	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
LOWER ANTERIOR RESCTION	20[redacted]
LARGE INTESTINAL POLYPECTOMY	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.28	0.30	0.20	60	0.15	[redacted]20[redacted] / 364

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	430.29		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	954.83		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	975.32		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	967.12		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	963.03		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 6
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	971.22		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	975.32		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	979.42		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	930.24		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	975.32		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	940.49		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	926.14		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	930.24		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14

M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	953.46		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 16	
M15-741 /ABBV-951	937.75		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951		128.06	SC / ONCE	[redacted]20[redacted] / 17	
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	976.69		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	932.97		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	933.66		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	927.51		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
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M15-741 /ABBV-951	925.46		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	924.09		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951	930.92		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 25	
M15-741 /ABBV-951	910.43		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951	941.17		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	939.80		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	924.78		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	920.00		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	926.14		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	915.22		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	894.04		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	910.43		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33

M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	[redacted]	/ 34				
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	[redacted]	/ 35				
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 36				
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]	20	[redacted]	/ 37				
M15-741 /ABBV-951	941.17		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 37	[redacted]	20	[redacted]	/ 37
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	[redacted]	/ 38				
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	[redacted]	/ 39				
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]	20	[redacted]	/ 40				
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]	20	[redacted]	/ 41				
M15-741 /ABBV-951	930.24		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 41	[redacted]	20	[redacted]	/ 41
M15-741 /ABBV-951	944.58		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 42	[redacted]	20	[redacted]	/ 42
M15-741 /ABBV-951	960.29		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 43	[redacted]	20	[redacted]	/ 43
M15-741 /ABBV-951	976.00		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 44	[redacted]	20	[redacted]	/ 44
M15-741 /ABBV-951	982.83		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 45	[redacted]	20	[redacted]	/ 45
M15-741 /ABBV-951	990.35		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 46	[redacted]	20	[redacted]	/ 46
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 47				
M15-741 /ABBV-951	978.05		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 47	[redacted]	20	[redacted]	/ 47
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]	20	[redacted]	/ 48				
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]	20	[redacted]	/ 49				
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 50				
M15-741 /ABBV-951	1012.20		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 50	[redacted]	20	[redacted]	/ 50
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 51				
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 52				
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 53				
M15-741 /ABBV-951	939.12		SC / CONTINUOUS	[redacted]	20	[redacted]	/ 53	[redacted]	20	[redacted]	/ 53
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]	20	[redacted]	/ 54				
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]	20	[redacted]	/ 55				

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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	985.56		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1026.54		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	991.03		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1037.47		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1001.27		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	929.56		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 62	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	937.75		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 64	
M15-741 /ABBV-951	965.07		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 65	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951	973.27		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1008.10		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 68	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 69	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 70	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 71	
M15-741 /ABBV-951	959.61		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 72	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 73	
M15-741 /ABBV-951	1030.64		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 74	

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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 75	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 76	
M15-741 /ABBV-951	915.22		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 76
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 77	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 78	
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M15-741 /ABBV-951	887.9		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 81	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 82	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 83	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 84	
M15-741 /ABBV-951	1011.52		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 85	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 86	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 87	
M15-741 /ABBV-951	997.86		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 88	
M15-741 /ABBV-951	990.35		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 88
M15-741 /ABBV-951	894.73		SC / CONTINUOUS	[redacted]20[redacted] / 89	[redacted]20[redacted] / 89
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 90	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 91	
M15-741 /ABBV-951	980.78		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	980.10		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 93	
M15-741 /ABBV-951	982.83		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 94	

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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 95	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 96	
M15-741 /ABBV-951	967.12		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 96
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 97	
M15-741 /ABBV-951	1001.27		SC / CONTINUOUS	[redacted]20[redacted] / 97	[redacted]20[redacted] / 97
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 98	
M15-741 /ABBV-951	924.09		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 100	
M15-741 /ABBV-951	953.46		SC / CONTINUOUS	[redacted]20[redacted] / 100	[redacted]20[redacted] / 100
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 101	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 105	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 106	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 107	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 108	
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 112	
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 118
M15-741 /ABBV-951	970.54		SC / CONTINUOUS	[redacted]20[redacted] / 118 [redacted]20[redacted] / 118
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 119
M15-741 /ABBV-951	1011.52		SC / CONTINUOUS	[redacted]20[redacted] / 119 [redacted]20[redacted] / 119
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M15-741 /ABBV-951	997.86		SC / CONTINUOUS	[redacted]20[redacted] / 221	[redacted]20[redacted] / 221
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M15-741 /ABBV-951	994.44		SC / CONTINUOUS	[redacted]20[redacted] / 222	[redacted]20[redacted] / 223
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 225	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 322	
M15-741 /ABBV-951	1008.10		SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 323	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 324	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 327	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 328	
M15-741 /ABBV-951	997.86		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 329	
M15-741 /ABBV-951	1008.10		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 331	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 332	
M15-741 /ABBV-951	997.86		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 333	
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M15-741 /ABBV-951	1008.10		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 340	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 342	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 344	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 345	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 346	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 347	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 348	
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M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 350	
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M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 351	
M15-741 /ABBV-951	1018.35		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
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M15-741 /ABBV-951	1016.30		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 354	
M15-741 /ABBV-951	1004.69		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 355	
M15-741 /ABBV-951	994.44		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] / 355
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M15-741 /ABBV-951	1062.06		SC / CONTINUOUS	[redacted]20[redacted] / 364 [redacted]20[redacted] / 364
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ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 418	
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ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 423	
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ABBV-951	1023.13		SC / CONTINUOUS	[redacted]20[redacted] / 430 [redacted]20[redacted] / 430
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 431
ABBV-951	1011.52		SC / CONTINUOUS	[redacted]20[redacted] / 431 [redacted]20[redacted] / 431
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 432
ABBV-951	991.03		SC / CONTINUOUS	[redacted]20[redacted] / 432 [redacted]20[redacted] / 432
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 433
ABBV-951	1032.01		SC / CONTINUOUS	[redacted]20[redacted] / 433 [redacted]20[redacted] / 433
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 434
ABBV-951	1024.5		SC / CONTINUOUS	[redacted]20[redacted] / 434 [redacted]20[redacted] / 434
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 435
ABBV-951	977.37		SC / CONTINUOUS	[redacted]20[redacted] / 435 [redacted]20[redacted] / 435
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 436
ABBV-951	1055.23		SC / CONTINUOUS	[redacted]20[redacted] / 436 [redacted]20[redacted] / 436
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 437
ABBV-951	1009.13		SC / CONTINUOUS	[redacted]20[redacted] / 437 [redacted]20[redacted] / 437
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 438
ABBV-951	1009.47		SC / CONTINUOUS	[redacted]20[redacted] / 438 [redacted]20[redacted] / 438
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 439
ABBV-951	963.71		SC / CONTINUOUS	[redacted]20[redacted] / 439 [redacted]20[redacted] / 439
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 440
ABBV-951	941.17		SC / CONTINUOUS	[redacted]20[redacted] / 440 [redacted]20[redacted] / 440

ABBV-951	819.6		SC / CONTINUOUS	[redacted]20[redacted] / 441 [redacted]20[redacted] / 442
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 443
ABBV-951	1004.69		SC / CONTINUOUS	[redacted]20[redacted] / 443 [redacted]20[redacted] / 443
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 444
ABBV-951	1011.52		SC / CONTINUOUS	[redacted]20[redacted] / 444 [redacted]20[redacted] / 444
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 445
ABBV-951	1062.06		SC / CONTINUOUS	[redacted]20[redacted] / 445 [redacted]20[redacted] / 445
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 446
ABBV-951	984.20		SC / CONTINUOUS	[redacted]20[redacted] / 446 [redacted]20[redacted] / 446
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 447
ABBV-951	967.12		SC / CONTINUOUS	[redacted]20[redacted] / 447 [redacted]20[redacted] / 447
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 448
ABBV-951	994.44		SC / CONTINUOUS	[redacted]20[redacted] / 448 [redacted]20[redacted] / 448
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 449
ABBV-951	1051.82		SC / CONTINUOUS	[redacted]20[redacted] / 449 [redacted]20[redacted] / 449
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 450
ABBV-951	1030.64		SC / CONTINUOUS	[redacted]20[redacted] / 450 [redacted]20[redacted] / 450
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 451
ABBV-951	1018.35		SC / CONTINUOUS	[redacted]20[redacted] / 451 [redacted]20[redacted] / 451
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 452
ABBV-951	1010.84		SC / CONTINUOUS	[redacted]20[redacted] / 452 [redacted]20[redacted] / 452
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 453
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 453 [redacted]20[redacted] / 453
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 454
ABBV-951	982.83		SC / CONTINUOUS	[redacted]20[redacted] / 454 [redacted]20[redacted] / 454
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 455
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 455 [redacted]20[redacted] / 455
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 456
ABBV-951	1014.93		SC / CONTINUOUS	[redacted]20[redacted] / 456 [redacted]20[redacted] / 456
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 457
ABBV-951	1003.32		SC / CONTINUOUS	[redacted]20[redacted] / 457 [redacted]20[redacted] / 457
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 458
ABBV-951	1004.69		SC / CONTINUOUS	[redacted]20[redacted] / 458 [redacted]20[redacted] / 458
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 459
ABBV-951	955.51		SC / CONTINUOUS	[redacted]20[redacted] / 459 [redacted]20[redacted] / 459
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 460
ABBV-951	1006.05		SC / CONTINUOUS	[redacted]20[redacted] / 460 [redacted]20[redacted] / 460

ABBV-951		102.45	SC / ONCE	[redacted] / 461
ABBV-951	1008.79		SC / CONTINUOUS	[redacted] / 461 [redacted] / 461
ABBV-951		102.45	SC / ONCE	[redacted] / 462
ABBV-951	996.49		SC / CONTINUOUS	[redacted] / 462 [redacted] / 462
ABBV-951		102.45	SC / ONCE	[redacted] / 463
ABBV-951	1036.79		SC / CONTINUOUS	[redacted] / 463 [redacted] / 463
ABBV-951		128.06	SC / ONCE	[redacted] / 464
ABBV-951	1010.15		SC / CONTINUOUS	[redacted] / 464 [redacted] / 464
ABBV-951		76.83	SC / ONCE	[redacted] / 465
ABBV-951	1043.62		SC / CONTINUOUS	[redacted] / 465 [redacted] / 465
ABBV-951		76.83	SC / ONCE	[redacted] / 466
ABBV-951	1037.47		SC / CONTINUOUS	[redacted] / 466 [redacted] / 466
ABBV-951		76.83	SC / ONCE	[redacted] / 467
ABBV-951	982.83		SC / CONTINUOUS	[redacted] / 467 [redacted] / 467
ABBV-951		76.83	SC / ONCE	[redacted] / 468
ABBV-951	1003.32		SC / CONTINUOUS	[redacted] / 468 [redacted] / 468
ABBV-951		76.83	SC / ONCE	[redacted] / 469
ABBV-951	1047.03		SC / CONTINUOUS	[redacted] / 469 [redacted] / 469
ABBV-951		102.45	SC / ONCE	[redacted] / 470
ABBV-951	1023.81		SC / CONTINUOUS	[redacted] / 470 [redacted] / 470
ABBV-951		102.45	SC / ONCE	[redacted] / 471
ABBV-951	1037.47		SC / CONTINUOUS	[redacted] / 471 [redacted] / 471
ABBV-951		76.83	SC / ONCE	[redacted] / 472
ABBV-951	1081.18		SC / CONTINUOUS	[redacted] / 472 [redacted] / 472
ABBV-951		76.83	SC / ONCE	[redacted] / 473
ABBV-951	1014.93		SC / CONTINUOUS	[redacted] / 473 [redacted] / 473
ABBV-951		76.83	SC / ONCE	[redacted] / 474
ABBV-951	982.83		SC / CONTINUOUS	[redacted] / 474 [redacted] / 475
ABBV-951		76.83	SC / ONCE	[redacted] / 475
ABBV-951		76.83	SC / ONCE	[redacted] / 476
ABBV-951	1010.15		SC / CONTINUOUS	[redacted] / 476 [redacted] / 476
ABBV-951		102.45	SC / ONCE	[redacted] / 477
ABBV-951	1003.32		SC / CONTINUOUS	[redacted] / 477 [redacted] / 477
ABBV-951		76.83	SC / ONCE	[redacted] / 478
ABBV-951	1067.52		SC / CONTINUOUS	[redacted] / 478 [redacted] / 478
ABBV-951		102.45	SC / ONCE	[redacted] / 479
ABBV-951	1051.13		SC / CONTINUOUS	[redacted] / 479 [redacted] / 479

ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 480
ABBV-951	1042.25		SC / CONTINUOUS	[redacted]20[redacted] / 480 [redacted]20[redacted] / 480
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 481
ABBV-951	1003.32		SC / CONTINUOUS	[redacted]20[redacted] / 481 [redacted]20[redacted] / 481
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 482
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 482 [redacted]20[redacted] / 482
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 483
ABBV-951	1051.13		SC / CONTINUOUS	[redacted]20[redacted] / 483 [redacted]20[redacted] / 483
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 484
ABBV-951	1030.64		SC / CONTINUOUS	[redacted]20[redacted] / 484 [redacted]20[redacted] / 484
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 485
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 485 [redacted]20[redacted] / 485
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 486
ABBV-951	1044.30		SC / CONTINUOUS	[redacted]20[redacted] / 486 [redacted]20[redacted] / 486
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 487
ABBV-951	1051.13		SC / CONTINUOUS	[redacted]20[redacted] / 487 [redacted]20[redacted] / 487
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 488
ABBV-951	993.08		SC / CONTINUOUS	[redacted]20[redacted] / 488 [redacted]20[redacted] / 488
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 489
ABBV-951	1016.98		SC / CONTINUOUS	[redacted]20[redacted] / 489 [redacted]20[redacted] / 489
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 490
ABBV-951	1068.21		SC / CONTINUOUS	[redacted]20[redacted] / 490 [redacted]20[redacted] / 490
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 491
ABBV-951	1047.03		SC / CONTINUOUS	[redacted]20[redacted] / 491 [redacted]20[redacted] / 491
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 492
ABBV-951	1040.20		SC / CONTINUOUS	[redacted]20[redacted] / 492 [redacted]20[redacted] / 492
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 493
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 493 [redacted]20[redacted] / 493
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 494
ABBV-951	1043.62		SC / CONTINUOUS	[redacted]20[redacted] / 494 [redacted]20[redacted] / 494
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 495
ABBV-951	982.83		SC / CONTINUOUS	[redacted]20[redacted] / 495 [redacted]20[redacted] / 495
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 496
ABBV-951	996.49		SC / CONTINUOUS	[redacted]20[redacted] / 496 [redacted]20[redacted] / 496
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 497
ABBV-951	1047.03		SC / CONTINUOUS	[redacted]20[redacted] / 497 [redacted]20[redacted] / 497
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 498

ABBV-951	1026.89		SC / CONTINUOUS	[redacted]20[redacted] / 498	[redacted]20[redacted] / 498
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 499	
ABBV-951	999.22		SC / CONTINUOUS	[redacted]20[redacted] / 499	[redacted]20[redacted] / 499
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 500	
ABBV-951	1033.37		SC / CONTINUOUS	[redacted]20[redacted] / 500	[redacted]20[redacted] / 500
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 501	
ABBV-951	978.73		SC / CONTINUOUS	[redacted]20[redacted] / 501	[redacted]20[redacted] / 502
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 502	
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 503	
ABBV-951	973.95		SC / CONTINUOUS	[redacted]20[redacted] / 503	[redacted]20[redacted] / 503
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 504	
ABBV-951	965.07		SC / CONTINUOUS	[redacted]20[redacted] / 504	[redacted]20[redacted] / 505
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 505	
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 506	
ABBV-951	973.27		SC / CONTINUOUS	[redacted]20[redacted] / 506	[redacted]20[redacted] / 506
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 507	
ABBV-951	984.88		SC / CONTINUOUS	[redacted]20[redacted] / 507	[redacted]20[redacted] / 507
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 508	
ABBV-951	1006.05		SC / CONTINUOUS	[redacted]20[redacted] / 508	[redacted]20[redacted] / 508
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 509	
ABBV-951	987.61		SC / CONTINUOUS	[redacted]20[redacted] / 509	[redacted]20[redacted] / 509
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 510	
ABBV-951	996.49		SC / CONTINUOUS	[redacted]20[redacted] / 510	[redacted]20[redacted] / 510
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 511	
ABBV-951	1025.86		SC / CONTINUOUS	[redacted]20[redacted] / 511	[redacted]20[redacted] / 511
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 512	
ABBV-951	1010.15		SC / CONTINUOUS	[redacted]20[redacted] / 512	[redacted]20[redacted] / 512
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 513	
ABBV-951	976.00		SC / CONTINUOUS	[redacted]20[redacted] / 513	[redacted]20[redacted] / 513
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 514	
ABBV-951	1016.98		SC / CONTINUOUS	[redacted]20[redacted] / 514	[redacted]20[redacted] / 514
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 515	
ABBV-951	1009.47		SC / CONTINUOUS	[redacted]20[redacted] / 515	[redacted]20[redacted] / 515
ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 516	
ABBV-951	999.22		SC / CONTINUOUS	[redacted]20[redacted] / 516	[redacted]20[redacted] / 516
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 517	
ABBV-951	993.08		SC / CONTINUOUS	[redacted]20[redacted] / 517	[redacted]20[redacted] / 517

ABBV-951		102.45	SC / ONCE	[redacted] / 518
ABBV-951	1023.81		SC / CONTINUOUS	[redacted] / 518 [redacted] / 518
ABBV-951		76.83	SC / ONCE	[redacted] / 519
ABBV-951	1016.98		SC / CONTINUOUS	[redacted] / 519 [redacted] / 519
ABBV-951		102.45	SC / ONCE	[redacted] / 520
ABBV-951	1014.93		SC / CONTINUOUS	[redacted] / 520 [redacted] / 520

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ISTRADEFYLLINE	40.000 mg	QD	Y-M: 20[redacted]
RASAGILINE MESYLATE	1.000 mg	QD	Y-M: 20[redacted]
OLMESARTAN MEDOXOMIL	15 mg	QD	Y-M: 20[redacted] / -358
CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FURSULTIAMINE HYDROCHLORIDE;ORYZANOL;PYRIDOXINE HYDROCHLORIDE;TOCOPHEROL CALCIUM SUCCINATE	3 OTHER: T	QD	Y-M: 20[redacted] / -27
BETAMETHASONE VALERATE	0.5 g	QD	Y-M: 20[redacted] / 182
GENTAMICIN SULFATE	0.5 g	QD	Y-M: 20[redacted] / 182
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0.5 g	QD	Y-M: 20[redacted] / 182
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	1 g	BID	Y-M: 20[redacted] / 271
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 291
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 312

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
OLMESARTAN MEDOXOMIL	15 mg	QD	Y-M: 20[redacted] / -358	NOT REPORTED
CALCIUM PANTOTHENATE;CYANOCOBALAMIN;FURSULTIAMINE HYDROCHLORIDE;ORYZANOL;PYRIDOXINE	3 OTHER: T	QD	Y-M: 20[redacted] / -27	NOT REPORTED

HYDROCHLORIDE;TOCOPHEROL CALCIUM SUCCINATE				
BETAMETHASONE VALERATE	0.5 g	QD	Y-M: 20[redacted] / 182	NOT REPORTED
GENTAMICIN SULFATE	0.5 g	QD	Y-M: 20[redacted] / 182	NOT REPORTED
MUCOPOLYSACCHARIDE POLYSULFURIC ACID ESTER	0.5 g	QD	Y-M: 20[redacted] / 182	NOT REPORTED
ADENOSINE TRIPHOSPHATE, DISODIUM SALT	1 g	BID	Y-M: 20[redacted] / 271	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 291	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 312	NOT REPORTED
MAGNESIUM OXIDE	500 mg	TID	Y-M: 20[redacted] / 390	NOT REPORTED
MOSAPRIDE CITRATE	5 mg	TID	Y-M: 20[redacted] / 390	NOT REPORTED
CEFCAPENE PIVOXIL HYDROCHLORIDE HYDRATE	100 mg	TID	Y-M: 20[redacted] / 404	NOT REPORTED
NADIFLOXACIN	0.5 g	BID	Y-M: 20[redacted] / 404	NOT REPORTED
SOTROVIMAB	500 mg	QD	Y-M: 20[redacted] / 501	Y-M: 20[redacted] / 501

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

Event Description	INDURATION IN THE RIGHT UPPER QUADRANT OF THE ABDOMEN AND CARDIAC REGION AT INFUSION SITE
Preferred Term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 399
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

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

Event #2: Serious Adverse Event

Event Description	COVID-19 INFECTION
Preferred Term	COVID-19
AE Onset Date / Rx Day	[redacted]20[redacted] / 498
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
[redacted]20[redacted] (RX DAY 500): OTHER NASOPHARYNGEAL SWAB ANTIGEN: POSITIVE-COVID-19	
AE Stopped Rx Day	505
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 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	BECAUSE OF AN ACCIDENTAL EVENT
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は日本の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に COVID-19 感染を発現した。

Event 2 の臨床経過：

関連する病歴は，特発性高血圧，パーキンソン病，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 498 日目，被験者は COVID-19 感染を発現した。投与 505 日目，COVID-19 感染は消失した。

投与 500 日目，被験者は微熱を出し，COVID-19 検査が陽性であった。投与 501 日目被験者は咽頭痛及び倦怠感を伴って入院した。投与 505 日目，被験者の発熱は回復し，退院後，ホテルで隔離を継続した。

被験者にソトロビマブ（遺伝子組換え）が投与された。

The patient's past medications include:

COMIRNATY INTRAMUSCULAR INJECTION(PFIZER) COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) 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-19 INFECTION

- Investigator: Because of an accidental event.

- AbbVie: The event is more likely related to a pandemic outbreak

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] COVID-19 ANTIGEN TEST:** NASOPHARYNGEAL SWAB : Positive

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
感覚鈍麻				X
注入部位蜂巣炎	X			X
注入部位硬結				X
注射部位蜂巣炎				X
錯感覚				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	ASIAN

Medical History	Onset Year
DUODENAL ULCER	19[redacted]
CALCULUS URINARY	19[redacted]
ANXIETY NEUROSIS	20[redacted]
CONSTIPATION	20[redacted]
INSOMNIA	20[redacted]
DROPPED HEAD SYNDROME	20[redacted]
NAUSEA	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1.5 CIGARETTE	17	20[redacted]
CIGARS	NEVER			

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	2 - 4 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.49	0.51	0.47	60	0.19	[redacted] / 365
ABBV-951	0.49	0.51	0.47	60	0.19	[redacted] / 536
ABBV-951	0.51	0.53	0.48	60	0.19	[redacted] / 562
ABBV-951	0.51	0.53	0.48	60	0.19	[redacted] / 694
ABBV-951	0.55	0.58	0.51	60	0.24	[redacted] / 809
ABBV-951	0.55	0.58	0.51	60	0.24	[redacted] / 855

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	785.45		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 2	[redacted] / 6
M15-741 /ABBV-951	1612.39		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	976.51		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 10	
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 10	[redacted] / 11
M15-741 /ABBV-951	1747.45		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1703.40		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	1680.18		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	1808.24		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 16	[redacted] / 17
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951	1770.67		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 19	
M15-741 /ABBV-951	1844.95		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19

M15-741 /ABBV-951	1856.90		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1782.63		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1863.73		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 29
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1805.68		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951	1845.80		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951	1753.94		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 36
M15-741 /ABBV-951	1874.83		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 40
M15-741 /ABBV-951	1805.68		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951	1751.89		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	1759.57		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	1844.1		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 59
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1898.56		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	1936.30		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	1890.20		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951	1790.31		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951	1836.24		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951	1847.85		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1925.37		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 90
M15-741 /ABBV-951	1996.57		SC / CONTINUOUS	[redacted]20[redacted] / 91	[redacted]20[redacted] / 91
M15-741 /ABBV-951	1650.12		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 127
M15-741 /ABBV-951	2036.36		SC / CONTINUOUS	[redacted]20[redacted] / 128	[redacted]20[redacted] / 128
M15-741 /ABBV-951	2057.19		SC / CONTINUOUS	[redacted]20[redacted] / 129	[redacted]20[redacted] / 129
M15-741 /ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 130	[redacted]20[redacted] / 152
M15-741 /ABBV-951	1988.21		SC / CONTINUOUS	[redacted]20[redacted] / 153	[redacted]20[redacted] / 153
M15-741 /ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 154	[redacted]20[redacted] / 154
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 155	

M15-741 /ABBV-951	2031.24	SC / CONTINUOUS	[redacted]20[redacted] / 155	[redacted]20[redacted] / 155
M15-741 /ABBV-951	1946.55	SC / CONTINUOUS	[redacted]20[redacted] / 156	[redacted]20[redacted] / 156
M15-741 /ABBV-951	1926.06	SC / CONTINUOUS	[redacted]20[redacted] / 157	[redacted]20[redacted] / 162
M15-741 /ABBV-951	1963.28	SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
M15-741 /ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
M15-741 /ABBV-951	2017.24	SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
M15-741 /ABBV-951	1938.01	SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
M15-741 /ABBV-951	1926.06	SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 177
M15-741 /ABBV-951	1935.79	SC / CONTINUOUS	[redacted]20[redacted] / 178	[redacted]20[redacted] / 178
M15-741 /ABBV-951	2041.48	SC / CONTINUOUS	[redacted]20[redacted] / 179	[redacted]20[redacted] / 179
M15-741 /ABBV-951	1991.62	SC / CONTINUOUS	[redacted]20[redacted] / 180	[redacted]20[redacted] / 180
M15-741 /ABBV-951	1985.13	SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951	1973.69	SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	1864.24	SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951	1966.18	SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 184
M15-741 /ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 185	[redacted]20[redacted] / 192
M15-741 /ABBV-951	1920.93	SC / CONTINUOUS	[redacted]20[redacted] / 193	[redacted]20[redacted] / 193
M15-741 /ABBV-951	1839.83	SC / CONTINUOUS	[redacted]20[redacted] / 194	[redacted]20[redacted] / 194
M15-741 /ABBV-951	1926.06	SC / CONTINUOUS	[redacted]20[redacted] / 195	[redacted]20[redacted] / 195
M15-741 /ABBV-951	1885.93	SC / CONTINUOUS	[redacted]20[redacted] / 196	[redacted]20[redacted] / 196
M15-741 /ABBV-951	1925.20	SC / CONTINUOUS	[redacted]20[redacted] / 197	[redacted]20[redacted] / 197
M15-741 /ABBV-951	1982.91	SC / CONTINUOUS	[redacted]20[redacted] / 198	[redacted]20[redacted] / 198
M15-741 /ABBV-951	1729.01	SC / CONTINUOUS	[redacted]20[redacted] / 199	[redacted]20[redacted] / 199
M15-741 /ABBV-951	1926.06	SC / CONTINUOUS	[redacted]20[redacted] / 200	[redacted]20[redacted] / 200
M15-741 /ABBV-951	1411.41	SC / CONTINUOUS	[redacted]20[redacted] / 201	[redacted]20[redacted] / 201
M15-741 /ABBV-951	1976.94	SC / CONTINUOUS	[redacted]20[redacted] / 202	[redacted]20[redacted] / 202
M15-741 /ABBV-951	1974.21	SC / CONTINUOUS	[redacted]20[redacted] / 203	[redacted]20[redacted] / 203
M15-741 /ABBV-951	1907.61	SC / CONTINUOUS	[redacted]20[redacted] / 204	[redacted]20[redacted] / 204
M15-741 /ABBV-951	2008.02	SC / CONTINUOUS	[redacted]20[redacted] / 205	[redacted]20[redacted] / 271
M15-741 /ABBV-951	1962.42	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	1898.74	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
M15-741 /ABBV-951	1950.47	SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274

M15-741 /ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 299
M15-741 /ABBV-951	1933.91		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 301	
M15-741 /ABBV-951	2011.09		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
M15-741 /ABBV-951	1997.43		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
M15-741 /ABBV-951	2007.33		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
M15-741 /ABBV-951	1977.96		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 362
M15-741 /ABBV-951	1893.95		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
M15-741 /ABBV-951	1745.40		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
ABBV-951	819.94		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
M15-741 /ABBV-951	1907.61		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	2008.02		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 439
ABBV-951	1990.77		SC / CONTINUOUS	[redacted]20[redacted] / 440	[redacted]20[redacted] / 440
ABBV-951	1936.30		SC / CONTINUOUS	[redacted]20[redacted] / 441	[redacted]20[redacted] / 441
ABBV-951	2011.60		SC / CONTINUOUS	[redacted]20[redacted] / 442	[redacted]20[redacted] / 442
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 443	[redacted]20[redacted] / 533
ABBV-951	1932.20		SC / CONTINUOUS	[redacted]20[redacted] / 534	[redacted]20[redacted] / 534
ABBV-951	1966.18		SC / CONTINUOUS	[redacted]20[redacted] / 535	[redacted]20[redacted] / 535
ABBV-951	2020.14		SC / CONTINUOUS	[redacted]20[redacted] / 536	[redacted]20[redacted] / 536
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 537	[redacted]20[redacted] / 614

ABBV-951	1978.48		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951	2073.75		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951	2004.60		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 617
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 618	[redacted]20[redacted] / 691
ABBV-951	2019.46		SC / CONTINUOUS	[redacted]20[redacted] / 692	[redacted]20[redacted] / 692
ABBV-951	2044.04		SC / CONTINUOUS	[redacted]20[redacted] / 693	[redacted]20[redacted] / 693
ABBV-951	1972.16		SC / CONTINUOUS	[redacted]20[redacted] / 694	[redacted]20[redacted] / 694
ABBV-951	2089.98		SC / CONTINUOUS	[redacted]20[redacted] / 695	[redacted]20[redacted] / 796
ABBV-951	2065.73		SC / CONTINUOUS	[redacted]20[redacted] / 797	[redacted]20[redacted] / 797
ABBV-951	1871.42		SC / CONTINUOUS	[redacted]20[redacted] / 798	[redacted]20[redacted] / 798
ABBV-951	2073.24		SC / CONTINUOUS	[redacted]20[redacted] / 799	[redacted]20[redacted] / 799
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 800	[redacted]20[redacted] / 852
ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 853	
ABBV-951	471.61		SC / CONTINUOUS	[redacted]20[redacted] / 853	[redacted]20[redacted] / 853
ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 854	[redacted]20[redacted] / 854

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
CLONAZEPAM	0.5 mg	QD	Y-M: 20[redacted]
ZONISAMIDE	100.000 mg	BID	Y-M: 20[redacted]
BROMAZEPAM	1 mg	PRN	Y-M: 20[redacted]
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted] / -226
HYALURONATE SODIUM	APPLICATION mL	QID	Y-M: 20[redacted] / 40
PIRENOXINE SODIUM	APPLICATION mL	QID	Y-M: 20[redacted] / 40
CLOBETASOL PROPIONATE	APPLICATION mg	PRN	Y-M: 20[redacted] / 65
GENTAMICIN SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 65
PYRIDOXAL PHOSPHATE	30 mg	QD	Y-M: 20[redacted] / 65
LUBIPROSTONE	24 ug	PRN	Y-M: 20[redacted] / 69
EPINASTINE HYDROCHLORIDE	20 mg	BID	Y-M: 20[redacted] / 79
ELOBIXIBAT	15 mg	PRN	Y-M: 20[redacted] / 80

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	QD	Y-M: 20[redacted]	NOT REPORTED
BROMAZEPAM	1 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
HYALURONATE SODIUM	APPLICATION mL	QID	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 642
PIRENOXINE SODIUM	APPLICATION mL	QID	Y-M: 20[redacted] / 40	Y-M: 20[redacted] / 642
CLOBETASOL PROPIONATE	APPLICATION mg	PRN	Y-M: 20[redacted] / 65	NOT REPORTED
GENTAMICIN SULFATE	APPLICATION OTHER: APPLICATION	PRN	Y-M: 20[redacted] / 65	NOT REPORTED
PYRIDOXAL PHOSPHATE	30 mg	QD	Y-M: 20[redacted] / 65	NOT REPORTED
LUBIPROSTONE	24 ug	PRN	Y-M: 20[redacted] / 69	NOT REPORTED
EPINASTINE HYDROCHLORIDE	20 mg	BID	Y-M: 20[redacted] / 79	NOT REPORTED
ELOBIXIBAT	15 mg	PRN	Y-M: 20[redacted] / 80	NOT REPORTED
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 454
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 644	NOT REPORTED
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted] / 647	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 665	NOT REPORTED
MECOBALAMIN	500 ug	TID	Y-M: 20[redacted] / 766	NOT REPORTED
CEFCAPENE PIVOXIL HYDROCHLORIDE	100 mg	TID	Y-M: 20[redacted] / 779	Y-M: 20[redacted] / 786
CLOSTRIDIUM BUTYRICUM	2 OTHER: TABLET	TID	Y-M: 20[redacted] / 779	Y-M: 20[redacted] / 786
CEFAZOLIN SODIUM	1 g	QD	Y-M: 20[redacted] / 812	Y-M: 20[redacted] / 812
HEPARIN SODIUM	5 mL	QD	Y-M: 20[redacted] / 812	Y-M: 20[redacted] / 812
CEFAZOLIN SODIUM	1 g	TID	Y-M: 20[redacted] / 813	Y-M: 20[redacted] / 813
HEPARIN SODIUM	5 mL	TID	Y-M: 20[redacted] / 813	Y-M: 20[redacted] / 813
HEPARIN SODIUM	5 mL	QD	Y-M: 20[redacted] / 814	Y-M: 20[redacted] / 815
CEFAZOLIN SODIUM	1 g	BID	Y-M: 20[redacted] / 814	Y-M: 20[redacted] / 819
HEPARIN SODIUM	5 mL	BID	Y-M: 20[redacted] / 816	Y-M: 20[redacted] / 817
HEPARIN SODIUM	5 mL	QD	Y-M: 20[redacted] / 818	Y-M: 20[redacted] / 819
CEFACLOR	250 mg	QD	Y-M: 20[redacted] / 820	Y-M: 20[redacted] / 820
CEFAZOLIN SODIUM	1 g	QD	Y-M: 20[redacted] / 820	Y-M: 20[redacted] / 820

CEFACLOR	250 mg	TID	Y-M: 20[redacted] / 821	Y-M: 20[redacted] / 825
GENTAMICIN SULFATE	APPLICATION mg	PRN	Y-M: 20[redacted] / 855	NOT REPORTED
FAROPENEM SODIUM	200 mg	TID	Y-M: 20[redacted] / 855	Y-M: 20[redacted] / 861
DOXYCYCLINE	50 mg	BID	Y-M: 20[redacted] / 864	NOT REPORTED

Event #1: 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] / 448
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	454
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 - Polyneuropathy

Event Description	NUMBNESS OF RT ULNAR NERVE REGION
Preferred Term	感覚鈍麻
AE Onset Date / Rx Day	[redacted]20[redacted] / 633
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	663
Duration of AE	31 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	A LOT OF INDURATION OF INFUSION SITE
Preferred Term	注入部位硬結
AE Onset Date / Rx Day	[redacted]20[redacted] / 646
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	671
Duration of AE	26 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 778
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	799
Duration of AE	22 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #5: Serious Adverse Event, Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS OF INFUSION SITE
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 811
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 812): Leukocytes: 7.5 [3.5 - 8.5] 10^9/L; NPTST020-CRP: 5.59 [NOT REPORTED - 0.3] mg/dL; Neutrophils/Leukocytes: 77.7 [41.2 - 74.7] %; [redacted]20[redacted] (RX DAY 815): Leukocytes: 4.5 [3.5 - 8.5] 10^9/L; NPTST020-CRP: 2.40 [NOT REPORTED - 0.3] mg/dL; Neutrophils/Leukocytes: 64.8 [41.2 - 74.7] %; [redacted]20[redacted] (RX DAY 820): Leukocytes: 4.1 [3.5 - 8.5] 10^9/L; NPTST020-CRP: 0.23 [NOT REPORTED - 0.3] mg/dL; Neutrophils/Leukocytes: 57.5 [41.2 - 74.7] %

Microbiology

[redacted]20[redacted] (RX DAY 812): BLOOD GNC: NEGATIVE; BLOOD GNR: NEGATIVE; BLOOD GPC: NEGATIVE; BLOOD GPR: NEGATIVE; BLOOD YEAST: NEGATIVE

AE Stopped Rx Day	855
Duration of AE	45 DAYS

Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Event of Interest - Polyneuropathy

Event Description	PARAESTHESIA OF BACK
Preferred Term	錯感覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 826
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	829
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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship 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 THE INJECTION SITE
Preferred Term	注射部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 852

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は日本の 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に注入部位の蜂巣炎を発現した。

Event 5 の臨床経過：

関連する病歴は，元喫煙者（1 日 1.5 本を 17 年間），パーキンソン病，及び飲酒者（1 日 2–4 杯未満）であった。

投与 811 日目，被験者は注入部位の蜂巣炎を発現した。投与 855 日目，注入部位の蜂巣炎は消失した。

本事象の発現前，被験者は投与から約 1 ヵ月後に非重篤な注入部位硬結，注入部位の発赤，及び注入部位の腫瘤を発現した。投与から約 2 ヵ月後及び投与 778 日目，被験者は非重篤な注入部位蜂巣炎を発現した。

投与 809 日目，被験者の腹部に注射針の挿入による複数の腫瘤，硬結，及び疼痛が認められた。対処法として，大腿部及び上腕部を用いて治験薬の投与を継続した。投与 810 日目，注射部位を右大腿部から左大腿部に変更した。

投与 811 日目，右大腿部の注射部位に広範囲に及ぶ発赤，腫脹，疼痛，及び 37.4°C の発熱が認められた。更に，被験者は気分が悪くなり，歩行が困難となった。治験責任医師によると，疼痛は強く，治験薬の効果は認められなかった。

投与 812 日目，被験者は入院し，右大腿部の中等度の蜂巣炎と診断された。蜂巣炎及び基礎疾患に対する治療が実施された。また，臨床検査及び診察が実施された。治験薬の投与は継続された。投与 820 日目，蜂巣炎は改善し，被験者は退院した。

被験者にセファゾリンナトリウム及びセファクロルが投与された。

The patient's past medications include:

COMIRNATY for COVID-19 VACCINE PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

CARBIDOPA/LEVODOPA 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.24.1] [10065455]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of CELLULITIS OF INFUSION SITE

- Investigator: Not applicable.

- AbbVie: Not applicable.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY TEMPERATURE:** 37.4 Degrees C

[redacted] **20[redacted] BODY WEIGHT:** 7[redacted] KG

[redacted] **20[redacted] COVID-19 TEST:** Molecular test negative

[redacted] **20[redacted] CRP:** 5.59 mg/dL (normal <0.3)

[redacted] **20[redacted] CRP:** 2.40 mg/dL (normal <0.3)

[redacted] **20[redacted] CRP:** 0.23 mg/dL (normal <0.3)

[redacted] **20[redacted] CT (FROM CHEST TO PELVIS):** Consistent with cellulitis

[redacted] **20[redacted] CULTURES:** Not reported

[redacted] **20[redacted] GNC (BLOOD):** Negative

[redacted] **20[redacted] GNR (BLOOD):** Negative

[redacted] **20[redacted] GPC (BLOOD):** Negative

[redacted] **20[redacted] GPR (BLOOD):** Negative

[redacted] **20[redacted] NEUTROPHILS %:** 77.7% (normal 41.2 to 74.7)

[redacted] **20[redacted] NEUTROPHILS %:** 64.8% (normal 41.2 to 74.7)

[redacted] **20[redacted] URINE TEST:** Not reported

[redacted] **20[redacted] WHITE BLOOD CELLS:** 7520 /uL (normal 3500 to 8500)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 4490 /uL (normal 3500 to 8500)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 4050 /uL (normal 3500 to 8500)

[redacted] **20[redacted] YEAST (BLOOD):** Negative

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
注入部位蜂巣炎	X			X
注入部位紅斑				X
注入部位腫脹				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
HYPERTENSION	20[redacted]
PARKINSON'S DISEASE	20[redacted]
SLEEP DISTUTBANCE	20[redacted]
SQUAMOUS CELL CARCINOMA	20[redacted]
SESATION OF PARESTHESIA BOTH FEET TRANSCIENTLY AFTER WALKING	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
REMOVAL OF SQUAMOUS CELL CARCINOMA FROM LEFT EYEBROW	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.28	0.29	0.24	60	0.11	[redacted] / 428
ABBV-951	0.28	0.29	0.24	60	0.11	[redacted] / 596

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	339.62		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	696.66		SC / CONTINUOUS	[redacted] / 2	[redacted] / 12
M15-741 /ABBV-951	765.81		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	819.6		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951	911.80		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 16	[redacted] / 19
M15-741 /ABBV-951	1027.23		SC / CONTINUOUS	[redacted] / 20	[redacted] / 20
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 21	[redacted] / 21
M15-741 /ABBV-951	1113.29		SC / CONTINUOUS	[redacted] / 22	[redacted] / 22
M15-741 /ABBV-951	1031.33		SC / CONTINUOUS	[redacted] / 23	[redacted] / 23
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 24	[redacted] / 40
M15-741 /ABBV-951	1004.01		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951	1096.89		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951	1143.34		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 44	[redacted] / 89
M15-741 /ABBV-951	1153.24		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951	1140.61		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951	1119.09		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted] / 93	[redacted] / 180
M15-741 /ABBV-951	1058.65		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1076.06		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 183	[redacted] / 271

M15-741 /ABBV-951	1067.69	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	1089.04	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
M15-741 /ABBV-951	986.08	SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
M15-741 /ABBV-951	983.52	SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 425
M15-741 /ABBV-951	1076.06	SC / CONTINUOUS	[redacted]20[redacted] / 426	[redacted]20[redacted] / 426
M15-741 /ABBV-951	1075.55	SC / CONTINUOUS	[redacted]20[redacted] / 427	[redacted]20[redacted] / 427
ABBV-951	525.91	SC / CONTINUOUS	[redacted]20[redacted] / 428	[redacted]20[redacted] / 428
M15-741 /ABBV-951	1088.18	SC / CONTINUOUS	[redacted]20[redacted] / 428	[redacted]20[redacted] / 428
ABBV-951	1147.44	SC / CONTINUOUS	[redacted]20[redacted] / 429	[redacted]20[redacted] / 509
ABBV-951	1167.41	SC / CONTINUOUS	[redacted]20[redacted] / 510	[redacted]20[redacted] / 510
ABBV-951	1089.21	SC / CONTINUOUS	[redacted]20[redacted] / 511	[redacted]20[redacted] / 511
ABBV-951	983.52	SC / CONTINUOUS	[redacted]20[redacted] / 512	[redacted]20[redacted] / 593
ABBV-951	1068.89	SC / CONTINUOUS	[redacted]20[redacted] / 594	[redacted]20[redacted] / 594
ABBV-951	1055.40	SC / CONTINUOUS	[redacted]20[redacted] / 595	[redacted]20[redacted] / 595
ABBV-951	983.52	SC / CONTINUOUS	[redacted]20[redacted] / 596	[redacted]20[redacted] / 670
ABBV-951	1066.67	SC / CONTINUOUS	[redacted]20[redacted] / 671	[redacted]20[redacted] / 671
ABBV-951	1058.13	SC / CONTINUOUS	[redacted]20[redacted] / 672	[redacted]20[redacted] / 672
ABBV-951	983.52	SC / CONTINUOUS	[redacted]20[redacted] / 673	[redacted]20[redacted] / 673

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
HYDROCHLOROTHIAZIDE	12.5 mg	QD	Y-M: 20[redacted]
IRBESARTAN	300 mg	QD	Y-M: 20[redacted]
MOXONIDINE	0.2 mg	QD	Y-M: 20[redacted]
VERAPAMIL HYDROCHLORIDE	180 mg	QD	Y-M: 20[redacted]
PRAMIPEXOLE	4.500 mg	QD	Y-M: 20[redacted]
LORAZEPAM	0.25 mg	PRN	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
MOXONIDINE	0.2 mg	QD	Y-M: 20[redacted]	NOT REPORTED
VERAPAMIL HYDROCHLORIDE	180 mg	QD	Y-M: 20[redacted]	NOT REPORTED
HYDROCHLOROTHIAZIDE	12.5 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 740
IRBESARTAN	300 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted]-[redacted] / 740
LORAZEPAM	0.25 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
AMOXICILLIN	500 mg	BID	Y-M: 20[redacted]-[redacted] / 731	Y-M: 20[redacted]-[redacted] / 732
ERYTHROMYCIN	250 mg	QID	Y-M: 20[redacted]-[redacted] / 732	Y-M: 20[redacted]-[redacted] / 739
FLUCLOXACILLIN SODIUM	500 mg	QID	Y-M: 20[redacted]-[redacted] / 740	Y-M: 20[redacted]-[redacted] / 742
FLUCLOXACILLIN	500MG mg	QID	Y-M: 20[redacted]-[redacted] / 742	NOT REPORTED

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

Event Description	ABDOMINAL REDNESS LEFT LOWER QUADRANT AT INFUSION SITE
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 731
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	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 APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ABDOMINAL SWELLING LEFT LOWER QUADRANT AT INFUSION SITE
Preferred Term	注入部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 731
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	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 APPLICABLE
SAE: Investigator Opinion of Relationship 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 ABDOMINAL WALL AT INFUSION SITE PLEASE NOTE THIS IS THE PRINCIPAL DIAGNOSIS ON THE SUBSEQUENT DISCHARGE SUMMARY
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 740
Age at AE Onset	6[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 740): Creatinine: 117 [45 - 90] UMOL/L; Creatinine: 147 [45 - 90] UMOL/L; Glucose: 5.9 [3 - 5.4] MMOL/L; Hemoglobin: 113 [115 - 160] G/L; Lactate Dehydrogenase: 3.1 [NOT REPORTED - 2] mmol/L; NPTST025-EGFR: 43 [60 - 60] ML/MIN/1.73M2; NPTST046-O2 SATURATION: 82 [70 - 80] %; NPTST048-PO2: 53 [36 - 44] MMHG; NPTST055-UREA: 18.6 [3 - 8] MMOL/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に注入部位の腹壁に蜂巣炎を発現した。

Event 3 の臨床経過：

関連する病歴は，高血圧，パーキンソン病，睡眠障害，非喫煙者，及び非飲酒者であった。

投与 740 日目，被験者は注入部位の腹壁に蜂巣炎を発現した。

本事象の発現前，被験者は投与 731 日目に非重篤な有害事象として，注入部位である左下腹部の発赤，左下腹部の腫脹，悪心，及び疲労を発現した。

投与 740 日目，被験者は低血圧及び徐脈を伴って救急診療部に来院した。被験者は腹部の注入部位の蜂巣炎に対してエリスロマイシンを 7 日間投与していた。被験者はジスキネジアが増強したため，発汗が認められた。検査では，被験者の腹部は固く，注入部位周辺に直径 5 cm の触診可能な軽度の紅斑部位が認められた。同日，被験者は入院した。被験者に対し，静脈内輸液及びフルクロキサシリンの静脈内投与を実施した。腎毒性のある抗高血圧治療薬であるヒドロクロロチアジド及びイルベサルタンの投与は休止した。静脈内輸液後に浮動性めまい及びジスキネジアは改善し，その後も抗生物質の投与により蜂巣炎は改善した。投与 742 日目，被験者は退院した。

被験者にフルクロキサシリン及びエリスロマイシンが投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site cellulitis (10065455) (Infusion site cellulitis (10065455)) [v.24.1] [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 ABDOMINAL WALL AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ABDOMINAL ULTRASOUND:** left lateral wall, irregular hypoechoic area spanning 17 mm likely to represent fluids with echogenic margins and adjacent echogenic fat. Representing superficial soft tissue infection, no drainable collection.

[redacted] **20[redacted] BODY TEMPERATURE:** afebrile

[redacted] **20[redacted] BODY WEIGHT:** 5[redacted].[redacted] KG

[redacted] **20[redacted] BP:** 100/70mmhg

[redacted] **20[redacted] CREATININE:** 117 umol/L (normal 45 to 90)

[redacted] **20[redacted] CREATININE:** 147 umol/L (normal 45 to 90)

[redacted] **20[redacted] EGFR:** 43 mL/min/1.73m2 (normal >60)

[redacted] **20[redacted] HEART RATE:** 65 bpm

[redacted] **20[redacted] LACTATE DEHYDROGENASE:** 3.1 MMOL/L (normal <2.0)

[redacted] **20[redacted] O2 SATURATION:** 82% (normal 70 to 80)

[redacted] **20[redacted] PO2:** 53 mmHg (normal 36 to 44)

[redacted] **20[redacted] RR:** 18 bpm

[redacted] **20[redacted] SPO2:** 94%

[redacted] **20[redacted] UREA:** 18.6 MMOL/L (normal 3.0 to 8.0)

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
不安	X			
注入部位膿瘍	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	4[redacted]	FEMALE	WHITE

Medical History	Onset Year
HAY FEVER	20[redacted]
ANXIETY	20[redacted]
LOW VITAMIN B6	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.35	0.30	60	0.11	[redacted] / 368
ABBV-951	0.34	0.35	0.30	60	0.11	[redacted] / 549
ABBV-951	0.35	0.36	0.31	60	0.11	[redacted] / 708
ABBV-951	0.36	0.37	0.32	60	0.15	[redacted] / 731

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	651.92		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	942.54		SC / CONTINUOUS	[redacted] / 7	[redacted] / 88
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 10	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951		112.69	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951		93.91	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 16	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 17	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 21	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 27	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 35	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 36	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 37	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 41	
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1146.07		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
M15-741 /ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 90	[redacted] / 272
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 273	
M15-741 /ABBV-951	1315.79		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951		37.56	SC / ONCE	[redacted] / 274	
M15-741 /ABBV-951	1312.38		SC / CONTINUOUS	[redacted] / 274	[redacted] / 274

M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	20[redacted] / 275	20[redacted] / 366
M15-741 /ABBV-951		56.34	SC / ONCE	20[redacted] / 367	
M15-741 /ABBV-951	1323.99		SC / CONTINUOUS	20[redacted] / 367	20[redacted] / 367
M15-741 /ABBV-951		18.78	SC / ONCE	20[redacted] / 368	
ABBV-951	551.52		SC / CONTINUOUS	20[redacted] / 368	20[redacted] / 368
M15-741 /ABBV-951	1371.12		SC / CONTINUOUS	20[redacted] / 368	20[redacted] / 368
ABBV-951	1393.32		SC / CONTINUOUS	20[redacted] / 369	20[redacted] / 456
ABBV-951		18.78	SC / ONCE	20[redacted] / 457	
ABBV-951	1400.32		SC / CONTINUOUS	20[redacted] / 457	20[redacted] / 457
ABBV-951	1362.58		SC / CONTINUOUS	20[redacted] / 458	20[redacted] / 458
ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 459	20[redacted] / 546
ABBV-951		18.78	SC / ONCE	20[redacted] / 547	
ABBV-951	1395.02		SC / CONTINUOUS	20[redacted] / 547	20[redacted] / 547
ABBV-951	1352.34		SC / CONTINUOUS	20[redacted] / 548	20[redacted] / 548
ABBV-951		18.78	SC / ONCE	20[redacted] / 549	
ABBV-951	1354.04		SC / CONTINUOUS	20[redacted] / 549	20[redacted] / 549
ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 550	20[redacted] / 631
ABBV-951	1423.03		SC / CONTINUOUS	20[redacted] / 632	20[redacted] / 632
ABBV-951		37.56	SC / ONCE	20[redacted] / 633	
ABBV-951	1333.55		SC / CONTINUOUS	20[redacted] / 633	20[redacted] / 633
ABBV-951		18.78	SC / ONCE	20[redacted] / 634	
ABBV-951	1362.58		SC / CONTINUOUS	20[redacted] / 634	20[redacted] / 634
ABBV-951	1434.3		SC / CONTINUOUS	20[redacted] / 635	20[redacted] / 704
ABBV-951	1400.15		SC / CONTINUOUS	20[redacted] / 705	20[redacted] / 705
ABBV-951	1320.75		SC / CONTINUOUS	20[redacted] / 706	20[redacted] / 706
ABBV-951	1340.38		SC / CONTINUOUS	20[redacted] / 707	20[redacted] / 707
ABBV-951	1388.19		SC / CONTINUOUS	20[redacted] / 708	20[redacted] / 708
ABBV-951	1475.28		SC / CONTINUOUS	20[redacted] / 709	20[redacted] / 783
ABBV-951	1406.98		SC / CONTINUOUS	20[redacted] / 784	20[redacted] / 784
ABBV-951	1447.96		SC / CONTINUOUS	20[redacted] / 785	20[redacted] / 785
ABBV-951	1311.36		SC / CONTINUOUS	20[redacted] / 786	20[redacted] / 864

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]

MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted] / 72
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 20[redacted] / 305

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
CETIRIZINE HYDROCHLORIDE	10 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
MOMETASONE FUROATE	50 ug	PRN	Y-M: 20[redacted]	NOT REPORTED
PYRIDOXINE	25 mg	OTHER: WEEKLY	Y-M: 20[redacted] / 72	NOT REPORTED
BOTULINUM TOXIN TYPE A	75 OTHER: UNITS	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted] / 458	ONGOING
LORAZEPAM	0.25 mg	PRN	Y-M: 20[redacted] / 503	NOT REPORTED
VENLAFAXINE HYDROCHLORIDE	150 mg	QD	Y-M: 20[redacted] / 507	NOT REPORTED
BOTULINUM TOXIN TYPE A	25 IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted] / 549	Y-M: 20[redacted] / 640
CLINDAMYCIN	250 mg	QID	Y-M: 20[redacted] / 634	Y-M: 20[redacted] / 637
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	125 mg	BID	Y-M: 20[redacted] / 638	NOT REPORTED
BOTULINUM TOXIN TYPE A	50 IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted] / 641	NOT REPORTED
LORAZEPAM	1 mg	PRN	Y-M: 20[redacted] / 702	NOT REPORTED
AMOXICILLIN	1000 mg	BID	Y-M: 20[redacted] / 723	NOT REPORTED
CLARITHROMYCIN	500 mg	BID	Y-M: 20[redacted] / 723	NOT REPORTED
ESOMEPRAZOLE MAGNESIUM	20 mg	BID	Y-M: 20[redacted] / 723	NOT REPORTED
CEFALEXIN	500 mg	QID	Y-M: 20[redacted] / 753	Y-M: 20[redacted] / 757
DIAZEPAM	5 mg	OTHER: ONCE ONLY	Y-M: 20[redacted] / 755	Y-M: 20[redacted] / 755
MAGNESIUM ASPARTATE	1000 mg	OTHER: STAT DOSE	Y-M: 20[redacted] / 755	Y-M: 20[redacted] / 755
MORPHINE	2.5 mg	PRN	Y-M: 20[redacted] / 755	Y-M: 20[redacted] / 755
POTASSIUM CHLORIDE	28 mmol	OTHER: STAT DOSE	Y-M: 20[redacted] / 755	Y-M: 20[redacted] / 755
POTASSIUM CHLORIDE;SODIUM CHLORIDE	100 mL	OTHER: STAT	Y-M: 20[redacted] / 755	Y-M: 20[redacted] / 755

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

Event Description	LEFT ABDOMINAL ABSCESS TO PREVIOUS INFUSION SITE.
Preferred Term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 636
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	637
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	WORSENING OF LEFT ABDOMINAL ABSCESS AT INFUSION SITE
Preferred Term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 637
Age at AE Onset	4[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
[redacted]20[redacted] (RX DAY 637): WOUND MC & S: POSITIVE-STAPHYLOCOCCUS AUREUS ISOLATED	
AE Stopped Rx Day	638
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	CAUSAL RELATIONSHIP

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Serious Adverse Event

Event Description	WORSENING OF ANXIETY
Preferred Term	不安
AE Onset Date / Rx Day	[redacted]20[redacted] / 755
Age at AE Onset	4[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 755): Magnesium: 0.69 [0.7 - 1.1] MMOL/L; Potassium: 2.7MMOL/ [3.2 - 5] mmol/L

Microbiology

[redacted]20[redacted] (RX DAY 756): URINE URINE MICROSCOPY: NEGATIVE-REPORT STATES: NO SIGNIFICANT BACTERIAL GROWTH.

AE Stopped Rx Day	756
Duration of AE	2 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT REPORTED
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	WORSENING OF ANXIETY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左腹部注入部位膿瘍の悪化を発現した。

Event 2 の臨床経過：

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

投与 637 日目，被験者は左腹部注入部位膿瘍の悪化を発現した。投与 638 日目左腹部注入部位膿瘍の悪化は消失した。

投与 638 日目，被験者は左下腹部の疼痛及び紅斑のため近医を受診した。医師は腹部皮下結節の感染症（非重篤）であると確定し，クリンダマイシンの経口投与を開始した。

投与 636 日目，被験者は以前の注入部位にある左腹部結節の疼痛及び紅斑の悪化の検査を受けるために救急診療部に来院し，以前の注入部位の左腹部膿瘍（非重篤）と診断された。被験者は自宅に帰された。

投与 637 日目，被験者は再度来院し，以前の注入部位の左腹部膿瘍に対し，切開及びドレナージが実施された。被験者は一晩入院し，抗生物質を静脈内投与された。投与 638 日目，被験者は退院した。

被験者にクリンダマイシン及びオーグメンチンが投与された。

Causality for ABBV-951 (Open Label)

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1) Infusion site abscess (10058464) (Infusion site abscess (10058464)) [v.24.0] [10058464]

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

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

Dechallenge: Yes

Rechallenge: No rechallenge was done, recurrence is not applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF LEFT ABDOMINAL ABSCESS AT INFUSION SITE

- Investigator: Not applicable

- AbbVie: Not applicable

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] WOUND CULTURE AND SENSITIVITY:** Positive: Staphlococcus aureus

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 4[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に不安の悪化を発現した。

Event 3 の臨床経過：

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

投与 755 日目，被験者は不安の悪化を発現した。投与 756 日目，不安の悪化は消失した。

本事象の発現前，被験者は投与 702 日目に非重篤な息切れ及び投与 753 日目に非重篤な尿路感染を発現した。

投与 755 日目，被験者は 2 日間のロラゼパム難治性の頻呼吸を伴い救急診療部に来院した。神経内科のチームに助言を求め，パーキンソン病及び被験者の病歴である不安と関連して最近発現した尿路感染により本エピソードが引き起こされた可能性があると結論付けた。被験者の前回の息切れのエピソードが今回と類似しており，感染と関連していると指摘された。被験者に電解質の静脈内投与，並びに経口カリウム及び経口マグネシウム投与を開始した。救急診療部に滞在している間に，被験者は重度の両側前頭部の頭痛を発現し，モルヒネが投与された。投与 756 日目，被験者は入院した。同日，被験者の頭痛は持続した。精密検査を実施し，被験者にモルヒネが投与された。被験者に頻呼吸のエピソードは認められず，投与 756 日目に退院した。

治験責任医師によると，被験者には不安に関連するリスク因子があった。

被験者にジアゼパムが投与された。

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1) Anxiety aggravated (10048339) (Anxiety (10002855)) [v.24.1] [10048339]

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 ANXIETY

- Investigator: Worsening of anxiety

- AbbVie: More likely related to recent urinary tract infection and history of anxiety

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] CHEST X-RAY:** clear

[redacted] **20[redacted] CT BRAIN:** NIL acute intracranial abnormality or hemorrhage

[redacted] **20[redacted] ECG:** Sinus Tachycardia, 1MM ST depression V4-6, lead ii twave flattenning lead II, QTC prolonged at 490MS – no dynamic features.

[redacted] **20[redacted] MAGNESIUM:** 0.69 MMOL/L (normal 0.70 to 1.10)

[redacted] **20[redacted] POTASSIUM:** 2.7 MMOL/L (noal 3.2 to 5.0)

[redacted] **20[redacted] URINE MICROSCOPY:** Negative - No significant bacterial growth

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻覚				X
注入部位紅斑				X
起立性低血圧	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	ASIAN

Medical History	Onset Year
ASPIRIN ALLERGY	NOT REPORTED
ASTHMA	19[redacted]
MIGRAINE	19[redacted]
DEPRESSION	20[redacted]
HYPERCHOLESTEROLEMIA	20[redacted]
CONSTIPATION	20[redacted]
POST MENOPAUSAL	20[redacted]
INFLAMMATORY ARTHRITIS	20[redacted]
CHRONIC OBSTRUCTIVE PULMONARY DISORDER	20[redacted]
GASTRO ESOPHOGEAL REFLUX DISEASE	20[redacted]

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

Prior Procedures	Procedure Year
LEFT KNEE ARTHROSCOPY	20[redacted]
COLONOSCOPY AND ENDOSCOPY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	25 CIGARETTE	28	20[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	FORMER	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.34	0.40	0.15	60	0.19	[redacted]20[redacted] / 364
ABBV-951	0.24	0.25	0.15	60	0.19	[redacted]20[redacted] / 391
ABBV-951	0.27	0.28	0.17	60	0.24	[redacted]20[redacted] / 441
ABBV-951	0.28	0.29	0.15	60	0.24	[redacted]20[redacted] / 469
ABBV-951	0.28	0.29	0.15	60	0.24	[redacted]20[redacted] / 525

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	448.73		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1014.25		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 19
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1514.55		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1518.30		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 27
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1477.32		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 40
M15-741 /ABBV-951	1408.00		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951	1182.61		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42

M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 43 [redacted] / 270
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 271
M15-741 /ABBV-951	1356.60		SC / CONTINUOUS	[redacted] / 271 [redacted] / 271
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 272
M15-741 /ABBV-951	1515.91		SC / CONTINUOUS	[redacted] / 272 [redacted] / 272
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted] / 273 [redacted] / 361
M15-741 /ABBV-951	1167.93		SC / CONTINUOUS	[redacted] / 362 [redacted] / 362
ABBV-951	638.60		SC / CONTINUOUS	[redacted] / 364 [redacted] / 364
ABBV-951	1393.32		SC / CONTINUOUS	[redacted] / 365 [redacted] / 454
ABBV-951		81.96	SC / ONCE	[redacted] / 455
ABBV-951	1172.36		SC / CONTINUOUS	[redacted] / 455 [redacted] / 455
ABBV-951		40.98	SC / ONCE	[redacted] / 456
ABBV-951	720.39		SC / CONTINUOUS	[redacted] / 456 [redacted] / 456
ABBV-951	696.66		SC / CONTINUOUS	[redacted] / 457 [redacted] / 522
ABBV-951		81.96	SC / ONCE	[redacted] / 523
ABBV-951	790.40		SC / CONTINUOUS	[redacted] / 523 [redacted] / 523
ABBV-951		40.98	SC / ONCE	[redacted] / 524
ABBV-951	1133.09		SC / CONTINUOUS	[redacted] / 524 [redacted] / 524

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]-[redacted] / 2
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted]-[redacted] / 56
DESVENLAFAXINE SUCCINATE MONOHYDRATE	200 mg	QD	Y-M: 20[redacted]-[redacted] / 231
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	TID	Y-M: 20[redacted]-[redacted] / 238
METFORMIN	1000 mg	QD	Y-M: 20[redacted]-[redacted] / 245
CLOZAPINE	100 mg	QD	Y-M: 20[redacted]-[redacted] / 252
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted]-[redacted] / 259
FAMOTIDINE	40 mg	QD	Y-M: 20[redacted]-[redacted] / 285
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted]-[redacted] / 285
INDACATEROL	150 ug	QD	Y-M: 20[redacted]-[redacted] / 293

CLOZAPINE	75 mg	QD	Y-M: 20[redacted] / 294
FLUDROCORTISONE	150 ug	QD	Y-M: 20[redacted] / 350
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 357
CLOZAPINE	175 mg	QD	Y-M: 20[redacted] / 363

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
INDACATEROL MALEATE	150 ug	QD	Y-M: 20[redacted]	NOT REPORTED
SALBUTAMOL	100 ug	PRN	Y-M: 20[redacted]	NOT REPORTED
EZETIMIBE;ROSUVASTATIN CALCIUM	10+10 mg	QD	Y-M: 20[redacted]	NOT REPORTED
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted] / 2	NOT REPORTED
FLUDROCORTISONE	0.1 mg	QD	Y-M: 20[redacted] / 56	NOT REPORTED
DESVENLAFAXINE SUCCINATE MONOHYDRATE	200 mg	QD	Y-M: 20[redacted] / 231	NOT REPORTED
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	TID	Y-M: 20[redacted] / 238	Y-M: 20[redacted] / 373
METFORMIN	1000 mg	QD	Y-M: 20[redacted] / 245	NOT REPORTED
CLOZAPINE	100 mg	QD	Y-M: 20[redacted] / 252	Y-M: 20[redacted] / 362
PANTOPRAZOLE	40 mg	BID	Y-M: 20[redacted] / 259	NOT REPORTED
FAMOTIDINE	40 mg	QD	Y-M: 20[redacted] / 285	NOT REPORTED
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 285	NOT REPORTED
INDACATEROL	150 ug	QD	Y-M: 20[redacted] / 293	NOT REPORTED
CLOZAPINE	75 mg	QD	Y-M: 20[redacted] / 294	Y-M: 20[redacted] / 362
FLUDROCORTISONE	150 ug	QD	Y-M: 20[redacted] / 350	NOT REPORTED
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 357	NOT REPORTED
CLOZAPINE	175 mg	QD	Y-M: 20[redacted] / 363	NOT REPORTED
BOTULINUM TOXIN TYPE A	75 IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted] / 525	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	WORSENING OF ORTHOSTATIC HYPOTENSION
Preferred Term	起立性低血圧
AE Onset Date / Rx Day	[redacted]20[redacted] / 357

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	POSSIBLY CONTRIBUTED TO INITIATION OF CLOZAPINE.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING OF HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 448
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE

Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	ERYTHEMA AT PREVIOUS INFUSION SITE.
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 524
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	527
Duration of AE	4 DAYS
Severity	MILD
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 RELATED
SAE: Investigator Opinion of 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]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はオーストラリアの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に起立性低血圧の悪化を発現した。

Event 1 の臨床経過：

投与 1 日目から 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の治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 357 日目，被験者は起立性低血圧の悪化を発現した。

被験者は本事象発現前の投与 15 日目に非重篤の起立性低血圧を発現し，投与 356 日目に消失した。

投与 357 日目，被験者は起立性低血圧の悪化の訴え，逆流性食道炎，継続中のクロザピン治療抵抗性の幻覚及びうつ病の二次診断のため入院した。起立性低血圧の悪化は，詳しくは自宅で立ったり歩いたりしている間の浮動性めまいとされた。被験者は逆流性食道炎による悪心及び嘔吐に苦しみ，経口摂取が少なかった。被験者に静脈内輸液を投与し，注意深くモニタリングした。経口レボドパ療法を行っている間，被験者は入院した。その結果，悪心及び嘔吐が消失し，経口摂取をモニタリングした。被験者の起立性血圧は改善し，幻視は顕著な改善が認められたものの継続した。投与 373 日目，被験者は退院した。

治験責任医師によると，起立性低血圧の悪化のリスク因子はパーキンソン病と考えられた。

被験者にレボドパが投与された。

Causality for ABBV-951 (Open Label)

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1) Orthostatic hypotension (10031127) (Orthostatic hypotension (10031127)) [v.24.1] [10031127]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING OF ORTHOSTATIC HYPOTENSION

- Investigator: Reflux oesophagitis

- AbbVie: More likely related to reported nausea, reflux esophagitis and history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 6[redacted] KG

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
筋骨格系胸痛	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
RECURRING TONSIL INFECTIONS	19[redacted]
CHRONIC VAGINAL BLEEDING	20[redacted]
ANXIETY	20[redacted]
DEPRESSION	20[redacted]
HEADACHES	20[redacted]
CHRONIC MIGRAINE	20[redacted]
CONSTIPATION	20[redacted]
FRACTURED 5TH METATARSAL	20[redacted]
LOW VITAMIN B6	20[redacted]

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

Prior Procedures	Procedure Year
TONSILLECTOMY	19[redacted]
CAESARIAN SECTION	20[redacted]
UTERINE ABLATION	20[redacted]
CAESARIAN SECTION	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	1 CIGARETTE	5	20[redacted]

CIGARS	NEVER
E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.21	0.22	0.19	60	0.15	[redacted]20[redacted]/ 371
ABBV-951	0.21	0.22	0.19	60	0.19	[redacted]20[redacted]/ 533

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	628.87		SC / CONTINUOUS	[redacted]20[redacted]/ 1	[redacted]20[redacted]/ 1
M15-741 /ABBV-951	1188.42		SC / CONTINUOUS	[redacted]20[redacted]/ 2	[redacted]20[redacted]/ 4
M15-741 /ABBV-951	1068.04		SC / CONTINUOUS	[redacted]20[redacted]/ 5	[redacted]20[redacted]/ 5
M15-741 /ABBV-951	1003.15		SC / CONTINUOUS	[redacted]20[redacted]/ 6	[redacted]20[redacted]/ 6
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted]/ 7	
M15-741 /ABBV-951	1034.06		SC / CONTINUOUS	[redacted]20[redacted]/ 7	[redacted]20[redacted]/ 7
M15-741 /ABBV-951	1042.77		SC / CONTINUOUS	[redacted]20[redacted]/ 8	[redacted]20[redacted]/ 8
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted]/ 9	
M15-741 /ABBV-951	1068.89		SC / CONTINUOUS	[redacted]20[redacted]/ 9	[redacted]20[redacted]/ 9
M15-741 /ABBV-951	921.02		SC / CONTINUOUS	[redacted]20[redacted]/ 10	[redacted]20[redacted]/ 10
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted]/ 11	[redacted]20[redacted]/ 12
M15-741 /ABBV-951	878.85		SC / CONTINUOUS	[redacted]20[redacted]/ 13	[redacted]20[redacted]/ 13
M15-741 /ABBV-951	813.62		SC / CONTINUOUS	[redacted]20[redacted]/ 14	[redacted]20[redacted]/ 14
M15-741 /ABBV-951	821.30		SC / CONTINUOUS	[redacted]20[redacted]/ 15	[redacted]20[redacted]/ 15
M15-741 /ABBV-951	810.03		SC / CONTINUOUS	[redacted]20[redacted]/ 16	[redacted]20[redacted]/ 16
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted]/ 17	[redacted]20[redacted]/ 19
M15-741 /ABBV-951	835.13		SC / CONTINUOUS	[redacted]20[redacted]/ 20	[redacted]20[redacted]/ 20
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted]/ 21	
M15-741 /ABBV-951	823.52		SC / CONTINUOUS	[redacted]20[redacted]/ 21	[redacted]20[redacted]/ 21
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted]/ 22	
M15-741 /ABBV-951	802.01		SC / CONTINUOUS	[redacted]20[redacted]/ 22	[redacted]20[redacted]/ 22

M15-741 /ABBV-951	819.94		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 26
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	865.70		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		56.34	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	882.77		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 29
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 34
M15-741 /ABBV-951	869.45		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35
M15-741 /ABBV-951	813.45		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951	815.33		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951	838.04		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 41
M15-741 /ABBV-951	873.72		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	818.23		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	813.28		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 91
M15-741 /ABBV-951	291.98		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	586.18		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951	801.84		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	838.72		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 183
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted]20[redacted] / 184	[redacted]20[redacted] / 270
M15-741 /ABBV-951	827.28		SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951		18.78	SC / ONCE	[redacted]20[redacted] / 273	
M15-741 /ABBV-951	754.71		SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 273
M15-741 /ABBV-951	817.03		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
M15-741 /ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 363
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 364	
M15-741 /ABBV-951	840.43		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
M15-741 /ABBV-951	811.23		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
M15-741 /ABBV-951	798.93		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
M15-741 /ABBV-951	833.08		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
M15-741 /ABBV-951	778.62		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 368
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 369	
M15-741 /ABBV-951	810.55		SC / CONTINUOUS	[redacted]20[redacted] / 369	[redacted]20[redacted] / 369

M15-741 /ABBV-951	806.79		SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370
ABBV-951	412.36		SC / CONTINUOUS	[redacted]20[redacted] / 371	[redacted]20[redacted] / 371
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 372	[redacted]20[redacted] / 459
ABBV-951	842.65		SC / CONTINUOUS	[redacted]20[redacted] / 460	[redacted]20[redacted] / 460
ABBV-951	852.38		SC / CONTINUOUS	[redacted]20[redacted] / 461	[redacted]20[redacted] / 461
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 462	
ABBV-951	810.89		SC / CONTINUOUS	[redacted]20[redacted] / 462	[redacted]20[redacted] / 462
ABBV-951	820.28		SC / CONTINUOUS	[redacted]20[redacted] / 463	[redacted]20[redacted] / 463
ABBV-951	860.58		SC / CONTINUOUS	[redacted]20[redacted] / 464	[redacted]20[redacted] / 529
ABBV-951	855.11		SC / CONTINUOUS	[redacted]20[redacted] / 530	[redacted]20[redacted] / 530
ABBV-951	799.45		SC / CONTINUOUS	[redacted]20[redacted] / 531	[redacted]20[redacted] / 531
ABBV-951	824.72		SC / CONTINUOUS	[redacted]20[redacted] / 532	[redacted]20[redacted] / 532

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
AMANTADINE	100.000 mg	TID	Y-M: 20[redacted]-[redacted]
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]
BOTULINUM TOXIN TYPE A	UNKNOWN IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]-[redacted]
MELOXICAM	15 mg	PRN	Y-M: 20[redacted]-[redacted] / 72

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
PARACETAMOL	1000 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
BOTULINUM TOXIN TYPE A	UNKNOWN IU	OTHER: EVERY 3 MONTHS	Y-M: 20[redacted]-[redacted]	NOT REPORTED
MELOXICAM	15 mg	PRN	Y-M: 20[redacted]-[redacted] / 72	NOT REPORTED
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 20[redacted]-[redacted] / 410	Y-M: 20[redacted]-[redacted] / 533
OXYCODONE HYDROCHLORIDE	2.5 mg	PRN	Y-M: 20[redacted]-[redacted] / 457	Y-M: 20[redacted]-[redacted] / 458
DOCUSATE SODIUM;SENNOSIDE B	2 OTHER: TABLETS	QD	Y-M: 20[redacted]-[redacted] / 458	NOT REPORTED
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted]-[redacted] / 458	NOT REPORTED
GADOBUTROL	7.5 mL	OTHER: ONCE ONLY	Y-M: 20[redacted]-[redacted] / 459	Y-M: 20[redacted]-[redacted] / 459

MELATONIN	2 mg	QD	Y-M: 20[redacted] / 534	NOT REPORTED
VENLAFAXINE HYDROCHLORIDE	150 mg	QD	Y-M: 20[redacted] / 534	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	MUSCULOSKELETAL PAIN TO LEFT CHEST
Preferred Term	筋骨格系胸痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 457
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 457): NPTST054-TROPONIN: 4 [4 - 50] NG/L; NPTST054-TROPONIN: 4 [4 - 50] NG/L;
20[redacted] (RX DAY 459): NPTST054-TROPONIN: 4 [4 - 50] NG/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	PRESUMED INTERCOSTAL MUSCLE STRAIN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオーストラリアの 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左胸部の筋骨格痛を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，元喫煙者（1 日 1 本を 5 年間），不安，うつ病，及び飲酒者（1 日 2 杯未満）であった。

投与 457 日目，被験者は左胸部の筋骨格痛を発現した。

本事象発現の 2 週間前に，被験者は左手が痛み始めた。痛みは一晩中増していき，動くと悪化し，被験者は苦痛と疼痛が続いた。

投与 457 日目，被験者は一般開業医を訪れた。開業医は評価のため，被験者を神経内科／パーキンソン病の救急診療部に紹介した。同日，被験者に診断検査を実施した。同日，被験者は左胸痛及び息切れを伴い救急診療部に来院した。投与 458 日目，被験者は入院した。投与 459 日目，腕神経叢炎の可能性に関して精密診断検査を実施した。検査の結果，上行結腸から肝彎曲まで伸展した蓄便及び便秘が認められた。投与 459 日目，被験者は退院した。

被験者に ENDONE 及びイブプロフェンが投与された。

Causality for ABBV-951 (Open Label)

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1) Musculoskeletal chest pain (10050819) (Musculoskeletal chest pain (10050819)) [v.24.1] [10050819]

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 MUSCULOSKELETAL PAIN TO LEFT CHEST

- Investigator: Presumed Intercostal Muscle strain

- AbbVie: More likely related to reported presumed intercostal muscle strain and history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **ABDOMINAL X-RAY:** There is marked faecal loading in the ascending colon extending up to the hepatic flexure and proximal transverse colon. Some faecal loading is also noted in the descending and sigmoid colon. No dilated loops of small or large bowel seen to suggest any mechanical bowel obstruction.

[redacted] 20[redacted] **BMI:** 34.9 KG/M2

[redacted] 20[redacted] **CHEST X-RAY:** THE LUNGS AND PLEURAL SPACE IS CLEAR ON XRAY

[redacted] 20[redacted] **CT PULMONARY ANGIOGRAM:** There is no filling defect to suggest an acute pulmonary embolus. No pulmonary mass. No pleural or pericardial effusion. Left adrenal nodule suggestive of an adenoma. Thyroid nodules are identified.

[redacted] 20[redacted] **ELECTROCARDIOGRAM:** Normal sinus rhythm. No PR depression, no ST segment changes.

[redacted] 20[redacted] **MRI CERVICAL SPINE AND BRACHIAL PLEXUS:** MRI SPINE CERVICAL AND BRACHIAL PLEXUS - NO OBVIOUS PATHOLOGY IS SEEN IN RELATION TO THE LEFT BRACHIAL PLEXUS ALLOWING FOR MOVEMENT ARTEFACT. NO OBSTRUCTING MASSES ARE SEEN ALONG THAT PATH OF THE LEFT BRACHIAL PLEXUS. THE SCALENE TRIANGLE IS INTACT. NO ANEURYSM OF THE LEFT SUBCLAVIAN ARTERY IS SEEN.

[redacted] 20[redacted] **MRI CERVICAL SPINE AND BRACHIAL PLEXUS:** MRI SPINE CERVICAL AND BRACHIAL PLEXUS - NO OBVIOUS PATHOLOGY IS SEEN IN RELATION TO THE LEFT BRACHIAL PLEXUS ALLOWING FOR MOVEMENT ARTEFACT. NO OBSTRUCTING MASSES ARE SEEN ALONG THAT PATH OF THE LEFT BRACHIAL PLEXUS. THE SCALENE TRIANGLE IS INTACT. NO ANEURYSM OF THE LEFT SUBCLAVIAN ARTERY IS SEEN.

[redacted] 20[redacted] **TROPONIN:** <4 ng/mL

[redacted] 20[redacted] **TROPONIN:** 4 NG/ML (normal 4 to 39)

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
滑液包炎	X			
転倒				X
幻覚				X
パーキンソン病	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
LIMITED NON-Q-WAVE ANTEROLATERAL MYOCARDINFACTION	19[redacted]
HYPERCHOLESTELOREMIA	20[redacted]
LUMBAL HERNIA	20[redacted]
HARD STOOLS	20[redacted]
CATARACT	20[redacted]
CATARACTS	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
LUMBAL HERNIA SURGERY	20[redacted]
CATARACT SURGERY	20[redacted]

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

E-CIGARETTES	NEVER
PIPES	NEVER

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.44	0.45	0.43	120	0.30	[redacted] / 362
ABBV-951	0.47	0.46	0.45	120	0.30	[redacted] / 516
ABBV-951	0.46	0.45	0.44	120	0.30	[redacted] / 684
ABBV-951	0.47	0.48	0.46	120	0.30	[redacted] / 707

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	901.56		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 2	[redacted] / 15
M15-741 /ABBV-951	1729.35		SC / CONTINUOUS	[redacted] / 16	[redacted] / 16
ABBV-951	408.43		SC / CONTINUOUS	[redacted] / 705	[redacted] / 705
ABBV-951	1767.26		SC / CONTINUOUS	[redacted] / 706	[redacted] / 706
ABBV-951	1885.08		SC / CONTINUOUS	[redacted] / 707	[redacted] / 770

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 19[redacted]
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]
PRAMIPEXOLE	0.260 mg	QD	Y-M: 20[redacted]-[redacted]
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / 343

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
OMEPRAZOLE	20 mg	QD	Y-M: 19[redacted]	NOT REPORTED
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]	NOT REPORTED
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted]	NOT REPORTED
ATORVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / 343	NOT REPORTED
PARACETAMOL	1 g	OTHER: MAXIMUM 4/DAY	Y-M: 20[redacted]-[redacted] / 376	NOT REPORTED
FUROSEMIDE	20 mg	QD	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 602
CALCIUM CARBONATE;COLECALCIFEROL	880 mg	QD	Y-M: 20[redacted]-[redacted] / 386	NOT REPORTED
COVID-19 VACCINE	1 OTHER: INJECTION	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 442	Y-M: 20[redacted]-[redacted] / 442
COVID-19 VACCINE	1 OTHER: INJECTION	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 477	Y-M: 20[redacted]-[redacted] / 477
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted]-[redacted] / 517	NOT REPORTED
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 517	Y-M: 20[redacted]-[redacted] / 522
FUROSEMIDE	30 mg	QD	Y-M: 20[redacted]-[redacted] / 603	NOT REPORTED
INFLUENZA VACCINE	1 OTHER: UNIT	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 658	Y-M: 20[redacted]-[redacted] / 658
TOZINAMERAN	1 OTHER: UNIT	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 670	Y-M: 20[redacted]-[redacted] / 670

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] / 366
Age at AE Onset	7[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	366
Duration of AE	1 DAY
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Serious Adverse Event

Event Description	TRONCHATERITIS LEFT
Preferred Term	滑液包炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 375
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	EVENT CAUSED BY FALL, THIS IS DUE TO PARKINSON DISEASE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #3: Event of Interest - Hallucinations/Psychosis

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 516
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	522
Duration of AE	7 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	MIRAPEXIN
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #4: Serious Adverse Event

Event Description	WORSENING PARKINSON DISEASE SYMPTOMS
Preferred Term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 681
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	684
Duration of AE	4 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	CAUSAL RELATIONSHIP

Infusion Pump	
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左転子炎を発現した。

Event 2 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，腰椎ヘルニア手術，非喫煙者，及び非飲酒者であった。

投与 376 日目，被験者は左転子炎を発現した。

本事象発現前の投与 366 日目，被験者は偶発的な転倒（非重篤）を発現した。投与 375 日目以降，被験者は左転子の痛みが強くなり始め，歩行が困難となった。投与 376 日目，被験者は歩行困難のため入院した。X 線検査が実施され，骨折が認められた。投与 378 日目，骨盤 CT スキャンが実施され，大転子に骨折が発見された。保存療法を開始した結果，被験者は直ちに回復した。投与 386 日目，被験者は退院した。

被験者にラシックス，VITAL FORTE，及び DAFALGAN が投与された。

The patient's past medications include:

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

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

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

PROLOPA HBS for PARKINSON'S DIESASE ([redacted] 20[redacted] - [redacted] 20[redacted])

SAFINAMIDE 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) Trochanteritis (10059077) (Osteitis (10031149)) [v.23.1] [10059077]

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 TRONCHATERITIS LEFT

- Investigator: Event caused by fall, this is due to Parkinson disease.

- AbbVie: More likely related to reported fall in an advanced age subject with Parkinson's disease and cataract

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BONE DENSIOMETRY:** Osteoporosis was detected

[redacted] **20[redacted] CT PELVIS:** Displaced fracture through trochanter major

[redacted] **20[redacted] RX HIP:** No fracture

[redacted] **20[redacted] RX PELVIS:** No fracture

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中にパーキンソン病症状の悪化を発現した。

Event 4 の臨床経過：

関連する病歴はパーキンソン病であった。

投与 681 日目，被験者はパーキンソン病症状の悪化を発現した。投与 684 日目，パーキンソン病症状の悪化は消失した。

本事象の発現前，被験者は投与 455 日目に非重篤な事象として突然かつ短期間で一過性の運動障害を発現した。

投与 681 日目の夜，電池が弱くなったため被験者のポンプアラームがオフになった。被験者の息子が電池を交換するために被験者の自宅に行った。電池の交換によりポンプの設定が工場出荷時の 20 mL バイアルにリセットされたが，被験者のバイアルは 15 mL であった。これが原因となり，シリンジ内に大量の空気が入り込み，ポンプの機能が停止した。この時点で，被験者及び被験者の息子は，工場出荷時の設定にリセットされたことがポンプの故障の原因であと分からなかった。被験者が多くの症状を発現し，気分が非常に悪かったため，同日入院した。この時点で，被験者及び被験者の息子は治験責任医師へ連絡できていなかった。この時点で被験者の状態が非常に悪かったため，病院のスタッフがレボドパ／ベンセラジド及びレボドパ／カルビドパ水和物／エンタカポンの経口薬を再投与した。投与 684 日目，被験者は退院した。

被験者にレボドパ／ベンセラジド及びレボドパ／カルビドパ水和物／エンタカポンが投与された。

The patient's past medications include:

PRAMIPEXOLE for PARKINSON'S DISEASE ([redacted] 20[redacted] - [redacted] 20[redacted])
COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted])

Causality for ABBV-951 (Open Label)

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1) Parkinson's disease (10061536) (Parkinson's disease (10061536)) [v.24.1] [10061536]

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

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

Dechallenge: Yes

Rechallenge: rechallenge was done, reaction did not recur

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING PARKINSON DISEASE SYMPTOMS

- **Investigator:** Not Reported

- **AbbVie:** More likely related to history of Parkinson's disease and advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20**[redacted] **BODY WEIGHT**: 5[redacted] KG

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
出血性腸憩室	X			
顔面骨骨折				X
転倒				X
幻覚	X			X
股関節部骨折	X			X
上腕骨骨折				X
パーキンソン病	X	X	X	
体重減少				X
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	8[redacted]	MALE	WHITE

Medical History	Onset Year
GROIN RUPTURE RIGHT	20[redacted]
BENING HYPERTROPHY PROSTATE	20[redacted]
DIVERTICULAR BLEEDING	20[redacted]
VIT B DEFFICIENCY	20[redacted]

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

Prior Procedures	Procedure Year
TRANSVESICAL PROSTATECTOMY	20[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	20 CIGARETTE	20	19[redacted]
CIGARS	FORMER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.45	0.46	0.44	120	0.30	[redacted]20[redacted] / 362
ABBV-951	0.43	0.44	0.42	120	0.30	[redacted]20[redacted] / 516

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	963.03		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1884.05		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 154

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
QUETIAPINE	12.5 mg	QD	Y-M: 20[redacted]-[redacted] / 154	Y-M: 20[redacted]-[redacted] / 421
PARACETAMOL	1 g	PRN	Y-M: 20[redacted]-[redacted] / 369	Y-M: 20[redacted]-[redacted] / 403
BLOOD CELLS, PACKED HUMAN	2 OTHER: UNITS	OTHER: ONCE	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 376
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	BID	Y-M: 20[redacted]-[redacted] / 376	Y-M: 20[redacted]-[redacted] / 379

FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 380
CALCIUM CARBONATE;COLECALCIFEROL	1000 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 421
CALCIUM CARBONATE;COLECALCIFEROL	880 mg	QD	Y-M: 20[redacted] / 376	Y-M: 20[redacted] / 421
BLOOD CELLS, PACKED HUMAN	2 OTHER: UNITS	OTHER: ONCE	Y-M: 20[redacted] / 383	Y-M: 20[redacted] / 383
TRANEXAMIC ACID	1 g	OTHER: ONCE	Y-M: 20[redacted] / 383	Y-M: 20[redacted] / 383
CLOZAPINE	12.5 mg	QD	Y-M: 20[redacted] / 398	Y-M: 20[redacted] / 493
CALCIUM CARBONATE;COLECALCIFEROL	100 mg	QD	Y-M: 20[redacted] / 421	Y-M: 20[redacted] / 535
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	25 mL	BID	Y-M: 20[redacted] / 421	Y-M: 20[redacted] / 535
CLOZAPINE	37.5 mg	QD	Y-M: 20[redacted] / 493	Y-M: 20[redacted] / 505
CLOZAPINE	50 mg	QD	Y-M: 20[redacted] / 506	Y-M: 20[redacted] / 535
FLUDROCORTISONE ACETATE	0.1 mg	QD	Y-M: 20[redacted] / 517	Y-M: 20[redacted] / 535
LORMETAZEPAM	1 mg	QD	Y-M: 20[redacted] / 517	Y-M: 20[redacted] / 535

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

Event Description	HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 158
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	535
Duration of AE	378 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	POSSIBLE

SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	NOSE FRACTURE
Preferred Term	顔面骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 369
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	453
Duration of AE	85 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	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 369
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	

Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	369
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 #4: Event of Interest - Falls and Associated Injuries

Event Description	SUBCAPITAL HUMERUS FRACTURE
Preferred Term	上腕骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 369
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	453
Duration of AE	85 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 #5: Serious Adverse Event

Event Description	DIVERTICULAR HEMORRHAGE
Preferred Term	出血性腸憩室
AE Onset Date / Rx Day	[redacted]20[redacted] / 376
Age at AE Onset	8[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 379): Hemoglobin: 100 [126 - 174] G/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	380
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	NOT REPORTED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	HISTORY OF DIVERTICULAR BLEEDING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #6: Serious Adverse Event

Event Description	DIVERTICULAR HEMMORHAGE
Preferred Term	出血性腸憩室
AE Onset Date / Rx Day	[redacted]20[redacted] / 383
Age at AE Onset	8[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 383): Hemoglobin: 86 [126 - 170] G/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	495
Duration of AE	113 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	HISTORY OF DIVERTICULAR BLEEDING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	ACCIDENTAL FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 393
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	393
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 #8: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	HIP FRACTURE
Preferred Term	股関節部骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 393
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	

Microbiology	
NOT REPORTED	
AE Stopped Rx Day	393
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 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	ACCIDENTAL FALL
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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] / 516
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	535
Duration of AE	20 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Serious Adverse Event, AE Leading to Discontinuation of Study Drug, Death

Event Description	END STAGE PARKINSON DISEASE
Preferred Term	パーキンソン病
AE Onset Date / Rx Day	[redacted]20[redacted] / 535
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	535
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 RELATED
Other Cause of Event	CARDIO RESPIRATORY FAILURE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	DEATH OF SUBJECT

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-741

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に幻覚を発現した。

Event 1 の臨床経過：

関連する病歴は，パーキンソン病，ビタミン B 欠乏症，元喫煙者（1 日 20 本を 20 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 1 日目から 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の治験薬の調整を必要とした。投与 5 週時に，被験者は本試験の 48 週間の維持期に移行した。本期間を通して ABBV-951 の用量が調整された可能性がある。被疑薬に関する情報は，本事象発現時の用量で示されている。

投与 158 日目，被験者は幻覚を発現した。投与 535 日目，幻覚は消失した。

投与 158 日目，被験者は幻覚のため入院した。被験者は自宅でそこにいない人々を見ており，被験者の家族は被験者のその状況を心配した。投与 161 日目，被験者は退院した。

被験者は同時に非重篤な尿路感染の治療も受けた。

被験者にクエチアピンが投与された。

The patient's past medications include:

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

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

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

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

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

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

VIT B 12 INJECTION for VIT B 12 DEFFICIENCY ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Hallucinations (10019077) (Hallucination (10019063)) [v.24.0] [10019077]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of HALLUCINATIONS

- Investigator: Not applicable

- AbbVie: More likely related to reported urinary tract infection in a 8[redacted] year old male with Parkinson's disease.

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中の投与 376 日目に出血性腸憩室，投与 383 日目に出血性腸憩室及び股関節部骨折を発現した。

Event 5，6，及び 8 の臨床経過：

関連する病歴は，パーキンソン病，憩室出血，ビタミン B 欠乏症，元喫煙者（1 日 20 本を 20 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 376 日目，被験者は出血性腸憩室を発現した。投与 380 日目，出血性腸憩室は消失した。投与 383 日目，被験者は出血性腸憩室を発現した。投与 393 日目，被験者は股関節部骨折を発現した。投与 393 日目，股関節部骨折は消失した。投与 495 日目，出血性腸憩室は消失した。

本事象発現前の投与 369 日目に，被験者は転倒のため非重篤の上腕骨骨頭下骨折及び鼻骨骨折を発現した。

投与 376 日目，被験者は直腸出血のエピソード後に入院した。同日，被験者は赤血球濃厚液を投与された。投与 380 日目，被験者は退院した。

投与 383 日目，被験者は自宅で直腸出血のエピソードを発現し，再度入院した。結腸内視鏡検査では，下行結腸及び S 状結腸に憩室症が認められた。腹部 CT では結腸憩室症が認められた。出血部位を閉塞し，被験者に赤血球濃厚液が 2 単位投与された。

入院期間中に，被験者は不慮の転倒を引き起こし，股関節を骨折したため，入院期間が延長となった。投与 393 日目，被験者は股関節部骨折の手術を受け，手術は成功した。投与 421 日目，被験者は退院した。

被験者に赤血球濃厚液，EXACYL，及びフルドロコルチゾン酢酸エステルが投与された。

Causality for ABBV-951 (Open Label)

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1) Diverticulum intestinal hemorrhagic (10055241) (Diverticulum intestinal haemorrhagic (10013560)) [v.24.0] [10055241]

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

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

Dechallenge: Not Applicable

2) Diverticulum intestinal hemorrhagic (10055241) (Diverticulum intestinal haemorrhagic (10013560)) [v.24.0] [10055241]

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

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

Dechallenge: Not Applicable

3) Hip fracture (10020100) (Hip fracture (10020100)) [v.24.0] [10020100]

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 DIVERTICULAR HEMORRHAGE

- Investigator: HISTORY OF DIVERTICULAR BLEEDING

- AbbVie: More likely related to a history of diverticular bleeding and Parkinson's disease in an advanced aged patient

Event of DIVERTICULAR HEMORRHAGE

- Investigator: HISTORY OF DIVERTICULAR BLEEDING

- AbbVie: More likely related to a history of diverticular bleeding and Parkinson's disease in an advanced aged patient

Event of HIP FRACTURE

- Investigator: ACCIDENTAL FALL

- AbbVie: More likely related to reported fall in an advanced age patient with a history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ANGIOGRAPHY ABDOMEN:** ACTIVE ARTERIAL BLEEDING, COLONDIVERTICULOSIS.

[redacted] **20[redacted] COLONSCOPY:** DIVERTICULOSIS IN COLON DESCENDENS AND IN SIGMOÏD WITH BLEEDING.

[redacted] **20[redacted] GASTROSCOPY:** Normal

[redacted] **20[redacted] HEMOLOBIN:** 10 G/DL (normal 12.6 to 17.4)

[redacted] **20[redacted] HEMOGLOBIN:** 8.6 G/DL (normal 12.6 to 17.0)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に死亡に至った終末期のパーキンソン病を発現した。

Event 10 の臨床経過：

投与 535 日目，被験者は終末期のパーキンソン病を発現した。投与 535 日目，被験者は死亡した。死因は終末期のパーキンソン病による心肺不全及び終末期のパーキンソン病と報告された。剖検は実施されなかった。

本事象の発現前，死亡に至るまでに治験薬の注入部位に感染の徴候は認められなかった。被験者は非常に進行したパーキンソン病であった。被験者は飲食を拒んでおり，嚥下に関して協調した動作をすることがもはやできない徴候が認められた。レボドパの継続的な皮下投与によって被験者の生活の質が以前と比べとても改善されたので，最後の数週間であっても，被験者が本試験に参加できて本当に幸せであったと，介護者は繰り返し強調していた。

投与 535 日目，被験者の介護者は介護施設に電話し，被験者が投与 534 日目から何も食べず何も飲んでいないことを告げられた。同日，被験者の介護者が被験者を訪ね，午前 10 時に薬剤ポンプを交換した。被験者は口を開けて息をしており，調子が良さそうではなかったため，一般開業医に電話した。午前 11 時 52 分，被験者が呼吸困難となったため，病院の救急チームに電話することを決めた。午後 0 時 1 分にチームが到着したが，被験者はチームの到着前に息を引き取っており，救急チームは被験者の死亡を確認できただけであった。

治験責任医師によると，被験者は終末期のパーキンソン病に関連した心肺停止によって死亡した。

The patient's past medications include:

DAFALGAN for SUBCAPITAL HUMERUS FRACTURE ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) End stage Parkinson's disease (10076917) (Parkinson's disease (10061536)) [v.24.0] [10076917]

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 END STAGE PARKINSON DISEASE

- Investigator: Cardiorespiratory failure.

- AbbVie: More likely related to progression of underlying Parkinson disease in an elderly subject.

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

Weight Decreased: Day 1 weight 5[redacted] kg. Weight at time of event 4[redacted] kg. Weight loss occurred over a period of 6 months. Change in diet or mobility level with pump/infusion therapy reported as immobilization due to hip fracture, in nursing home [redacted] - [redacted] 20[redacted]. Onset of weight loss did not coincide with worsening PD symptoms or eating difficulties. Subject experienced previous episode of cognitive decline and depression and/or other psychiatric disorders, temporal episodes of loss of appetite and dysphagia. No additional conditions or circumstances reported.

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
注入部位紅斑				X
注入部位腫瘤				X
注入部位浮腫				X
注入部位丘疹				X
四肢痛	X			
** Disc. due to adverse event				X

Disc = Discontinued.

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
NIGHT AKATHISIA	NOT REPORTED
DEPRESSION (INTERMITTENT)	19[redacted]
ARTHROSIS	19[redacted]
PERFORATED GASTRIC ULCUS	19[redacted]
HYPOTHYREOSIS	20[redacted]
PARKINSON DISEASE	20[redacted]
POST MENUPAUSAL STATUS	20[redacted]
PULMONARY EMBOLISM	20[redacted]
SLEEP APNEA	20[redacted]
DYSPNEA	20[redacted]
THORACIC SKIN HERPES	20[redacted]
SPINE DEGENERATIVE LESIONS INCREASED ON L4 L5	20[redacted]
LEFT CARPAL TUNNEL	20[redacted]
INTERMITTENT DYSSOMNIA	20[redacted]
RIGHT CARPAL TUNNEL	20[redacted]
LEFT WRIST EDEMA	20[redacted]

RIGHT HAND PARESTHESIAS	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
LOCAL RESECTION OF THE UTERUS	19[redacted]
OPERATED LEFT KNEE (PROTHESIS)	20[redacted]
OPERATED RIGHT KNEE (PROTHESIS)	20[redacted]
OPERATED LEFT CARPAL CANAL	20[redacted]
OPERATED RIGHT CARPAL CANAL	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.36	0.40	0.32	120	0.19	[redacted]20[redacted] / 367
ABBV-951	0.38	0.40	0.36	120	0.19	[redacted]20[redacted] / 479
ABBV-951	0.40	0.42	0.36	120	0.19	[redacted]20[redacted] / 535
ABBV-951	0	0	0	0	0.00	[redacted]20[redacted] / 710

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 1	

M15-741 /ABBV-951	553.23		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 2	
M15-741 /ABBV-951	1092.62		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1097.23		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1074.18		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	1108.50		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 6	
M15-741 /ABBV-951	1101.84		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 7
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1318.70		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951	1381.70		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1248.18		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951	1381.70		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	1414.83		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951	1430.88		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951	1387.51		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951	1416.88		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951	1402.54		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951	1420.64		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1426.44		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	1386.14		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951	1443.86		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1426.10		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	1361.21		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	1368.04		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951	1390.24		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951	1388.19		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1413.46		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 27	

M15-741 /ABBV-951	1422.68		SC / CONTINUOUS	[redacted] / 27	[redacted] / 27
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 28	
M15-741 /ABBV-951	1423.37		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	1472.20		SC / CONTINUOUS	[redacted] / 29	[redacted] / 29
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 30	
M15-741 /ABBV-951	1432.59		SC / CONTINUOUS	[redacted] / 30	[redacted] / 30
M15-741 /ABBV-951	1403.56		SC / CONTINUOUS	[redacted] / 31	[redacted] / 31
M15-741 /ABBV-951	1416.54		SC / CONTINUOUS	[redacted] / 32	[redacted] / 32
M15-741 /ABBV-951	1419.95		SC / CONTINUOUS	[redacted] / 33	[redacted] / 33
M15-741 /ABBV-951	1454.10		SC / CONTINUOUS	[redacted] / 34	[redacted] / 34
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 35	
M15-741 /ABBV-951	1420.98		SC / CONTINUOUS	[redacted] / 35	[redacted] / 35
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 36	
M15-741 /ABBV-951	1458.54		SC / CONTINUOUS	[redacted] / 36	[redacted] / 36
M15-741 /ABBV-951	1398.78		SC / CONTINUOUS	[redacted] / 37	[redacted] / 37
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 38	
M15-741 /ABBV-951	1488.59		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	1467.76		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	1531.28		SC / CONTINUOUS	[redacted] / 41	[redacted] / 41
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 42	
M15-741 /ABBV-951	1440.10		SC / CONTINUOUS	[redacted] / 42	[redacted] / 42
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 43	
M15-741 /ABBV-951	1514.55		SC / CONTINUOUS	[redacted] / 43	[redacted] / 43
M15-741 /ABBV-951	1469.13		SC / CONTINUOUS	[redacted] / 44	[redacted] / 44
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 45	
M15-741 /ABBV-951	1438.39		SC / CONTINUOUS	[redacted] / 45	[redacted] / 45
M15-741 /ABBV-951	1431.05		SC / CONTINUOUS	[redacted] / 46	[redacted] / 46
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 47	[redacted] / 51
M15-741 /ABBV-951	915.90		SC / CONTINUOUS	[redacted] / 52	[redacted] / 52
M15-741 /ABBV-951	534.78		SC / CONTINUOUS	[redacted] / 53	[redacted] / 53
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 54	[redacted] / 89
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	1480.74		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 91	
M15-741 /ABBV-951	1457.52		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951	1417.90		SC / CONTINUOUS	[redacted] / 92	[redacted] / 92

M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 180
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 181	
M15-741 /ABBV-951	1527.87		SC / CONTINUOUS	[redacted]20[redacted] / 181	[redacted]20[redacted] / 181
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 182	
M15-741 /ABBV-951	1495.77		SC / CONTINUOUS	[redacted]20[redacted] / 182	[redacted]20[redacted] / 182
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted]20[redacted] / 183	[redacted]20[redacted] / 273
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 274	
M15-741 /ABBV-951	1508.06		SC / CONTINUOUS	[redacted]20[redacted] / 274	[redacted]20[redacted] / 274
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 275	
M15-741 /ABBV-951	1359.17		SC / CONTINUOUS	[redacted]20[redacted] / 275	[redacted]20[redacted] / 275
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted]20[redacted] / 276	[redacted]20[redacted] / 364
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 365	
M15-741 /ABBV-951	1400.83		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 366	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	485.61		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 367
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 368	[redacted]20[redacted] / 448
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 449	
ABBV-951	1469.13		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 450	
ABBV-951	1462.98		SC / CONTINUOUS	[redacted]20[redacted] / 450	[redacted]20[redacted] / 450
ABBV-951	1475.28		SC / CONTINUOUS	[redacted]20[redacted] / 451	[redacted]20[redacted] / 451
ABBV-951	1081.87		SC / CONTINUOUS	[redacted]20[redacted] / 452	[redacted]20[redacted] / 452
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 624	
ABBV-951	1004.01		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 624
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 625	
ABBV-951	1617.68		SC / CONTINUOUS	[redacted]20[redacted] / 625	[redacted]20[redacted] / 625
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 626	[redacted]20[redacted] / 707
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 708	
ABBV-951	1688.37		SC / CONTINUOUS	[redacted]20[redacted] / 708	[redacted]20[redacted] / 708
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 709	
ABBV-951	1577.73		SC / CONTINUOUS	[redacted]20[redacted] / 709	[redacted]20[redacted] / 709

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 19[redacted]

LEVOTHYROXINE	87.5 ug	QD	Y-M: 20[redacted]
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -70
AMANTADINE	100.000 mg	BID	Y-M: 20[redacted] / 21
MELATONIN	2 mg	QD	Y-M: 20[redacted] / 22
ETILEFRINE HYDROCHLORIDE	10 gtt	TID	Y-M: 20[redacted] / 198

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
VENLAFAXINE HYDROCHLORIDE	75 mg	QD	Y-M: 19[redacted]	Y-M: 20[redacted] / 535
LEVOTHYROXINE	87.5 ug	QD	Y-M: 20[redacted]	NOT REPORTED
ACETYLSALICYLIC ACID	80 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CLONAZEPAM	0.5 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
COLECALCIFEROL	1000 IU	QD	Y-M: 20[redacted] / -70	NOT REPORTED
MELATONIN	2 mg	QD	Y-M: 20[redacted] / 22	Y-M: 20[redacted] / 478
ETILEFRINE HYDROCHLORIDE	10 gtt	TID	Y-M: 20[redacted] / 198	Y-M: 20[redacted] / 710
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 451	Y-M: 20[redacted] / 456
D-MANNOSE;VACCINIUM MACROCARPON	1 OTHER: BAG	PRN	Y-M: 20[redacted] / 456	NOT REPORTED
CIPROFLOXACIN HYDROCHLORIDE	500 mg	BID	Y-M: 20[redacted] / 457	Y-M: 20[redacted] / 460
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 472	NOT REPORTED
MELATONIN	3 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 710
VALERIANA OFFICINALIS	300 mg	QD	Y-M: 20[redacted] / 479	Y-M: 20[redacted] / 710
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 507	NOT REPORTED
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 518	Y-M: 20[redacted] / 525
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 531	Y-M: 20[redacted] / 538
VENLAFAXINE HYDROCHLORIDE	112.50 mg	QD	Y-M: 20[redacted] / 535	ONGOING
CYANOCOBALAMIN; FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	1 OTHER: PILL	QD	Y-M: 20[redacted] / 550	Y-M: 20[redacted] / 710

AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	QID	Y-M: 20[redacted] / 554	Y-M: 20[redacted] / 560
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 565	Y-M: 20[redacted] / 572
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 584	Y-M: 20[redacted] / 590
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 616	Y-M: 20[redacted] / 622
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 620	Y-M: 20[redacted] / 625
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 629	Y-M: 20[redacted] / 641
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 644	Y-M: 20[redacted] / 647
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 660	NOT REPORTED
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted] / 676	Y-M: 20[redacted] / 684
FLUOXETINE HYDROCHLORIDE	20 mg	QD	Y-M: 20[redacted] / 681	NOT REPORTED
NITROFURANTOIN	100 mg	TID	Y-M: 20[redacted] / 690	Y-M: 20[redacted] / 697
FLUCLOXACILLIN SODIUM	500 mg	QID	Y-M: 20[redacted] / 694	Y-M: 20[redacted] / 697
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	875 mg	TID	Y-M: 20[redacted] / 697	Y-M: 20[redacted] / 710
CYANOCOBALAMIN; FOLIC ACID;PYRIDOXINE HYDROCHLORIDE	1 OTHER: PILL	PRN	Y-M: 20[redacted] / 710	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 712	NOT REPORTED
CIPROFLOXACIN	500 mg	BID	Y-M: 20[redacted] / 712	Y-M: 20[redacted] / 715

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

Event Description	SKIN DEFINITE EDEMA AT INFUSION SITE (ABDOMEN)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 367

Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	372
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 #2: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	MULTIPLE SKIN MINIMAL PAPULAR RESPONSE AT INFUSION SITE (ABDOMEN)
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	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE

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

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

Event Description	PANNICULUS ADIPOSUS AT INFUSION SITE
Preferred Term	注入部位腫瘤
AE Onset Date / Rx Day	[redacted]20[redacted] / 554
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	562
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	SKIN DEFINITE EDEMA AT INFUSION SITE (LEG)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 584
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	591
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 #5: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	SKIN DEFINITE EDEMA AT INFUSION SITE (LEG)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 620
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	638
Duration of AE	19 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	SKIN DEFINITE EDEMA ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 629

Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	653
Duration of AE	25 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	MINIMAL ERYTHEMA ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位紅斑
AE Onset Date / Rx Day	[redacted]20[redacted] / 643
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	653
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: Serious Adverse Event

Event Description	PAIN LEFT LEG
Preferred Term	四肢痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 660
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	710
Duration of AE	51 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 RELATED
Other Cause of Event	PATIENT HOSPITALIZED IN ORDER TO BE EVALUATED BY KINESIOLOGIST AND LOGOPEDE. THIS IS MORE LIKE AND HOSPITALIZATION TO REVIEW THE PATIENT'S CONDITION THEN A SEVERE AE THAT NEEDED TO BE HOSPITALIZED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	SKIN DEFINITE EDEMA ON INFUSION SITE (ABDOMEN, PATIENT'S RIGHT SIDE)
Preferred Term	注入部位浮腫
AE Onset Date / Rx Day	[redacted]20[redacted] / 674
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	

AE Stopped Rx Day	681
Duration of AE	8 DAYS
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: AE Leading to Discontinuation of Study Drug, Event of Interest - Infusion Site Related Infections

Event Description	CUTANEOUS ABSCESS ON INFUSION SITE (ABDOMEN)
Preferred Term	注入部位膿瘍
AE Onset Date / Rx Day	[redacted]20[redacted] / 692
Age at AE Onset	8[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	752 (42 DAYS AFTER LAST TREATMENT)
Duration of AE	61 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	YES
SAE Criteria	NONE

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はベルギーの 8[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に左下肢の疼痛を発現した。

Event 8 の臨床経過：

関連する病歴は，うつ病，関節症，甲状腺機能低下症，パーキンソン病，肺塞栓症，睡眠時無呼吸，呼吸困難，左膝の手術（補装具），右膝の手術（補装具），骨粗鬆症，間欠性睡眠異常，及び現飲酒者（1 日 2 杯未満）であった。

投与 660 日目，被験者は左下肢の疼痛を発現した。

投与 674 日目，被験者は左下肢の疼痛のため入院した。被験者の左下肢の状態を評価するために運動機能学者（Kinesiologist）及び言語療法士に相談した。投与から約 22 ヵ月後，股関節の X 線検査が実施され，関節症が認められた。投与 676 日目，腰部の CT スキャンが実施され，骨粗鬆症及び関節症が認められた。予定された股関節超音波検査が完了するまでに，理学療法チームは中臀筋腱炎の疑いと最終診断を下した。投与 684 日目，被験者は自宅療養のため退院した。

治験責任医師によると，被験者には関連するリスク因子としてパーキンソン病及び股関節症の病歴があった。投与 710 日目，左脚の疼痛は消失した。

被験者に DAFALGAN が投与された。

The patient's past medications include:

COVID-19 VACCINE (Pfizer) for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Leg pain (10024130) (Pain in extremity (10033425)) [v.24.1] [10024130]

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 PAIN LEFT LEG

- Investigator: PATIENT HOSPITALIZED IN ORDER TO BE EVALUATED BY KINESIOLOGIST AND LOGOPEDE. THIS IS MORE LIKE AND HOSPITALIZATION TO REVIEW THE PATIENT'S CONDITION THEN A SEVERE AE THAT NEEDED TO BE HOSPITALIZED

- AbbVie: More likely related to elderly age, hip arthrosis and underlying Parkinson disease.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ELECTROCARDIOGRAM:** SINUSAL RHYTHM

[redacted] **20[redacted] HIP RADIOGRAPHY:** Arthrosis
[redacted] **20[redacted] LUMBAR CT SCAN:** OSTEOPOROSIS ARTHROSIS NO INTRACANALAR COMPRESSION. SIGNIFICANT FORAMINAL NAROWNESS AT L1-L2, L2-L3, L3-L4 AND FORAMINAL NAROWNESS AT D11-D12 AND D12-L1

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
注入部位炎症				X
一過性脳虚血発作	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	MALE	WHITE

Medical History	Onset Year
PARKINSONS DISEASE	20[redacted]
DISCUS PROLAPS L5 DEX	20[redacted]
OBSTIPATION	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
HEMILAMINEKTOMI L4/L5	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.55	0.60	0.50	60	0.15	[redacted] / 365
ABBV-951	0.55	0.6	0.5		0.15	[redacted] / 522
ABBV-951	0.55	0.85	0.5	60	0.15	[redacted] / 694

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	496.88		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 2	
M15-741 /ABBV-951	1229.4		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 3	
M15-741 /ABBV-951	1354.38		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 4	
M15-741 /ABBV-951	1401.51		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 5	
M15-741 /ABBV-951	1475.28		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1462.98		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 7	
M15-741 /ABBV-951	1413.81		SC / CONTINUOUS	[redacted] / 7	[redacted] / 7
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 8	
M15-741 /ABBV-951	1652.51		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 9	
M15-741 /ABBV-951	1678.13		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 10	
M15-741 /ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	1709.89		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	1635.10		SC / CONTINUOUS	[redacted] / 12	[redacted] / 12
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	1706.81		SC / CONTINUOUS	[redacted] / 13	[redacted] / 14
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 14	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1728.33		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted] / 16	

M15-741 /ABBV-951	1795.60		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 17	
M15-741 /ABBV-951	1788.09		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1712.96		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	1757.35		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1788.09		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951	1873.46		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	2072.90		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 23	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951	2040.46		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 27
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1955.08		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	2161.69		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	2112.17		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	2192.43		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 36
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	2228.28		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 39	

M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 42
M15-741 /ABBV-951		76.83	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	2317.07		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951	2304.27		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 48
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 51
M15-741 /ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 54
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 57
M15-741 /ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951	2141.20		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 64
M15-741 /ABBV-951	2141.20		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 67
M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] / 68
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 69	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 69	[redacted]20[redacted] / 70
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 71	[redacted]20[redacted] / 71
M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 72	[redacted]20[redacted] / 72
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 73	[redacted]20[redacted] / 73
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 74	[redacted]20[redacted] / 74
M15-741 /ABBV-951	1211.47		SC / CONTINUOUS	[redacted]20[redacted] / 75	[redacted]20[redacted] / 75

M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 76	[redacted]20[redacted] / 77
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 78	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 78	[redacted]20[redacted] / 78
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 79	[redacted]20[redacted] / 79
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 80	[redacted]20[redacted] / 81
M15-741 /ABBV-951	2329.88		SC / CONTINUOUS	[redacted]20[redacted] / 82	[redacted]20[redacted] / 82
M15-741 /ABBV-951	2443.43		SC / CONTINUOUS	[redacted]20[redacted] / 83	[redacted]20[redacted] / 83
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 84	[redacted]20[redacted] / 84
M15-741 /ABBV-951	2325.61		SC / CONTINUOUS	[redacted]20[redacted] / 85	[redacted]20[redacted] / 85
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 86	
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 86	[redacted]20[redacted] / 86
M15-741 /ABBV-951	2150.59		SC / CONTINUOUS	[redacted]20[redacted] / 87	[redacted]20[redacted] / 87
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 88	[redacted]20[redacted] / 89
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 90	[redacted]20[redacted] / 91
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 92	
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 92	[redacted]20[redacted] / 92
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 93	[redacted]20[redacted] / 93
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 94	[redacted]20[redacted] / 94
M15-741 /ABBV-951	2169.37		SC / CONTINUOUS	[redacted]20[redacted] / 95	[redacted]20[redacted] / 95
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 96	[redacted]20[redacted] / 97
M15-741 /ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 98	[redacted]20[redacted] / 98
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 99	[redacted]20[redacted] / 100
M15-741 /ABBV-951	2150.59		SC / CONTINUOUS	[redacted]20[redacted] / 101	[redacted]20[redacted] / 101
M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 102	[redacted]20[redacted] / 102
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 103	
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 108	[redacted]20[redacted] / 108

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M15-741 /ABBV-951	2159.98		SC / CONTINUOUS	[redacted]20[redacted] / 113	[redacted]20[redacted] / 113
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 147	[redacted]20[redacted] / 148
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 149	
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M15-741 /ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 293
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M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 295	
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M15-741 /ABBV-951	2150.59		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
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M15-741 /ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 330
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M15-741 /ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 338
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M15-741 /ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
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ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 539	[redacted]20[redacted] / 539
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 540	[redacted]20[redacted] / 544
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 542	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 545	[redacted]20[redacted] / 545
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 546	[redacted]20[redacted] / 546
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 547	
ABBV-951	2240.24		SC / CONTINUOUS	[redacted]20[redacted] / 547	[redacted]20[redacted] / 547
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 548	[redacted]20[redacted] / 550
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 551	[redacted]20[redacted] / 551
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 552	[redacted]20[redacted] / 552
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 553	[redacted]20[redacted] / 553
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 554	[redacted]20[redacted] / 554
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 555	[redacted]20[redacted] / 555
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 556	[redacted]20[redacted] / 556
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 557	[redacted]20[redacted] / 558
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 559	[redacted]20[redacted] / 559
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 560	[redacted]20[redacted] / 560
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 561	[redacted]20[redacted] / 561
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 562	
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 562	[redacted]20[redacted] / 562
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 563	[redacted]20[redacted] / 563
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 564	[redacted]20[redacted] / 564
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 565	[redacted]20[redacted] / 565
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 566	[redacted]20[redacted] / 566
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 567	[redacted]20[redacted] / 567
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 568	[redacted]20[redacted] /

					568
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 569	
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 569	[redacted]20[redacted] / 569
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 570	[redacted]20[redacted] / 570
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 571	[redacted]20[redacted] / 571
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 572	[redacted]20[redacted] / 572
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 573	[redacted]20[redacted] / 573
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 574	[redacted]20[redacted] / 574
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 575	[redacted]20[redacted] / 575
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 576	[redacted]20[redacted] / 576
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 577	[redacted]20[redacted] / 577
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 578	
ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 578	[redacted]20[redacted] / 578
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 579	
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 579	[redacted]20[redacted] / 579
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 580	[redacted]20[redacted] / 580
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 581	[redacted]20[redacted] / 583
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 584	
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 584	[redacted]20[redacted] / 584
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 585	[redacted]20[redacted] / 585
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 586	[redacted]20[redacted] / 586
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 587	[redacted]20[redacted] / 587
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 588	[redacted]20[redacted] / 588
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 589	[redacted]20[redacted] / 589
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 590	[redacted]20[redacted] / 590
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 591	[redacted]20[redacted] / 591
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 592	[redacted]20[redacted] / 597
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 598	

ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 598	[redacted]20[redacted] / 598
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 599	[redacted]20[redacted] / 599
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 600	[redacted]20[redacted] / 600
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 601	
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 601	[redacted]20[redacted] / 601
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 602	[redacted]20[redacted] / 602
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 603	[redacted]20[redacted] / 603
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 604	[redacted]20[redacted] / 605
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 606	[redacted]20[redacted] / 606
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 607	[redacted]20[redacted] / 607
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 608	[redacted]20[redacted] / 609
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 610	[redacted]20[redacted] / 610
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 611	[redacted]20[redacted] / 611
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 612	[redacted]20[redacted] / 612
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 613	[redacted]20[redacted] / 614
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 615	[redacted]20[redacted] / 615
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 616	[redacted]20[redacted] / 616
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 617	[redacted]20[redacted] / 617
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 618	[redacted]20[redacted] / 618
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 619	[redacted]20[redacted] / 619
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 620	[redacted]20[redacted] / 621
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 622	[redacted]20[redacted] / 622
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 623	[redacted]20[redacted] / 623
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 624	[redacted]20[redacted] / 627
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 628	[redacted]20[redacted] / 628
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 629	[redacted]20[redacted] / 629
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 630	[redacted]20[redacted] / 630

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 631	[redacted]20[redacted] / 633
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 634	[redacted]20[redacted] / 634
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 635	[redacted]20[redacted] / 636
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 637	[redacted]20[redacted] / 637
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 638	[redacted]20[redacted] / 641
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 642	[redacted]20[redacted] / 642
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 643	
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 643	[redacted]20[redacted] / 643
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 644	[redacted]20[redacted] / 644
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 645	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 645	[redacted]20[redacted] / 645
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 646	[redacted]20[redacted] / 646
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 647	[redacted]20[redacted] / 647
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 648	[redacted]20[redacted] / 648
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 649	[redacted]20[redacted] / 649
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 650	[redacted]20[redacted] / 651
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 652	[redacted]20[redacted] / 652
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 653	[redacted]20[redacted] / 665
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 666	[redacted]20[redacted] / 666
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 667	[redacted]20[redacted] / 667
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 668	[redacted]20[redacted] / 671
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 672	[redacted]20[redacted] / 672

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 673	[redacted]20[redacted] / 673
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 674	[redacted]20[redacted] / 674
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 675	[redacted]20[redacted] / 676
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 677	[redacted]20[redacted] / 678
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 679	[redacted]20[redacted] / 679
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 680	[redacted]20[redacted] / 681
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 682	[redacted]20[redacted] / 682
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 683	[redacted]20[redacted] / 686
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 687	[redacted]20[redacted] / 688
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 689	[redacted]20[redacted] / 692
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 693	[redacted]20[redacted] / 693
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 694	[redacted]20[redacted] / 694
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 695	[redacted]20[redacted] / 695
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 696	[redacted]20[redacted] / 696
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 697	[redacted]20[redacted] / 697
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 698	[redacted]20[redacted] / 700
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ABBV-951	2131.81		SC / CONTINUOUS	[redacted]20[redacted] / 701	[redacted]20[redacted] / 701
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 702	
ABBV-951	1981.55		SC / CONTINUOUS	[redacted]20[redacted] / 702	[redacted]20[redacted] / 702
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 703
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 704	[redacted]20[redacted] / 704

ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 705	[redacted]20[redacted] / 706
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 707	[redacted]20[redacted] / 707
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 708	[redacted]20[redacted] / 709
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 710	[redacted]20[redacted] / 710
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 711	[redacted]20[redacted] / 711
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 712	[redacted]20[redacted] / 717
ABBV-951	2469.04		SC / CONTINUOUS	[redacted]20[redacted] / 718	[redacted]20[redacted] / 718
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 719	
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 719	[redacted]20[redacted] / 719
ABBV-951	2628.69		SC / CONTINUOUS	[redacted]20[redacted] / 720	[redacted]20[redacted] / 720
ABBV-951	2562.10		SC / CONTINUOUS	[redacted]20[redacted] / 721	[redacted]20[redacted] / 721
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 722	[redacted]20[redacted] / 722
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 723	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 723	[redacted]20[redacted] / 723
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 724	[redacted]20[redacted] / 724
ABBV-951	2216.33		SC / CONTINUOUS	[redacted]20[redacted] / 725	[redacted]20[redacted] / 726
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 727	[redacted]20[redacted] / 727
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 728	[redacted]20[redacted] / 728
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 729	[redacted]20[redacted] / 729
ABBV-951	1878.25		SC / CONTINUOUS	[redacted]20[redacted] / 730	[redacted]20[redacted] / 730
ABBV-951	122.08		SC / CONTINUOUS	[redacted]20[redacted] / 731	[redacted]20[redacted] / 731
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 732	[redacted]20[redacted] / 732
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 733	[redacted]20[redacted] / 733
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 734	[redacted]20[redacted] / 734
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 735	[redacted]20[redacted] / 736
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 737	[redacted]20[redacted] / 737
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 738	[redacted]20[redacted] / 738
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 739	[redacted]20[redacted] / 742
ABBV-951	2197.55		SC / CONTINUOUS	[redacted]20[redacted] / 743	[redacted]20[redacted] / 743
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 744	
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 744	[redacted]20[redacted] / 744
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 745	[redacted]20[redacted] / 746
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 746	
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 747	[redacted]20[redacted] / 747
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 748	[redacted]20[redacted] / 748
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 749	[redacted]20[redacted] / 749
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 750	[redacted]20[redacted] / 750

ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 751	[redacted]20[redacted] / 751
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 752	[redacted]20[redacted] / 753
ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 754	
ABBV-951	2219.75		SC / CONTINUOUS	[redacted]20[redacted] / 754	[redacted]20[redacted] / 754
ABBV-951	2060.09		SC / CONTINUOUS	[redacted]20[redacted] / 755	[redacted]20[redacted] / 755
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 756	[redacted]20[redacted] / 758
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 759	[redacted]20[redacted] / 759
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 760	[redacted]20[redacted] / 760
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 761	[redacted]20[redacted] / 761
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 762	[redacted]20[redacted] / 762
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 763	[redacted]20[redacted] / 764
ABBV-951	2244.50		SC / CONTINUOUS	[redacted]20[redacted] / 765	[redacted]20[redacted] / 765

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	9 MG/ML + 90 MG/ML OTHER: MG/ML + MG/ML	PRN	Y-M: 20[redacted]-[redacted] / -98
CARBIDOPA;LEVODOPA	100.000 mg	PRN	Y-M: 20[redacted]-[redacted] / -39
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: UNIT	PRN	Y-M: 20[redacted]-[redacted] / 135

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
SODIUM CITRATE;SODIUM LAURYL SULFOACETATE	9 MG/ML + 90 MG/ML OTHER: MG/ML + MG/ML	PRN	Y-M: 20[redacted]-[redacted] / -98	NOT REPORTED
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: UNIT	PRN	Y-M: 20[redacted]-[redacted] / 135	NOT REPORTED
ACETYLSALICYLIC ACID	300 mg	OTHER: SD	Y-M: 20[redacted]-[redacted] / 423	Y-M: 20[redacted]-[redacted] / 423
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]-[redacted] / 424	NOT REPORTED

TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 431	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 452	NOT REPORTED
SILDENAFIL	20 mg	PRN	Y-M: 20[redacted] / 497	ONGOING
DICLOXACILLIN	1000 mg	QID	Y-M: 20[redacted] / 519	Y-M: 20[redacted] / 526
INFLUENZA VACCINE INACT SAG 4V	1 OTHER: UNIT	OTHER: ONCE	Y-M: 20[redacted] / 613	Y-M: 20[redacted] / 613
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 654	NOT REPORTED
OXAZEPAM	7.5 mg	PRN	Y-M: 20[redacted] / 681	ONGOING

Event #1: Serious Adverse Event

Event Description	TRANSIENT ISCHEMIC ATTACK
Preferred Term	一過性脳虚血発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 423
Age at AE Onset	7[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 424): Albumin: 36 [34 - 45] G/L; Alkaline Phosphatase: 61 [35 - 105] U/L; Bilirubin: 16 [5 - 25] UMOL/L; Cholesterol: 3.4 [NOT REPORTED - 5] mmol/L; Creatinine: 63 [60 - 105] UMOL/L; Ery. Mean Corpuscular HGB Concentration: 359.33 [317.43 - 357.72] G/L; Glucose: 6.2 [4.2 - 7.8] MMOL/L; Hemoglobin: 158 [134 - 169] G/L; NPTST002-ALANINE TRANSAMINASE ALAT: 9 [10 - 70] U/L; NPTST011-C-REACTIVE PROTEIN (CRP): 1.5 [NOT REPORTED - 8] mg/L; NPTST013-CHELESTEROL LDL: 1.8 [NOT REPORTED - 3] mmol/L; NPTST014-CHOLESTEROL HDL: 1.2 [1 - NOT REPORTED] mmol/L; NPTST032-GLOMERULAR FILTRATION RATE (GFR: 90 [60 - NOT REPORTED] ML/MIN; NPTST037-INR: 1.2 [NOT REPORTED - 1.2] RATIO; Potassium: 3.8 [3.5 - 4.6] MMOL/L; Sodium: 141 [137 - 145] MMOL/L; Triglycerides: 1.0 [NOT REPORTED - 2] mmol/L

Microbiology

[redacted]20[redacted] (RX DAY 424): OTHER PHARYNGEAL SWAB CORONAVIRUS SARS-CO-V-2 DNA/RNA: NEGATIVE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	AGE AND STRESED AT THE TIME OF EVENT,
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	ABDOMEN INFUSION SITE INFLAMMATION.
Preferred Term	注入部位炎症
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	526
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

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はデンマークの 7[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に一過性脳虚血発作を発現した。

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，及び飲酒者（1 日 2 杯未満）であった。

投与 423 日目，被験者は一過性脳虚血発作を発現した。本事象発現前に，被験者は手首にわずかに締め付けられるような感覚及び右親指と人差し指にわずかに眠ったような感覚があった。しかし，これらの症状は軽減した。

投与 423 日目，被験者は胸部圧迫感を伴った失語症の突然の発症により入院した。約 1 時間症状が持続した後に，被験者は習慣的状態を感じた。大脳の CT スキャンの結果，軽度の中心性萎縮症及び頸動脈と中心動脈の開放が認められた。神経学的検査の結果，被験者は客観的に見て習慣的状態であった。脳神経：I.a。上肢：力及び感受性は正常。深部反射は均衡。指鼻試験は正常。下肢：右足首の屈曲によるわずかな力の減少を除き力は正常，深部反射なし。踵膝試験は正常。歩行 / 起立：正常な歩行で右側にやや下垂足，ただし以前より認められていた。一過性血栓症の疑いがあり，クロピドグレルの予防投与を開始した。投与 424 日目被験者は習慣的状態で退院した。

治験責任医師によると，被験者の母親は 5[redacted] 歳で心臓発作によって死亡した。

被験者にクロピドグレル及びアセチルサリチル酸が投与された。

Causality for ABBV-951 (Open Label)

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1) Transient ischemic attack (10072760) (Transient ischaemic attack (10044390)) [v.23.1] [10072760]

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 TRANSIENT ISCHEMIC ATTACK

- Investigator: Age and stressed at the time of event

- AbbVie: More likely related to advanced age.

Relevant Laboratory & Other Diagnostic Tests

[redacted] 20[redacted] **ALANINE TRANSAMINASE ALAT:** <9 U/L

[redacted] 20[redacted] **ALBUMIN:** 36 G/L (normal 34 to 45)

[redacted] 20[redacted] **ALKALINE PHOSPHATASE:** 61 U/L (normal 35 to 105)

[redacted] 20[redacted] **BILIRUBIN:** 16 umol/L (normal 5 to 25)

[redacted] 20[redacted] **C-REACTIVE PROTEIN:** 1.5 MG/L (normal <8.0)

[redacted] 20[redacted] **CARDIAC MONITORING AT HOME FOR 3 DAYS:** Normal heart rhythm

[redacted] 20[redacted] **CHOLESTEROL:** 3.4 MMOL/L (normal <5.0)

[redacted] 20[redacted] **CHOLESTEROL HDL:** 1.2 MMOL/L (normal >1.0)

[redacted] 20[redacted] **CHOLESTEROL LDL:** 1.8 MMOL/L (normal <3.0)

[redacted] 20[redacted] **CREATININE:** 63 umol/L (normal 60 to 105)

[redacted] 20[redacted] **CT ANGIOGRAPHY OF HEAD AND NECK:** Normal contrast filling in the vessels. Open carotid arteries and central cerebral arteries. There are no stenoses or caliber differences. No infiltrates in co-scanned lungs. Degenerative changes in the culumna cervicalis.

[redacted] 20[redacted] **CT CEREBRUM:** Discrete central atrophy. There are no signs of infarction, bleeding or space-filling processes. The ventricular system is centralized and normally calibrated. There are inconspicuous surface sulci.

[redacted] 20[redacted] **GLOMERULAR FILTRATION RATE:** 90 mL/min (normal >60)

[redacted] 20[redacted] **GLUCOSE:** 6.2 MMOL/L (normal 4.2 to 7.8)

[redacted] 20[redacted] **HEMOGLOBIN:** 9.8 MMOL/L (normal 8.3 to 10.5)

[redacted] 20[redacted] **INR:** 1.2 NO UNITS (normal <1.2)

[redacted] 20[redacted] **MCHC:** 22.3 MMOL/L (normal 19.7 to 22.2)

[redacted] 20[redacted] **POTASSIUM:** 3.8 MMOL/L (normal 3.5 to 4.6)

[redacted] 20[redacted] **SARS-COV-2 TEST:** Pharyngeal swab: Negative

[redacted] 20[redacted] **SODIUM:** 141 MMOL/L (normal 137 to 145)

[redacted] 20[redacted] **TRIGLYCERIDES:** 1.0 MMOL/L (normal <2.0)

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
転倒	X			X
大腿骨骨折	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	7[redacted]	FEMALE	WHITE

Medical History	Onset Year
ARTERIAL HYPERTENSION	20[redacted]
CONSTIPATION	20[redacted]
HYPOTHYREOSIS	20[redacted]
MENOPAUSAL	20[redacted]
PRESBYOPIA	20[redacted]
CEREBRAL ISCHEMIA	20[redacted]
HYPOMIMIA	20[redacted]
MORBUS PARKINSON	20[redacted]
CHRONIC BACK PAIN	20[redacted]
DIABETES MELLITUS TYPE 2	20[redacted]
SPINALCANALSTENOSIS	20[redacted]
HYPOPHONIA	20[redacted]
DYSARTHROPHONIA	20[redacted]
NYCTURIA	20[redacted]
SLEEP THROUGH DISORDER	20[redacted]
DYSKINESIA	20[redacted]
ADAPTION DISORDER	20[redacted]
SIALORRHOEA	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	CURRENT	2 CIGARETTE	40	
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.27	0.32	0.22	60	0.24	[redacted] / 375

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	556.81		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	813.11		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
M15-741 /ABBV-951	956.02		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
M15-741 /ABBV-951	977.37		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
M15-741 /ABBV-951	1126.95		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951	1311.36		SC / CONTINUOUS	[redacted] / 6	[redacted] / 7
M15-741 /ABBV-951	1177.32		SC / CONTINUOUS	[redacted] / 8	[redacted] / 8
M15-741 /ABBV-951	845.72		SC / CONTINUOUS	[redacted] / 9	[redacted] / 9
M15-741 /ABBV-951	955.85		SC / CONTINUOUS	[redacted] / 10	[redacted] / 10
M15-741 /ABBV-951	966.44		SC / CONTINUOUS	[redacted] / 11	[redacted] / 11
M15-741 /ABBV-951	1106.46		SC / CONTINUOUS	[redacted] / 12	[redacted] / 13
M15-741 /ABBV-951	1179.02		SC / CONTINUOUS	[redacted] / 14	[redacted] / 14
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 15	
M15-741 /ABBV-951	1183.80		SC / CONTINUOUS	[redacted] / 15	[redacted] / 15
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 16	

M15-741 /ABBV-951	1217.44		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 17	
M15-741 /ABBV-951	1223.08		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1205.32		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	894.55		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1019.37		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	983.34		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1077.60		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22
M15-741 /ABBV-951	947.83		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951	1095.87		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 25	
M15-741 /ABBV-951	1016.98		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1007.25		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	976.69		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	696.66		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1037.98		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1002.30		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1037.98		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 31
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951	1070.09		SC / CONTINUOUS	[redacted]20[redacted] / 32	[redacted]20[redacted] / 32
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951	1074.01		SC / CONTINUOUS	[redacted]20[redacted] / 33	[redacted]20[redacted] / 33
M15-741 /ABBV-951	1068.55		SC / CONTINUOUS	[redacted]20[redacted] / 34	[redacted]20[redacted] / 34
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951	847.09		SC / CONTINUOUS	[redacted]20[redacted] / 35	[redacted]20[redacted] / 35

M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951	1073.67		SC / CONTINUOUS	[redacted]20[redacted] / 36	[redacted]20[redacted] / 36
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	1033.20		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 38	
M15-741 /ABBV-951	1276.52		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 39	
M15-741 /ABBV-951	1284.89		SC / CONTINUOUS	[redacted]20[redacted] / 39	[redacted]20[redacted] / 39
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	1416.37		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	1308.79		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 43	
M15-741 /ABBV-951	1286.08		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 43
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 44	
M15-741 /ABBV-951	961.66		SC / CONTINUOUS	[redacted]20[redacted] / 44	[redacted]20[redacted] / 44
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 45	
M15-741 /ABBV-951	1053.69		SC / CONTINUOUS	[redacted]20[redacted] / 45	[redacted]20[redacted] / 45
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 46	
M15-741 /ABBV-951	921.87		SC / CONTINUOUS	[redacted]20[redacted] / 46	[redacted]20[redacted] / 46
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 47	
M15-741 /ABBV-951	1222.74		SC / CONTINUOUS	[redacted]20[redacted] / 47	[redacted]20[redacted] / 47
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 48	
M15-741 /ABBV-951	1053.86		SC / CONTINUOUS	[redacted]20[redacted] / 48	[redacted]20[redacted] / 48
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 49	
M15-741 /ABBV-951	1034.57		SC / CONTINUOUS	[redacted]20[redacted] / 49	[redacted]20[redacted] / 49
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 50	
M15-741 /ABBV-951	1086.31		SC / CONTINUOUS	[redacted]20[redacted] / 50	[redacted]20[redacted] / 50
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 51	
M15-741 /ABBV-951	1102.02		SC / CONTINUOUS	[redacted]20[redacted] / 51	[redacted]20[redacted] / 51
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 52	
M15-741 /ABBV-951	1110.21		SC / CONTINUOUS	[redacted]20[redacted] / 52	[redacted]20[redacted] / 52
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 53	
M15-741 /ABBV-951	841.62		SC / CONTINUOUS	[redacted]20[redacted] / 53	[redacted]20[redacted] / 53
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 54	

M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 54	[redacted]20[redacted] / 54
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 55	
M15-741 /ABBV-951	1238.10		SC / CONTINUOUS	[redacted]20[redacted] / 55	[redacted]20[redacted] / 55
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 56	
M15-741 /ABBV-951	1083.57		SC / CONTINUOUS	[redacted]20[redacted] / 56	[redacted]20[redacted] / 56
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 57	
M15-741 /ABBV-951	1042.25		SC / CONTINUOUS	[redacted]20[redacted] / 57	[redacted]20[redacted] / 57
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 58	
M15-741 /ABBV-951	1125.92		SC / CONTINUOUS	[redacted]20[redacted] / 58	[redacted]20[redacted] / 58
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 59	
M15-741 /ABBV-951	1080.50		SC / CONTINUOUS	[redacted]20[redacted] / 59	[redacted]20[redacted] / 59
M15-741 /ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	1140.26		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	1210.27		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 62	
M15-741 /ABBV-951	1120.63		SC / CONTINUOUS	[redacted]20[redacted] / 62	[redacted]20[redacted] / 62
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 63	
M15-741 /ABBV-951	1028.93		SC / CONTINUOUS	[redacted]20[redacted] / 63	[redacted]20[redacted] / 63
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 64	
M15-741 /ABBV-951	1162.97		SC / CONTINUOUS	[redacted]20[redacted] / 64	[redacted]20[redacted] / 64
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 65	
M15-741 /ABBV-951	1069.74		SC / CONTINUOUS	[redacted]20[redacted] / 65	[redacted]20[redacted] / 65
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 66	
M15-741 /ABBV-951	1097.23		SC / CONTINUOUS	[redacted]20[redacted] / 66	[redacted]20[redacted] / 66
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 67	
M15-741 /ABBV-951	1100.82		SC / CONTINUOUS	[redacted]20[redacted] / 67	[redacted]20[redacted] / 67
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 68	
M15-741 /ABBV-951	1063.43		SC / CONTINUOUS	[redacted]20[redacted] / 68	[redacted]20[redacted] /

				68
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 69
M15-741 /ABBV-951	1186.20		SC / CONTINUOUS	[redacted]20[redacted] / 69 [redacted]20[redacted] / 69
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 70
M15-741 /ABBV-951	1015.79		SC / CONTINUOUS	[redacted]20[redacted] / 70 [redacted]20[redacted] / 70
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 71
M15-741 /ABBV-951	1006.74		SC / CONTINUOUS	[redacted]20[redacted] / 71 [redacted]20[redacted] / 71
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 72
M15-741 /ABBV-951	1307.60		SC / CONTINUOUS	[redacted]20[redacted] / 72 [redacted]20[redacted] / 72
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 73
M15-741 /ABBV-951	1247.84		SC / CONTINUOUS	[redacted]20[redacted] / 73 [redacted]20[redacted] / 73
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 74
M15-741 /ABBV-951	939.46		SC / CONTINUOUS	[redacted]20[redacted] / 74 [redacted]20[redacted] / 74
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 75
M15-741 /ABBV-951	1099.63		SC / CONTINUOUS	[redacted]20[redacted] / 75 [redacted]20[redacted] / 75
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 76
M15-741 /ABBV-951	1133.09		SC / CONTINUOUS	[redacted]20[redacted] / 76 [redacted]20[redacted] / 76
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 77
M15-741 /ABBV-951	1155.80		SC / CONTINUOUS	[redacted]20[redacted] / 77 [redacted]20[redacted] / 77
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 78
M15-741 /ABBV-951	1167.93		SC / CONTINUOUS	[redacted]20[redacted] / 78 [redacted]20[redacted] / 78
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 79
M15-741 /ABBV-951	1100.99		SC / CONTINUOUS	[redacted]20[redacted] / 79 [redacted]20[redacted] / 79
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 80
M15-741 /ABBV-951	1102.02		SC / CONTINUOUS	[redacted]20[redacted] / 80 [redacted]20[redacted] / 80
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 81
M15-741 /ABBV-951	1042.25		SC / CONTINUOUS	[redacted]20[redacted] / 81 [redacted]20[redacted] / 81
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 82

M15-741 /ABBV-951	1271.74		SC / CONTINUOUS	[redacted]20[redacted] / 82 [redacted]20[redacted] / 82
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 83
M15-741 /ABBV-951	1305.21		SC / CONTINUOUS	[redacted]20[redacted] / 83 [redacted]20[redacted] / 83
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 84
M15-741 /ABBV-951	1105.60		SC / CONTINUOUS	[redacted]20[redacted] / 84 [redacted]20[redacted] / 84
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 85
M15-741 /ABBV-951	1162.97		SC / CONTINUOUS	[redacted]20[redacted] / 85 [redacted]20[redacted] / 85
M15-741 /ABBV-951	1034.06		SC / CONTINUOUS	[redacted]20[redacted] / 86 [redacted]20[redacted] / 86
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 87
M15-741 /ABBV-951	1097.23		SC / CONTINUOUS	[redacted]20[redacted] / 87 [redacted]20[redacted] / 87
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 88
M15-741 /ABBV-951	1140.26		SC / CONTINUOUS	[redacted]20[redacted] / 88 [redacted]20[redacted] / 88
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 89
M15-741 /ABBV-951	1090.06		SC / CONTINUOUS	[redacted]20[redacted] / 89 [redacted]20[redacted] / 89
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 90
M15-741 /ABBV-951	1266.96		SC / CONTINUOUS	[redacted]20[redacted] / 90 [redacted]20[redacted] / 90
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 91
M15-741 /ABBV-951	1300.43		SC / CONTINUOUS	[redacted]20[redacted] / 91 [redacted]20[redacted] / 91
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 92
M15-741 /ABBV-951	1043.45		SC / CONTINUOUS	[redacted]20[redacted] / 92 [redacted]20[redacted] / 92
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 93
M15-741 /ABBV-951	1135.99		SC / CONTINUOUS	[redacted]20[redacted] / 93 [redacted]20[redacted] / 93
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 94
M15-741 /ABBV-951	1033.03		SC / CONTINUOUS	[redacted]20[redacted] / 94 [redacted]20[redacted] / 94
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 95
M15-741 /ABBV-951	1266.96		SC / CONTINUOUS	[redacted]20[redacted] / 95 [redacted]20[redacted] / 95
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 96 [redacted]20[redacted] / 157
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 158
M15-741 /ABBV-951	1439.25		SC / CONTINUOUS	[redacted]20[redacted] / 158 [redacted]20[redacted] / 158
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 159
M15-741 /ABBV-951	1518.30		SC / CONTINUOUS	[redacted]20[redacted] / 159 [redacted]20[redacted] /

					159
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 160	
M15-741 /ABBV-951	1424.90		SC / CONTINUOUS	[redacted]20[redacted] / 160	[redacted]20[redacted] / 160
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 161	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 161	[redacted]20[redacted] / 161
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 162	
M15-741 /ABBV-951	1399.29		SC / CONTINUOUS	[redacted]20[redacted] / 162	[redacted]20[redacted] / 162
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 163	
M15-741 /ABBV-951	1327.58		SC / CONTINUOUS	[redacted]20[redacted] / 163	[redacted]20[redacted] / 163
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 164	
M15-741 /ABBV-951	1260.13		SC / CONTINUOUS	[redacted]20[redacted] / 164	[redacted]20[redacted] / 164
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 165	
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted]20[redacted] / 165	[redacted]20[redacted] / 165
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 166	
M15-741 /ABBV-951	1374.53		SC / CONTINUOUS	[redacted]20[redacted] / 166	[redacted]20[redacted] / 166
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 167	
M15-741 /ABBV-951	1424.90		SC / CONTINUOUS	[redacted]20[redacted] / 167	[redacted]20[redacted] / 167
M15-741 /ABBV-951	1438.56		SC / CONTINUOUS	[redacted]20[redacted] / 168	[redacted]20[redacted] / 168
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 169	[redacted]20[redacted] / 169
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 170	
M15-741 /ABBV-951	1452.22		SC / CONTINUOUS	[redacted]20[redacted] / 170	[redacted]20[redacted] / 170
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 171	
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 171	[redacted]20[redacted] / 171
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 172	
M15-741 /ABBV-951	1491.67		SC / CONTINUOUS	[redacted]20[redacted] / 172	[redacted]20[redacted] / 172
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 173	
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 173	[redacted]20[redacted] / 173

M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 174
M15-741 /ABBV-951	1454.79		SC / CONTINUOUS	[redacted]20[redacted] / 174 [redacted]20[redacted] / 174
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 175
M15-741 /ABBV-951	1514.89		SC / CONTINUOUS	[redacted]20[redacted] / 175 [redacted]20[redacted] / 175
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 176
M15-741 /ABBV-951	1434.81		SC / CONTINUOUS	[redacted]20[redacted] / 176 [redacted]20[redacted] / 176
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 177
M15-741 /ABBV-951	1555.53		SC / CONTINUOUS	[redacted]20[redacted] / 177 [redacted]20[redacted] / 177
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 178
M15-741 /ABBV-951	1541.70		SC / CONTINUOUS	[redacted]20[redacted] / 178 [redacted]20[redacted] / 178
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 179
M15-741 /ABBV-951	1469.47		SC / CONTINUOUS	[redacted]20[redacted] / 179 [redacted]20[redacted] / 179
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 180
M15-741 /ABBV-951	1390.75		SC / CONTINUOUS	[redacted]20[redacted] / 180 [redacted]20[redacted] / 180
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 181
M15-741 /ABBV-951	1557.24		SC / CONTINUOUS	[redacted]20[redacted] / 181 [redacted]20[redacted] / 182
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 183
M15-741 /ABBV-951	1303.33		SC / CONTINUOUS	[redacted]20[redacted] / 183 [redacted]20[redacted] / 183
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 184
M15-741 /ABBV-951	1413.81		SC / CONTINUOUS	[redacted]20[redacted] / 184 [redacted]20[redacted] / 184
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 185
M15-741 /ABBV-951	1531.62		SC / CONTINUOUS	[redacted]20[redacted] / 185 [redacted]20[redacted] / 185
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 186
M15-741 /ABBV-951	1269.01		SC / CONTINUOUS	[redacted]20[redacted] / 186 [redacted]20[redacted] / 186
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 187
M15-741 /ABBV-951	1384.78		SC / CONTINUOUS	[redacted]20[redacted] / 187 [redacted]20[redacted] / 187
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 188
M15-741 /ABBV-951	1253.64		SC / CONTINUOUS	[redacted]20[redacted] / 188 [redacted]20[redacted] / 188
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 189
M15-741 /ABBV-951	1290.01		SC / CONTINUOUS	[redacted]20[redacted] / 189 [redacted]20[redacted] / 189
M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 190
M15-741 /ABBV-951	1385.29		SC / CONTINUOUS	[redacted]20[redacted] / 190 [redacted]20[redacted] / 190
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 191

M15-741 /ABBV-951	1429.68		SC / CONTINUOUS	[redacted]20[redacted] / 191 [redacted]20[redacted] / 191
M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 192
M15-741 /ABBV-951	1439.42		SC / CONTINUOUS	[redacted]20[redacted] / 192 [redacted]20[redacted] / 192
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 193
M15-741 /ABBV-951	1226.15		SC / CONTINUOUS	[redacted]20[redacted] / 193 [redacted]20[redacted] / 193
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 194
M15-741 /ABBV-951	1177.66		SC / CONTINUOUS	[redacted]20[redacted] / 194 [redacted]20[redacted] / 194
M15-741 /ABBV-951		163.92	SC / ONCE	[redacted]20[redacted] / 195
M15-741 /ABBV-951	1147.44		SC / CONTINUOUS	[redacted]20[redacted] / 195 [redacted]20[redacted] / 274
M15-741 /ABBV-951		40.98	SC / ONCE	[redacted]20[redacted] / 197
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 275
M15-741 /ABBV-951	1113.29		SC / CONTINUOUS	[redacted]20[redacted] / 275 [redacted]20[redacted] / 275
M15-741 /ABBV-951		122.94	SC / ONCE	[redacted]20[redacted] / 276
M15-741 /ABBV-951	1043.96		SC / CONTINUOUS	[redacted]20[redacted] / 276 [redacted]20[redacted] / 276
M15-741 /ABBV-951		81.96	SC / ONCE	[redacted]20[redacted] / 277
M15-741 /ABBV-951	1022.79		SC / CONTINUOUS	[redacted]20[redacted] / 277 [redacted]20[redacted] / 277

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
LEVOTHYROXINE SODIUM	50 ug	QD	Y-M: 20[redacted]
OPICAPONE	50.000 mg	QD	Y-M: 20[redacted]
ROTIGOTINE	4.000 mg	QD	Y-M: 20[redacted]-[redacted]
CANNABIDIOL;DRONABINOL	2.5 mg	PRN	Y-M: 20[redacted]
GLIMEPIRIDE	2 mg	QD	Y-M: 20[redacted]
RAMIPRIL	5 mg	QD	Y-M: 20[redacted]-[redacted]
CARBIDOPA MONOHYDRATE;LEVODOPA	100.000 mg	6 TIMES PER DAY	Y-M: 20[redacted]-[redacted] / -187
METAMIZOLE SODIUM	500 mg	PRN	Y-M: 20[redacted]-[redacted] / 207
ENOXAPARIN SODIUM	0.4 mL	QD	Y-M: 20[redacted]-[redacted] / 220

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
LEVOTHYROXINE SODIUM	50 ug	QD	Y-M: 20[redacted]	NOT REPORTED
CANNABIDIOL;DRONABINOL	2.5 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
GLIMEPIRIDE	2 mg	QD	Y-M: 20[redacted]	NOT REPORTED
RAMIPRIL	5 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
METAMIZOLE SODIUM	500 mg	PRN	Y-M: 20[redacted]-[redacted] / 207	NOT REPORTED
ENOXAPARIN SODIUM	0.4 mL	QD	Y-M: 20[redacted]-[redacted] / 220	NOT REPORTED

Event #1: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 395
Age at AE Onset	7[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	395
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 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	STUMBLING OVER A STEP
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	FEMUR FRACTURE

Preferred Term	大腿骨骨折
AE Onset Date / Rx Day	[redacted]20[redacted] / 395
Age at AE Onset	7[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 402): Hemoglobin: 79 [112 - 157] G/L; Hemoglobin: 333 [322 - 355] G/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	PATIENT STAMBLED OVER DOORSTEP AND FELL. FEMUR FRACTURE WAS DIAGNOSED IN HOSPITAL. SURGERY WAS PERFORMED ON [redacted] 20[redacted]. DRUG WAS NOT INTERRUPTED. MEDICAL REPORT PENDING.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はドイツの 7[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に大腿骨骨折及び転倒を発現した。

Event 1 及び 2 の臨床経過：

関連する病歴は，動脈性高血圧症，便秘，閉経，仮面様顔貌，MORBUS パーキンソン，パーキンソン病，慢性背部痛，脊柱管狭窄症，発声不全，運動障害性構音発声障害，夜間多尿，ジスキネジア，適応障害，流涎，喫煙者（1 日 2 本を 40 年間），及び飲酒者（1 日 2 杯未満）であった。

投与 395 日目，被験者は大腿骨骨折及び転倒を発現した。投与 395 日目，転倒は消失した。

投与 394 日目，被験者は大腿骨頚部骨折及びその後の固定手術のために入院した。被験者は玄関前の階段で躓いて転倒し，右臀部の強い痛みに苦しんだ。画像検査の結果，大腿骨頸部が粉砕骨折していた。投与 395 日目，被験者は大腿骨骨折の整復外科手術を受けた。投与 403 日目，被験者は退院した。

Causality for ABBV-951 (Open Label)

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1) Femur fracture (10016454) (Femur fracture (10016454)) [v.24.1] [10016454]

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

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

Dechallenge: Not Applicable

2) Fall (10016173) (Fall (10016173)) [v.24.1] [10016173]

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 FEMUR FRACTURE

- **Investigator:** Patient stumbled over doorstep and fell. Femur fracture was diagnosed in hospital. Surgery was performed on [redacted] 20[redacted]. Drug was not interrupted. Medical report pending.

- **AbbVie:** More likely the result of an accidental event (fall) due to stumbling over the door step as reported in this advanced aged subject with Parkinson's disease

Event of FALL

- Investigator: STUMBLING OVER A STEP

- AbbVie: The event is more likely related stumbling over a door step as reported in this advanced aged subject with Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] X-RAY HIP:** MULTIFRAGMENTIAL FRACTURE OF FEMOR NECK

[redacted] **20[redacted] X-RAY PELVIC:** MULTIFRAGMENTIAL FRACTURE OF FEMOR NECK

[redacted] **20[redacted] X-RAY THORAX:** MULTIFRAGMENTIAL FRACTURE OF FEMOR NECK

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

Reason for Narrative

Adverse Event Preferred Term(s)	Serious Adverse Event	Adverse Event Leading to Discontinuation of Study Drug	Death	Event of Interest
幻覚				X
注入部位蜂巣炎				X
精神病性障害	X			X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	FEMALE	WHITE

Medical History	Onset Year
ALLERGY FOR WASP STING. HAD ONCE AN ANAPHYLACTIC SHOCK AFTER A WASP STING	NOT REPORTED
EMOTION REGULATION DISORDER	NOT REPORTED
OBSESSIVE THOUGHTS	NOT REPORTED
PARANOID THOUGHTS	NOT REPORTED
HYPERCHOLESTEROLEMIA	20[redacted]
ANGINA PECTORIS	20[redacted]
TRANSIENT ISCHEMIC ATTACK	20[redacted]
IMPINGEMENT SYNDROME	20[redacted]
DEPRESSION AND ANXIETY DISORDER	20[redacted]
OBSTIPATION	20[redacted]
OCCASIONALLY DIFFICULTIES FALLING ASLEEP	20[redacted]
PERSISTENT PAIN AFTER HALLUX VALGUS OSTEOTOMY LEFT SIDE	20[redacted]
DELAYED GASTRIC EMPTYING	20[redacted]
NEGATIVE SELF-IMAGE	20[redacted]
ORTHOSTATIC HYPOTENSION	20[redacted]
URINARY TRACT INFECTION	20[redacted]
VITAMIN B6 DEFICIENCT	20[redacted]

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

PARKINSON'S DISEASE DIAGNOSIS	20[redacted]
ONSET OF MOTOR FLUCTUATION	20[redacted]

Prior Procedures	Procedure Year
RIGHT SHOULDER SURGERY	20[redacted]
LEFT SHOULDER SURGERY	20[redacted]
CHEVRON OSTEOTOMY HALLUX VALGUS LEFT SIDE	20[redacted]

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

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.31	0.33	0.28	60	0.15	[redacted]20[redacted] / 364
ABBV-951	0.31	0.31	0.28	60	0.15	[redacted]20[redacted] / 525
ABBV-951	0.31	0.31	0.28	60	0.00	[redacted]20[redacted] / 531
ABBV-951	0.27	0.30	0.27	60	0.00	[redacted]20[redacted] / 588
ABBV-951	0.24	0.27	0.24	60	0.00	[redacted]20[redacted] / 616
ABBV-951	0.24	0.27	0.24	60	0.11	[redacted]20[redacted] / 657
ABBV-951	0.24	0.27	0.24	60	0.11	[redacted]20[redacted] / 700

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 1	
M15-741 /ABBV-951	1343.97		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	2792.95		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951	2691.02		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3
M15-741 /ABBV-951	2523.85		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4

M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	2413.72		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951	2054.12		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 10
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	2253.55		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	2296.92		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	2392.20		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 18
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	2483.04		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	2297.09		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	2359.76		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951	2540.76		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 25
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	2529.66		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	2370.52		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	2555.10		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951	2663.7		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 39
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 40	
M15-741 /ABBV-951	2465.97		SC / CONTINUOUS	[redacted]20[redacted] / 40	[redacted]20[redacted] / 40
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 41	
M15-741 /ABBV-951	2377.52		SC / CONTINUOUS	[redacted]20[redacted] / 41	[redacted]20[redacted] / 41
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 42	
M15-741 /ABBV-951	2275.75		SC / CONTINUOUS	[redacted]20[redacted] / 42	[redacted]20[redacted] / 42
M15-741 /ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / 43	[redacted]20[redacted] / 59
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 60	
M15-741 /ABBV-951	2140.18		SC / CONTINUOUS	[redacted]20[redacted] / 60	[redacted]20[redacted] / 60
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 61	
M15-741 /ABBV-951	2085.71		SC / CONTINUOUS	[redacted]20[redacted] / 61	[redacted]20[redacted] / 61
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted]20[redacted] / 62	

M15-741 /ABBV-951	1775.8		SC / CONTINUOUS	[redacted] / 62	[redacted] / 62
M15-741 /ABBV-951	1639.2		SC / CONTINUOUS	[redacted] / 63	[redacted] / 88
M15-741 /ABBV-951	1474.25		SC / CONTINUOUS	[redacted] / 89	[redacted] / 89
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 90	
M15-741 /ABBV-951	1330.14		SC / CONTINUOUS	[redacted] / 90	[redacted] / 90
M15-741 /ABBV-951	1339.53		SC / CONTINUOUS	[redacted] / 91	[redacted] / 91
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 92	[redacted] / 179
M15-741 /ABBV-951	1422.17		SC / CONTINUOUS	[redacted] / 180	[redacted] / 180
M15-741 /ABBV-951	1066.67		SC / CONTINUOUS	[redacted] / 181	[redacted] / 181
M15-741 /ABBV-951	1379.66		SC / CONTINUOUS	[redacted] / 182	[redacted] / 182
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 183	[redacted] / 270
M15-741 /ABBV-951		25.61	SC / ONCE	[redacted] / 271	
M15-741 /ABBV-951	1426.61		SC / CONTINUOUS	[redacted] / 271	[redacted] / 271
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted] / 272	[redacted] / 272
M15-741 /ABBV-951	1354.21		SC / CONTINUOUS	[redacted] / 273	[redacted] / 273
M15-741 /ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 274	[redacted] / 361
M15-741 /ABBV-951	1261.33		SC / CONTINUOUS	[redacted] / 362	[redacted] / 362
M15-741 /ABBV-951	1249.20		SC / CONTINUOUS	[redacted] / 363	[redacted] / 363
ABBV-951	476.39		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
M15-741 /ABBV-951	1238.62		SC / CONTINUOUS	[redacted] / 364	[redacted] / 364
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 365	[redacted] / 445
ABBV-951	449.92		SC / CONTINUOUS	[redacted] / 446	[redacted] / 446
ABBV-951	805.76		SC / CONTINUOUS	[redacted] / 447	[redacted] / 447
ABBV-951	1324.16		SC / CONTINUOUS	[redacted] / 448	[redacted] / 448
ABBV-951	1352.34		SC / CONTINUOUS	[redacted] / 449	[redacted] / 522
ABBV-951		25.61	SC / ONCE	[redacted] / 523	
ABBV-951	1341.07		SC / CONTINUOUS	[redacted] / 523	[redacted] / 523
ABBV-951	1329.80		SC / CONTINUOUS	[redacted] / 524	[redacted] / 524
ABBV-951	1285.23		SC / CONTINUOUS	[redacted] / 525	[redacted] / 525
ABBV-951	1270.38		SC / CONTINUOUS	[redacted] / 526	[redacted] / 620
ABBV-951	1072.82		SC / CONTINUOUS	[redacted] / 621	[redacted] / 621
ABBV-951	389.31		SC / CONTINUOUS	[redacted] / 622	[redacted] / 622
ABBV-951	631.60		SC / CONTINUOUS	[redacted] / 698	[redacted] / 698
ABBV-951		18.78	SC / ONCE	[redacted] / 699	
ABBV-951	1097.23		SC / CONTINUOUS	[redacted] / 699	[redacted] / 699
ABBV-951	1001.96		SC / CONTINUOUS	[redacted] / 700	[redacted] / 700
ABBV-951	983.52		SC / CONTINUOUS	[redacted] / 701	[redacted] / 781

ABBV-951		18.78	SC / ONCE	[redacted] / 782	
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 782	[redacted] / 782
ABBV-951	1001.44		SC / CONTINUOUS	[redacted] / 783	[redacted] / 783
ABBV-951	979.42		SC / CONTINUOUS	[redacted] / 784	[redacted] / 784

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]
TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]
PYRIDOXINE	50 mg	QD	Y-M: 20[redacted] / 63
FLUTICASONE	0.5 OTHER: MG/G	QD	Y-M: 20[redacted] / 133
ISOSORBIDE MONONITRATE	60 mg	QD	Y-M: 20[redacted] / 187
GLYCERYL TRINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 212
METFORMIN	500 mg	QD	Y-M: 20[redacted] / 212
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 258
TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / 258
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 361

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
EPINEPHRINE	0.3 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
ROSUVASTATIN	10 mg	QD	Y-M: 20[redacted]	NOT REPORTED
TEMAZEPAM	10 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
CLOPIDOGREL	75 mg	QD	Y-M: 20[redacted]	NOT REPORTED
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
PYRIDOXINE	50 mg	QD	Y-M: 20[redacted] / 63	Y-M: 20[redacted] / 706
FLUTICASONE	0.5 OTHER: MG/G	QD	Y-M: 20[redacted] / 133	NOT REPORTED
ISOSORBIDE MONONITRATE	60 mg	QD	Y-M: 20[redacted] / 187	NOT REPORTED
GLYCERYL TRINITRATE	0.4 mg	PRN	Y-M: 20[redacted] / 212	NOT REPORTED
METFORMIN	500 mg	QD	Y-M: 20[redacted] / 212	NOT REPORTED
IBUPROFEN	400 mg	PRN	Y-M: 20[redacted] / 258	NOT REPORTED

TRAMADOL	50 mg	PRN	Y-M: 20[redacted] / 258	NOT REPORTED
CLOZAPINE	25 mg	QD	Y-M: 20[redacted] / 361	Y-M: 20[redacted] / 471
FLUDROCORTISONE	0.100 mg	QD	Y-M: 20[redacted] / 372	Y-M: 20[redacted] / 448
TRIAMCINOLONE ACETONIDE	80 mg	OTHER: ONCE	Y-M: 20[redacted] / 400	Y-M: 20[redacted] / 400
LIDOCAINE	2 mL	OTHER: ONCE	Y-M: 20[redacted] / 408	Y-M: 20[redacted] / 408
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 418	Y-M: 20[redacted] / 428
PANTOPRAZOLE	40 mg	QD	Y-M: 20[redacted] / 439	Y-M: 20[redacted] / 611
FLUDROCORTISONE	0.200 mg	QD	Y-M: 20[redacted] / 448	NOT REPORTED
AMOXICILLIN	1000 mg	BID	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 455
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 455
OXAZEPAM	10 mg	BID	Y-M: 20[redacted] / 471	Y-M: 20[redacted] / 579
CLOZAPINE	31.25 mg	QD	Y-M: 20[redacted] / 472	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 503	NOT REPORTED
AMOXICILLIN	1000 mg	BID	Y-M: 20[redacted] / 520	Y-M: 20[redacted] / 530
METRONIDAZOLE	500 mg	BID	Y-M: 20[redacted] / 520	Y-M: 20[redacted] / 530
DOMPERIDONE	10 mg	TID	Y-M: 20[redacted] / 526	Y-M: 20[redacted] / 539
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 538	NOT REPORTED
OXAZEPAM	10 mg	TID	Y-M: 20[redacted] / 579	NOT REPORTED
PANTOPRAZOLE	40 mg	PRN	Y-M: 20[redacted] / 611	Y-M: 20[redacted] / 772
CLINDAMYCIN	600 mg	TID	Y-M: 20[redacted] / 642	Y-M: 20[redacted] / 656
NALOXONE;OXYCODONE	5/2.5 mg	BID	Y-M: 20[redacted] / 671	Y-M: 20[redacted] / 678
PANTOPRAZOLE SODIUM SESQUIHYDRATE	40 mg	QD	Y-M: 20[redacted] / 772	NOT REPORTED

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

Event Description	CELLULITIS AT INFUSION SITE AT RIGHT LOWER QUADRANT
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 413
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	428
Duration of AE	16 DAYS

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

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING HALLUCINATIONS
Preferred Term	幻覚
AE Onset Date / Rx Day	[redacted]20[redacted] / 471
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	525
Duration of AE	55 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event, Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING PSYCHOSIS
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 525

Age at AE Onset	6[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	539
Duration of AE	15 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 RELATED
Other Cause of Event	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #4: Event of Interest - Hallucinations/Psychosis

Event Description	WORSENING PSYCHOSIS
Preferred Term	精神病性障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 579
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	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 INFUSION SITE LEFT UPPER QUADRANT ABDOMEN
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 642
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	656
Duration of AE	15 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #6: Event of Interest - Infusion Site Related Infections

Event Description	CELLULITIS AT INFUSION SITE AT LEFT UPPER QUADRANT OF ABDOMEN
Preferred Term	注入部位蜂巣炎
AE Onset Date / Rx Day	[redacted]20[redacted] / 775
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED

Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of 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]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はオランダの 6[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に精神病性障害を発現した。

Event 3 の臨床経過：

関連する病歴は，パーキンソン病，うつ病及び不安障害，強迫観念，妄想観念，非喫煙者，及び飲酒者（1 日 2 杯未満）であった。

投与 525 日目，被験者は精神病性障害を発現した。

本事象発現前に，被験者は娘の声及び男性の合唱隊の音楽が聞こえることを含む精神病性症状を約 1.5 年発現していた。

投与 525 日目，被験者は症状が増強したため入院し，試験での dF2 の注入速度を落とした。投与 531 日目，治験薬のボーラス投与を 0.0 mL に減量したところ，硬直が増強するとともに精神病的な現象が減少した。投与 539 日目，被験者は退院した。

治験責任医師によると，本事象に関連する被験者のリスク因子はパーキンソン病であった。

Causality for ABBV-951 (Open Label)

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1) Psychosis aggravated (10048343) (Psychotic disorder (10061920)) [v.24.0] [10048343]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of WORSENING PSYCHOSIS

- Investigator: Not applicable

- AbbVie: More likely related to Parkinson disease, with reported ongoing psychotic symptoms and history of paranoid and obsessive thoughts, depression and anxiety in a 6[redacted] year old subject.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] MONTRAL COGNITIVE ASSESSMENT:** 25 points out of 30

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
処置による疼痛	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	MALE	WHITE

Medical History	Onset Year
DYSLIPIDEMIA	19[redacted]
HYPERTENSION	19[redacted]
ISCHEMIC HEART DISEASE	19[redacted]
STENOSIS SPINAL CANAL IN THE LUMBAR	20[redacted]
BLEPHAROSPASM	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
CORONARY BYPASS	19[redacted]
VASECTOMY	19[redacted]

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	40 CIGARETTE	9	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	NEVER	

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.60	0.70	0	60	0.30	[redacted] / 372
ABBV-951	0.6	0.7	0	60	0.30	[redacted] / 555
ABBV-951	0.6	0.7	0	60	0.30	[redacted] / 705
ABBV-951	0.7	0.8	0	60	0.30	[redacted] / 806

Daily Dose (mg LD) by Molecular Weight

Feeder Study / Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/ Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	725.68		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 2	[redacted] / 4
M15-741 /ABBV-951	1980.7		SC / CONTINUOUS	[redacted] / 5	[redacted] / 5
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 6	
M15-741 /ABBV-951	1989.23		SC / CONTINUOUS	[redacted] / 6	[redacted] / 6
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 7	[redacted] / 10
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 11	
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 11	[redacted] / 12
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 12	
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted] / 13	
M15-741 /ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 13	[redacted] / 13
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 14	[redacted] / 16
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 17	[redacted] / 17
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 18	[redacted] / 18
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 19	[redacted] / 19
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 20	[redacted] / 21
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 22	[redacted] / 25
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 26	[redacted] / 27
M15-741 /ABBV-951	1997.77		SC / CONTINUOUS	[redacted] / 28	[redacted] / 28
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 29	[redacted] / 37
M15-741 /ABBV-951	2014.85		SC / CONTINUOUS	[redacted] / 38	[redacted] / 38
M15-741 /ABBV-951	2006.31		SC / CONTINUOUS	[redacted] / 39	[redacted] / 39
M15-741 /ABBV-951	2023.38		SC / CONTINUOUS	[redacted] / 40	[redacted] / 40
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 41	[redacted] / 93
M15-741 /ABBV-951	1989.23		SC / CONTINUOUS	[redacted] / 94	[redacted] / 94
M15-741 /ABBV-951	2049		SC / CONTINUOUS	[redacted] / 95	[redacted] / 102

M15-741 /ABBV-951	2014.85	SC / CONTINUOUS	[redacted]20[redacted] / 103	[redacted]20[redacted] / 103
M15-741 /ABBV-951	2023.38	SC / CONTINUOUS	[redacted]20[redacted] / 104	[redacted]20[redacted] / 104
M15-741 /ABBV-951	2049	SC / CONTINUOUS	[redacted]20[redacted] / 105	[redacted]20[redacted] / 116
M15-741 /ABBV-951	2057.53	SC / CONTINUOUS	[redacted]20[redacted] / 117	[redacted]20[redacted] / 117
M15-741 /ABBV-951	2428.06	SC / CONTINUOUS	[redacted]20[redacted] / 118	[redacted]20[redacted] / 118
M15-741 /ABBV-951	2387.08	SC / CONTINUOUS	[redacted]20[redacted] / 119	[redacted]20[redacted] / 119
M15-741 /ABBV-951	2397.33	SC / CONTINUOUS	[redacted]20[redacted] / 120	[redacted]20[redacted] / 120
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 121	[redacted]20[redacted] / 186
M15-741 /ABBV-951	1219.15	SC / CONTINUOUS	[redacted]20[redacted] / 187	[redacted]20[redacted] / 187
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 188	[redacted]20[redacted] / 270
M15-741 /ABBV-951	2397.33	SC / CONTINUOUS	[redacted]20[redacted] / 271	[redacted]20[redacted] / 271
M15-741 /ABBV-951	2387.08	SC / CONTINUOUS	[redacted]20[redacted] / 272	[redacted]20[redacted] / 272
M15-741 /ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 273	[redacted]20[redacted] / 369
M15-741 /ABBV-951	2417.82	SC / CONTINUOUS	[redacted]20[redacted] / 370	[redacted]20[redacted] / 370
M15-741 /ABBV-951	2253.9	SC / CONTINUOUS	[redacted]20[redacted] / 371	[redacted]20[redacted] / 371
ABBV-951	40.98	SC / CONTINUOUS	[redacted]20[redacted] / 467	[redacted]20[redacted] / 468
ABBV-951	901.56	SC / CONTINUOUS	[redacted]20[redacted] / 469	[redacted]20[redacted] / 469
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 470	[redacted]20[redacted] / 553
ABBV-951	2428.06	SC / CONTINUOUS	[redacted]20[redacted] / 554	[redacted]20[redacted] / 554
ABBV-951	2458.8	SC / CONTINUOUS	[redacted]20[redacted] / 555	[redacted]20[redacted] / 702
ABBV-951	2554.42	SC / CONTINUOUS	[redacted]20[redacted] / 703	[redacted]20[redacted] / 703
ABBV-951	2832.74	SC / CONTINUOUS	[redacted]20[redacted] / 704	[redacted]20[redacted] / 704

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]-[redacted]
OLMESARTAN MEDOXOMIL	40 mg	QD	Y-M: 20[redacted]-[redacted]
ROSUVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]-[redacted]
ROPINIROLE	8.000 mg	QD	Y-M: 20[redacted]-[redacted]

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

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day	Stop Year-Month / RX Day
ACETYLSALICYLIC ACID	100 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED
OLMESARTAN MEDOXOMIL	40 mg	QD	Y-M: 20[redacted]-[redacted]	NOT REPORTED

ROSUVASTATIN CALCIUM	20 mg	QD	Y-M: 20[redacted]	NOT REPORTED
FENTANYL	50 OTHER: MCG/H	OTHER: C/72H	Y-M: 20[redacted] / 519	NOT REPORTED
METAMIZOLE MAGNESIUM	575 mg	TID	Y-M: 20[redacted] / 519	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 580	NOT REPORTED
CYANOCOBALAMIN; FOLIC ACID	1 OTHER: CAPSULE	QD	Y-M: 20[redacted] / 602	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 603	NOT REPORTED
BOTULINUM TOXIN TYPE A	10 IU	QD	Y-M: 20[redacted] / 623	Y-M: 20[redacted] / 623
BOTULINUM TOXIN TYPE A	5 IU	QD	Y-M: 20[redacted] / 623	Y-M: 20[redacted] / 623
DEXKETOPROFEN TROMETAMOL	25 mg	BID	Y-M: 20[redacted] / 686	NOT REPORTED

Event #1: Serious Adverse Event

Event Description	POSTOPERATIVE/PROCEDURAL PAIN
Preferred Term	処置による疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 519
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	686
Duration of AE	168 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 RELATED
Other Cause of Event	THIS WAS A CONSEQUENCE OF THE FIRST SURGERY
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者はスペインの 5[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に術後 / 処置による疼痛を発現した。

Event 1 の臨床経過：

関連する病歴は，虚血性心疾患，パーキンソン病，腰部脊柱管狭窄症，及び元喫煙者（1 日 40 本を 9 年間）であった。

投与 519 日目，被験者は術後 / 処置による疼痛を発現した。投与 686 日目，術後 / 処置による疼痛は消失した。

投与の約 18 ヵ月前，被験者は腰部脊柱管狭窄症を発現した。投与の約 19 ヵ月前，狭窄症に対して手術が実施された。L2～L5 及び S1 に椎弓根スクリューが埋め込まれ，L4～S4 の椎弓切除術が実施された。手術後，被験者は背部痛に苦しんだ。

投与 686 日目，被験者は入院し，椎弓根スクリューが交換された。手術後の疼痛は軽度であった。投与 689 日目，被験者は退院した。

被験者に ENANTYUM 及びロピニロールが投与された。

Causality for ABBV-951 (Open Label)

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1) Postoperative pain (10054711) (Procedural pain (10064882)) [v.24.0] [10054711]

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 POSTOPERATIVE/PROCEDURAL PAIN

- **Investigator:** This was a consequence of the first surgery.

- **AbbVie:** More likely related to reported first lumbar surgery and history of stenosis spinal canal in the lumbar

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			
カテーテル留置部位内出血				X
カテーテル留置部位疼痛				X
カテーテル留置部位腫脹				X
失見当識	X			
嚥下障害				X
幻嗅				X
注入部位内出血				X
注入部位感染				X
注入部位刺激感				X

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	6[redacted]	MALE	WHITE

Medical History	Onset Year
EPIDIDYMAL CYST	19[redacted]
BAKERS CYST	20[redacted]
PARKINSON'S DISEASE	20[redacted]
DEPRESSION	20[redacted]
IRRITABLE BOWEL SYNDROME	20[redacted]
MIGRAINES	20[redacted]
ERECTILE DYSFUNCTION	20[redacted]
ALLERGY TO ROTIGOTINE PATCH	20[redacted]
POLYNEUROPATHY	20[redacted]
SWALLOWING DIFFICULTY	20[redacted]
INSOMNIA	20[redacted]
KNEE OSTEOARTHRITIS	20[redacted]
ABDOMINAL WALL CELLULITIS AT INFUSION SITE.	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
FIREARM PELLETS REMOVED FOLLOWING OCCASION OF STREET SHOOTING	19[redacted]
VASECTOMY	19[redacted]
EPIDIDIMAL CYST DRAINAGE	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	CURRENT	2 - 4 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.41	0.42	0.40	60	0.30	[redacted]20[redacted] / 366
ABBV-951	0.46	0.47	0.45	60	0.30	[redacted]20[redacted] / 542
ABBV-951	0.49	0.50	0.48	60	0.30	[redacted]20[redacted] / 632
ABBV-951	0.52	0.53	0.51	60	0.30	[redacted]20[redacted] / 667
ABBV-951	0.54	0.55	0.53	60	0.30	[redacted]20[redacted] / 702
ABBV-951	0.56	0.57	0.55	60	0.30	[redacted]20[redacted] / 792

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951	532.74		SC / CONTINUOUS	[redacted]20[redacted] / 1	[redacted]20[redacted] / 1
M15-741 /ABBV-951	1238.10		SC / CONTINUOUS	[redacted]20[redacted] / 2	[redacted]20[redacted] / 2
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 3	
M15-741 /ABBV-951	1266.28		SC / CONTINUOUS	[redacted]20[redacted] / 3	[redacted]20[redacted] / 3

M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 4	
M15-741 /ABBV-951	1225.30		SC / CONTINUOUS	[redacted]20[redacted] / 4	[redacted]20[redacted] / 4
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 5	
M15-741 /ABBV-951	1220.17		SC / CONTINUOUS	[redacted]20[redacted] / 5	[redacted]20[redacted] / 5
M15-741 /ABBV-951	1350.80		SC / CONTINUOUS	[redacted]20[redacted] / 6	[redacted]20[redacted] / 6
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 7	
M15-741 /ABBV-951	1230.93		SC / CONTINUOUS	[redacted]20[redacted] / 7	[redacted]20[redacted] / 7
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 8	
M15-741 /ABBV-951	1262.18		SC / CONTINUOUS	[redacted]20[redacted] / 8	[redacted]20[redacted] / 8
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 9	
M15-741 /ABBV-951	1256.54		SC / CONTINUOUS	[redacted]20[redacted] / 9	[redacted]20[redacted] / 9
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 10	
M15-741 /ABBV-951	1268.84		SC / CONTINUOUS	[redacted]20[redacted] / 10	[redacted]20[redacted] / 10
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 11	
M15-741 /ABBV-951	1275.50		SC / CONTINUOUS	[redacted]20[redacted] / 11	[redacted]20[redacted] / 11
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 12	
M15-741 /ABBV-951	1271.40		SC / CONTINUOUS	[redacted]20[redacted] / 12	[redacted]20[redacted] / 12
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 13	
M15-741 /ABBV-951	1299.06		SC / CONTINUOUS	[redacted]20[redacted] / 13	[redacted]20[redacted] / 13
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 14	
M15-741 /ABBV-951	1260.13		SC / CONTINUOUS	[redacted]20[redacted] / 14	[redacted]20[redacted] / 14
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 15	
M15-741 /ABBV-951	1279.60		SC / CONTINUOUS	[redacted]20[redacted] / 15	[redacted]20[redacted] / 15
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 16	
M15-741 /ABBV-951	1234.52		SC / CONTINUOUS	[redacted]20[redacted] / 16	[redacted]20[redacted] / 16
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 17	
M15-741 /ABBV-951	1279.08		SC / CONTINUOUS	[redacted]20[redacted] / 17	[redacted]20[redacted] / 17
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 18	
M15-741 /ABBV-951	1285.74		SC / CONTINUOUS	[redacted]20[redacted] / 18	[redacted]20[redacted] / 18
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 19	
M15-741 /ABBV-951	1289.33		SC / CONTINUOUS	[redacted]20[redacted] / 19	[redacted]20[redacted] / 19
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 20	
M15-741 /ABBV-951	1275.50		SC / CONTINUOUS	[redacted]20[redacted] / 20	[redacted]20[redacted] / 20
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 21	
M15-741 /ABBV-951	1258.59		SC / CONTINUOUS	[redacted]20[redacted] / 21	[redacted]20[redacted] / 21
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 22	
M15-741 /ABBV-951	1267.30		SC / CONTINUOUS	[redacted]20[redacted] / 22	[redacted]20[redacted] / 22

M15-741 /ABBV-951	1322.80		SC / CONTINUOUS	[redacted]20[redacted] / 23	[redacted]20[redacted] / 23
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 24	
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 24	[redacted]20[redacted] / 24
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 25	
M15-741 /ABBV-951	1383.07		SC / CONTINUOUS	[redacted]20[redacted] / 25	[redacted]20[redacted] / 25
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 26	
M15-741 /ABBV-951	1320.75		SC / CONTINUOUS	[redacted]20[redacted] / 26	[redacted]20[redacted] / 26
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 27	
M15-741 /ABBV-951	1347.21		SC / CONTINUOUS	[redacted]20[redacted] / 27	[redacted]20[redacted] / 27
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 28	
M15-741 /ABBV-951	1303.67		SC / CONTINUOUS	[redacted]20[redacted] / 28	[redacted]20[redacted] / 28
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 29	
M15-741 /ABBV-951	1326.72		SC / CONTINUOUS	[redacted]20[redacted] / 29	[redacted]20[redacted] / 29
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 30	
M15-741 /ABBV-951	1353.19		SC / CONTINUOUS	[redacted]20[redacted] / 30	[redacted]20[redacted] / 30
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 31	
M15-741 /ABBV-951	1393.32		SC / CONTINUOUS	[redacted]20[redacted] / 31	[redacted]20[redacted] / 36
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 32	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 33	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 34	
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 35	
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 36	
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 37	
M15-741 /ABBV-951	1377.95		SC / CONTINUOUS	[redacted]20[redacted] / 37	[redacted]20[redacted] / 37
M15-741 /ABBV-951	1434.3		SC / CONTINUOUS	[redacted]20[redacted] / 38	[redacted]20[redacted] / 38
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M15-741 /ABBV-951	1505.50		SC / CONTINUOUS	[redacted]20[redacted] / 270 [redacted]20[redacted] / 270
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 271
M15-741 /ABBV-951	1512.33		SC / CONTINUOUS	[redacted]20[redacted] / 271 [redacted]20[redacted] / 271
M15-741 /ABBV-951	1516.26		SC / CONTINUOUS	[redacted]20[redacted] / 272 [redacted]20[redacted] / 272
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 273

M15-741 /ABBV-951	1480.74		SC / CONTINUOUS	[redacted]20[redacted] / 273 [redacted]20[redacted] / 273
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 274
M15-741 /ABBV-951	1491.50		SC / CONTINUOUS	[redacted]20[redacted] / 274 [redacted]20[redacted] / 274
M15-741 /ABBV-951	1571.07		SC / CONTINUOUS	[redacted]20[redacted] / 275 [redacted]20[redacted] / 275
M15-741 /ABBV-951	1595.65		SC / CONTINUOUS	[redacted]20[redacted] / 276 [redacted]20[redacted] / 276
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 277
M15-741 /ABBV-951	1542.21		SC / CONTINUOUS	[redacted]20[redacted] / 277 [redacted]20[redacted] / 277
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 278
M15-741 /ABBV-951	1603.51		SC / CONTINUOUS	[redacted]20[redacted] / 278 [redacted]20[redacted] / 278
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 279
M15-741 /ABBV-951	1598.04		SC / CONTINUOUS	[redacted]20[redacted] / 279 [redacted]20[redacted] / 279
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 280
M15-741 /ABBV-951	1595.31		SC / CONTINUOUS	[redacted]20[redacted] / 280 [redacted]20[redacted] / 280
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 281
M15-741 /ABBV-951	1604.70		SC / CONTINUOUS	[redacted]20[redacted] / 281 [redacted]20[redacted] / 281
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 282
M15-741 /ABBV-951	1605.56		SC / CONTINUOUS	[redacted]20[redacted] / 282 [redacted]20[redacted] / 282
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 283
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 283 [redacted]20[redacted] / 283
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 284
M15-741 /ABBV-951	1600.78		SC / CONTINUOUS	[redacted]20[redacted] / 284 [redacted]20[redacted] / 284
M15-741 /ABBV-951	1592.58		SC / CONTINUOUS	[redacted]20[redacted] / 285 [redacted]20[redacted] / 285
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 286
M15-741 /ABBV-951	1602.14		SC / CONTINUOUS	[redacted]20[redacted] / 286 [redacted]20[redacted] / 286
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 287
M15-741 /ABBV-951	1594.46		SC / CONTINUOUS	[redacted]20[redacted] / 287 [redacted]20[redacted] / 287
M15-741 /ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 288
M15-741 /ABBV-951	1607.09		SC / CONTINUOUS	[redacted]20[redacted] / 288 [redacted]20[redacted] / 288
M15-741 /ABBV-951	1595.65		SC / CONTINUOUS	[redacted]20[redacted] / 289 [redacted]20[redacted] / 289
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 290
M15-741 /ABBV-951	1605.05		SC / CONTINUOUS	[redacted]20[redacted] / 290 [redacted]20[redacted] / 290
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 291

M15-741 /ABBV-951	1601.63		SC / CONTINUOUS	[redacted]20[redacted] / 291	[redacted]20[redacted] / 291
M15-741 /ABBV-951	1599.92		SC / CONTINUOUS	[redacted]20[redacted] / 292	[redacted]20[redacted] / 292
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 293	
M15-741 /ABBV-951	1603.51		SC / CONTINUOUS	[redacted]20[redacted] / 293	[redacted]20[redacted] / 293
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 294	
M15-741 /ABBV-951	1603.34		SC / CONTINUOUS	[redacted]20[redacted] / 294	[redacted]20[redacted] / 294
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 295	
M15-741 /ABBV-951	1597.87		SC / CONTINUOUS	[redacted]20[redacted] / 295	[redacted]20[redacted] / 295
M15-741 /ABBV-951	1607.26		SC / CONTINUOUS	[redacted]20[redacted] / 296	[redacted]20[redacted] / 296
M15-741 /ABBV-951	1602.14		SC / CONTINUOUS	[redacted]20[redacted] / 297	[redacted]20[redacted] / 297
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 298	
M15-741 /ABBV-951	1603.68		SC / CONTINUOUS	[redacted]20[redacted] / 298	[redacted]20[redacted] / 298
M15-741 /ABBV-951		256.12	SC / ONCE	[redacted]20[redacted] / 299	
M15-741 /ABBV-951	1614.09		SC / CONTINUOUS	[redacted]20[redacted] / 299	[redacted]20[redacted] / 299
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 300	
M15-741 /ABBV-951	1599.24		SC / CONTINUOUS	[redacted]20[redacted] / 300	[redacted]20[redacted] / 300
M15-741 /ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 301	
M15-741 /ABBV-951	1602.14		SC / CONTINUOUS	[redacted]20[redacted] / 301	[redacted]20[redacted] / 301
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 302	
M15-741 /ABBV-951	1609.66		SC / CONTINUOUS	[redacted]20[redacted] / 302	[redacted]20[redacted] / 302
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 303	
M15-741 /ABBV-951	1609.14		SC / CONTINUOUS	[redacted]20[redacted] / 303	[redacted]20[redacted] / 303
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 304	
M15-741 /ABBV-951	1609.83		SC / CONTINUOUS	[redacted]20[redacted] / 304	[redacted]20[redacted] / 304
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 305	
M15-741 /ABBV-951	1598.73		SC / CONTINUOUS	[redacted]20[redacted] / 305	[redacted]20[redacted] / 305

M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 306	
M15-741 /ABBV-951	1596.51		SC / CONTINUOUS	[redacted]20[redacted] / 306	[redacted]20[redacted] / 306
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 307	
M15-741 /ABBV-951	1598.90		SC / CONTINUOUS	[redacted]20[redacted] / 307	[redacted]20[redacted] / 307
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 308	
M15-741 /ABBV-951	1589.85		SC / CONTINUOUS	[redacted]20[redacted] / 308	[redacted]20[redacted] / 308
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 309	
M15-741 /ABBV-951	1610.00		SC / CONTINUOUS	[redacted]20[redacted] / 309	[redacted]20[redacted] / 309
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 310	
M15-741 /ABBV-951	1609.48		SC / CONTINUOUS	[redacted]20[redacted] / 310	[redacted]20[redacted] / 310
M15-741 /ABBV-951	1599.75		SC / CONTINUOUS	[redacted]20[redacted] / 311	[redacted]20[redacted] / 311
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 312	
M15-741 /ABBV-951	1602.65		SC / CONTINUOUS	[redacted]20[redacted] / 312	[redacted]20[redacted] / 312
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 313	
M15-741 /ABBV-951	1600.09		SC / CONTINUOUS	[redacted]20[redacted] / 313	[redacted]20[redacted] / 313
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 314	
M15-741 /ABBV-951	1597.87		SC / CONTINUOUS	[redacted]20[redacted] / 314	[redacted]20[redacted] / 314
M15-741 /ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 315	
M15-741 /ABBV-951	1599.41		SC / CONTINUOUS	[redacted]20[redacted] / 315	[redacted]20[redacted] / 315
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 316	
M15-741 /ABBV-951	1613.58		SC / CONTINUOUS	[redacted]20[redacted] / 316	[redacted]20[redacted] / 316
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 317	
M15-741 /ABBV-951	1606.58		SC / CONTINUOUS	[redacted]20[redacted] / 317	[redacted]20[redacted] / 317
M15-741 /ABBV-951	1605.22		SC / CONTINUOUS	[redacted]20[redacted] / 318	[redacted]20[redacted] / 318
M15-741 /ABBV-951	1605.90		SC / CONTINUOUS	[redacted]20[redacted] /	[redacted]20[redacted] /

				319	319
M15-741 /ABBV-951	1600.09		SC / CONTINUOUS	[redacted]20[redacted] / 320	[redacted]20[redacted] / 320
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 321	
M15-741 /ABBV-951	1600.43		SC / CONTINUOUS	[redacted]20[redacted] / 321	[redacted]20[redacted] / 321
M15-741 /ABBV-951	1606.75		SC / CONTINUOUS	[redacted]20[redacted] / 322	[redacted]20[redacted] / 322
M15-741 /ABBV-951	1618.53		SC / CONTINUOUS	[redacted]20[redacted] / 323	[redacted]20[redacted] / 323
M15-741 /ABBV-951	1607.44		SC / CONTINUOUS	[redacted]20[redacted] / 324	[redacted]20[redacted] / 324
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 325	
M15-741 /ABBV-951	1604.70		SC / CONTINUOUS	[redacted]20[redacted] / 325	[redacted]20[redacted] / 325
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 326	
M15-741 /ABBV-951	1607.26		SC / CONTINUOUS	[redacted]20[redacted] / 326	[redacted]20[redacted] / 326
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 327	
M15-741 /ABBV-951	1616.83		SC / CONTINUOUS	[redacted]20[redacted] / 327	[redacted]20[redacted] / 327
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 328	
M15-741 /ABBV-951	1598.90		SC / CONTINUOUS	[redacted]20[redacted] / 328	[redacted]20[redacted] / 328
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 329	
M15-741 /ABBV-951	1598.39		SC / CONTINUOUS	[redacted]20[redacted] / 329	[redacted]20[redacted] / 329
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 330	
M15-741 /ABBV-951	1593.09		SC / CONTINUOUS	[redacted]20[redacted] / 330	[redacted]20[redacted] / 330
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 331	
M15-741 /ABBV-951	1596.85		SC / CONTINUOUS	[redacted]20[redacted] / 331	[redacted]20[redacted] / 331
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 332	

M15-741 /ABBV-951	1600.61		SC / CONTINUOUS	[redacted]20[redacted] / 332	[redacted]20[redacted] / 332
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 333	
M15-741 /ABBV-951	1601.63		SC / CONTINUOUS	[redacted]20[redacted] / 333	[redacted]20[redacted] / 333
M15-741 /ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 334	
M15-741 /ABBV-951	1593.43		SC / CONTINUOUS	[redacted]20[redacted] / 334	[redacted]20[redacted] / 334
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 335	
M15-741 /ABBV-951	1601.29		SC / CONTINUOUS	[redacted]20[redacted] / 335	[redacted]20[redacted] / 335
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 336	
M15-741 /ABBV-951	1614.95		SC / CONTINUOUS	[redacted]20[redacted] / 336	[redacted]20[redacted] / 336
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 337	
M15-741 /ABBV-951	1617.00		SC / CONTINUOUS	[redacted]20[redacted] / 337	[redacted]20[redacted] / 337
M15-741 /ABBV-951	1598.22		SC / CONTINUOUS	[redacted]20[redacted] / 338	[redacted]20[redacted] / 348
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 349	
M15-741 /ABBV-951	1602.31		SC / CONTINUOUS	[redacted]20[redacted] / 349	[redacted]20[redacted] / 349
M15-741 /ABBV-951	1585.07		SC / CONTINUOUS	[redacted]20[redacted] / 350	[redacted]20[redacted] / 350
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 351	
M15-741 /ABBV-951	1585.41		SC / CONTINUOUS	[redacted]20[redacted] / 351	[redacted]20[redacted] / 351
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 352	
M15-741 /ABBV-951	1584.21		SC / CONTINUOUS	[redacted]20[redacted] / 352	[redacted]20[redacted] / 352
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 353	
M15-741 /ABBV-951	1602.14		SC / CONTINUOUS	[redacted]20[redacted] / 353	[redacted]20[redacted] / 353
M15-741 /ABBV-951	1593.26		SC / CONTINUOUS	[redacted]20[redacted] / 354	[redacted]20[redacted] / 354
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 355	
M15-741 /ABBV-951	1601.80		SC / CONTINUOUS	[redacted]20[redacted] / 355	[redacted]20[redacted] /

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M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 356	
M15-741 /ABBV-951	1593.26		SC / CONTINUOUS	[redacted]20[redacted] / 356	[redacted]20[redacted] / 356
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 357	
M15-741 /ABBV-951	1590.70		SC / CONTINUOUS	[redacted]20[redacted] / 357	[redacted]20[redacted] / 357
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 358	
M15-741 /ABBV-951	1593.09		SC / CONTINUOUS	[redacted]20[redacted] / 358	[redacted]20[redacted] / 358
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 359	
M15-741 /ABBV-951	1598.73		SC / CONTINUOUS	[redacted]20[redacted] / 359	[redacted]20[redacted] / 359
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 360	
M15-741 /ABBV-951	1599.75		SC / CONTINUOUS	[redacted]20[redacted] / 360	[redacted]20[redacted] / 360
M15-741 /ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 361	
M15-741 /ABBV-951	1600.61		SC / CONTINUOUS	[redacted]20[redacted] / 361	[redacted]20[redacted] / 361
M15-741 /ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 362	
M15-741 /ABBV-951	1600.78		SC / CONTINUOUS	[redacted]20[redacted] / 362	[redacted]20[redacted] / 362
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 363	
M15-741 /ABBV-951	1596.51		SC / CONTINUOUS	[redacted]20[redacted] / 363	[redacted]20[redacted] / 363
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 364	
M15-741 /ABBV-951	1571.24		SC / CONTINUOUS	[redacted]20[redacted] / 364	[redacted]20[redacted] / 364
M15-741 /ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 365	
M15-741 /ABBV-951	1545.45		SC / CONTINUOUS	[redacted]20[redacted] / 365	[redacted]20[redacted] / 365
ABBV-951	721.07		SC / CONTINUOUS	[redacted]20[redacted] / 366	[redacted]20[redacted] / 366
ABBV-951	1680.18		SC / CONTINUOUS	[redacted]20[redacted] / 367	[redacted]20[redacted] / 447
ABBV-951	1680.35		SC / CONTINUOUS	[redacted]20[redacted] / 448	[redacted]20[redacted] / 448
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 449	
ABBV-951	1670.27		SC / CONTINUOUS	[redacted]20[redacted] / 449	[redacted]20[redacted] / 449

ABBV-951	1680.18		SC / CONTINUOUS	[redacted]20[redacted] / [redacted]20[redacted] / 539 450
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 540
ABBV-951	1574.82		SC / CONTINUOUS	[redacted]20[redacted] / 540 [redacted]20[redacted] / 540
ABBV-951		358.57	SC / ONCE	[redacted]20[redacted] / 541
ABBV-951	1663.78		SC / CONTINUOUS	[redacted]20[redacted] / 541 [redacted]20[redacted] / 541
ABBV-951	1721.16		SC / CONTINUOUS	[redacted]20[redacted] / 542 [redacted]20[redacted] / 609
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 610
ABBV-951	1810.80		SC / CONTINUOUS	[redacted]20[redacted] / 610 [redacted]20[redacted] / 610
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 611
ABBV-951	1877.90		SC / CONTINUOUS	[redacted]20[redacted] / 611 [redacted]20[redacted] / 611
ABBV-951	1926.06		SC / CONTINUOUS	[redacted]20[redacted] / 612 [redacted]20[redacted] / 699
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 700
ABBV-951	2026.63		SC / CONTINUOUS	[redacted]20[redacted] / 700 [redacted]20[redacted] / 700
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 701
ABBV-951	2139.49		SC / CONTINUOUS	[redacted]20[redacted] / 701 [redacted]20[redacted] / 701
ABBV-951	2171.94		SC / CONTINUOUS	[redacted]20[redacted] / [redacted]20[redacted] / 778 702
ABBV-951		102.45	SC / ONCE	[redacted]20[redacted] / 779
ABBV-951	2185.6		SC / CONTINUOUS	[redacted]20[redacted] / 779 [redacted]20[redacted] / 779
ABBV-951		204.9	SC / ONCE	[redacted]20[redacted] / 780
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 780 [redacted]20[redacted] / 780
ABBV-951		153.67	SC / ONCE	[redacted]20[redacted] / 781
ABBV-951	2188.16		SC / CONTINUOUS	[redacted]20[redacted] / 781 [redacted]20[redacted] / 782
ABBV-951		51.22	SC / ONCE	[redacted]20[redacted] / 782
ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 783 [redacted]20[redacted] / 786
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 787
ABBV-951	2225.72		SC / CONTINUOUS	[redacted]20[redacted] / 787 [redacted]20[redacted] / 787
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 788
ABBV-951	2206.94		SC / CONTINUOUS	[redacted]20[redacted] / 788 [redacted]20[redacted] / 788

ABBV-951	2253.9		SC / CONTINUOUS	[redacted]20[redacted] / 789 [redacted]20[redacted] / 789
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 790
ABBV-951	2178.77		SC / CONTINUOUS	[redacted]20[redacted] / 790 [redacted]20[redacted] / 790
ABBV-951		307.35	SC / ONCE	[redacted]20[redacted] / 791
ABBV-951	2235.11		SC / CONTINUOUS	[redacted]20[redacted] / 791 [redacted]20[redacted] / 791

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]
SUMATRIPTAN	50 mg	PRN	Y-M: 20[redacted]
SILDENAFIL	100 mg	PRN	Y-M: 20[redacted]
GLUCOSAMINE SULFATE	700 mg	QD	Y-M: 20[redacted]
MAGNESIUM	250 mg	QD	Y-M: 20[redacted]
VITAMIN B COMPLEX	1 OTHER: TABLET	QD	Y-M: 20[redacted]
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]
CALCIUM CARBONATE	500 mg	BID	Y-M: 20[redacted] / -325
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 33
LOPERAMIDE	4 mg	PRN	Y-M: 20[redacted] / 36
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / 344
BENZALKONIUM CHLORIDE;CHLORHEXIDINE HYDROCHLORIDE;ISOPROPYL MYRISTATE;PARAFFIN, LIQUID	0.1%	PRN	Y-M: 20[redacted] / 354

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
SUMATRIPTAN	50 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
SILDENAFIL	100 mg	PRN	Y-M: 20[redacted]	NOT REPORTED
VITAMIN B COMPLEX	1 OTHER: TABLET	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 459
MAGNESIUM	250 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 551
CITALOPRAM	20 mg	QD	Y-M: 20[redacted]	Y-M: 20[redacted] / 424
CALCIUM CARBONATE	500 mg	BID	Y-M: 20[redacted] / -325	NOT REPORTED
PARACETAMOL	1 g	PRN	Y-M: 20[redacted] / 33	NOT REPORTED
LOPERAMIDE	4 mg	PRN	Y-M: 20[redacted] / 36	NOT REPORTED
MIRABEGRON	25 mg	QD	Y-M: 20[redacted] / 344	Y-M: 20[redacted] / 457

BENZALKONIUM CHLORIDE;CHLORHEXIDINE HYDROCHLORIDE;ISOPROPYL MYRISTATE;PARAFFIN, LIQUID	0.1%	PRN	Y-M: 20[redacted] / 354	NOT REPORTED
RIVASTIGMINE	1.5 mg	BID	Y-M: 20[redacted] / 366	Y-M: 20[redacted] / 447
FOLIC ACID	5 mg	QD	Y-M: 20[redacted] / 383	ONGOING
BISACODYL	5 mg	PRN	Y-M: 20[redacted] / 407	NOT REPORTED
MACROGOL	1 OTHER: SACHET	PRN	Y-M: 20[redacted] / 407	Y-M: 20[redacted] / 618
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	NOT REPORTED	ONCE	Y-M: 20[redacted] / 418	NOT REPORTED
LATANOPROST	50 mg	QD	Y-M: 20[redacted] / 421	ONGOING
MIRTAZAPINE	15 mg	QD	Y-M: 20[redacted] / 430	Y-M: 20[redacted] / 470
RIVASTIGMINE	3 mg	BID	Y-M: 20[redacted] / 448	NOT REPORTED
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 471	Y-M: 20[redacted] / 702
HYDROCORTISONE	1%	BID	Y-M: 20[redacted] / 487	Y-M: 20[redacted] / 515
GLUCOSAMINE SULFATE	500 mg	QD	Y-M: 20[redacted] / 489	NOT REPORTED
COVID-19 VACCINE NRVV AD (CHADOX1 NCOV-19)	NOT REPORTED	ONCE	Y-M: 20[redacted] / 491	NOT REPORTED
HYDROCORTISONE	1%	PRN	Y-M: 20[redacted] / 527	NOT REPORTED
MAGNESIUM	500 mg	QD	Y-M: 20[redacted] / 552	NOT REPORTED
VITAMIN B12 NOS	11 OTHER: MCGS	QD	Y-M: 20[redacted] / 563	ONGOING
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 569	Y-M: 20[redacted] / 579
PYRIDOXINE HYDROCHLORIDE	1 OTHER: TABLET	QD	Y-M: 20[redacted] / 570	ONGOING
FLUCLOXACILLIN	500 mg	QID	Y-M: 20[redacted] / 592	Y-M: 20[redacted] / 599
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	1 OTHER: SACHET	QD	Y-M: 20[redacted] / 619	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 678	NOT REPORTED
MIRTAZAPINE	45 mg	QD	Y-M: 20[redacted] / 702	NOT REPORTED
MIDAZOLAM	2.5 mg	OTHER: STAT	Y-M: 20[redacted] / 799	NOT REPORTED
DEXAMETHASONE	6.6 mg	OTHER: TWO DOSES ONLY	Y-M: 20[redacted] / 799	Y-M: 20[redacted] / 799

GENTAMICIN	240 mg	OTHER: ONCE	Y-M: 20[redacted] / 799	Y-M: 20[redacted] / 799
PARECOXIB SODIUM	40 mg	OTHER: ONCE	Y-M: 20[redacted] / 799	Y-M: 20[redacted] / 799
TEICOPLANIN	600 mg	OTHER: ONCE	Y-M: 20[redacted] / 799	Y-M: 20[redacted] / 799
TRANEXAMIC ACID	0.2 g	OTHER: ONCE	Y-M: 20[redacted] / 799	Y-M: 20[redacted] / 799
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 800	NOT REPORTED
OXYCODONE HYDROCHLORIDE	5 mg	BID	Y-M: 20[redacted] / 800	NOT REPORTED
ACETYLSALICYLIC ACID	300 mg	OTHER: STAT	Y-M: 20[redacted] / 800	Y-M: 20[redacted] / 800
CLOPIDOGREL	300 mg	OTHER: STAT	Y-M: 20[redacted] / 800	Y-M: 20[redacted] / 800
FONDAPARINUX SODIUM	2.5 mg	OTHER: STAT	Y-M: 20[redacted] / 800	Y-M: 20[redacted] / 800
OXYGEN	2 OTHER: L/MIN	OTHER: CONTINUOUS	Y-M: 20[redacted] / 800	Y-M: 20[redacted] / 801
OXYCODONE HYDROCHLORIDE	5 mg	PRN	Y-M: 20[redacted] / 801	NOT REPORTED

Event #1: Event of Interest - Weight Loss

Event Description	WORSENING SWALLOW
Preferred Term	嚥下障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 412
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to	NOT APPLICABLE

[redacted] **Infusion Set**	
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #2: Event of Interest - Hallucinations/Psychosis

Event Description	OLFACTORY HALLUCINATIONS
Preferred Term	幻嗅
AE Onset Date / Rx Day	[redacted]20[redacted] / 518
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	SKIN IRRITATION AT INFUSION SITE.
Preferred Term	注入部位刺激感
AE Onset Date / Rx Day	[redacted]20[redacted] / 541
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED

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

Event #4: Event of Interest - Infusion Site Related Infections

Event Description	INFECTION AT INFUSION SITE
Preferred Term	注入部位感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 569
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	592
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 #5: 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] / 592
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	ONGOING
Duration of AE	ONGOING
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	BRUISE AT OLD INFUSION SITE
Preferred Term	注入部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 609
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	628
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 #7: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	PAINFUL CANNULA SITE
Preferred Term	カテーテル留置部位疼痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 705
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	709
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 #8: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT CATHETER SITE
Preferred Term	カテーテル留置部位内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 761
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED

Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship 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	SWELLING UNDER OLD CATHETER SITE
Preferred Term	カテーテル留置部位腫脹
AE Onset Date / Rx Day	[redacted]20[redacted] / 761
Age at AE Onset	6[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	PROBABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #10: Serious Adverse Event

Event Description	NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)
Preferred Term	急性心筋梗塞
AE Onset Date / Rx Day	[redacted]20[redacted] / 799

Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 799): Creatinine: 54 [64 - 111] UMOL/L; Erythrocytes: 4.3 [4.5 - 5.6] 10^12/L; Hematocrit: 0.4 [0.4 - 0.5] FRACTION OF 1; Leukocytes: 12.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST024-D-DIMER: 11.8 [0 - 0.7] UG/ML; NPTST054-TROPONIN: 18 [0 - 34] NG/L; Neutrophils: 10.6 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 800): NPTST054-TROPONIN: 31 [0 - 34] NG/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	800
Duration of AE	2 DAYS
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT 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	POSSIBLE VASCULAR STENOSIS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Event #11: Serious Adverse Event

Event Description	DISORIENTATION
Preferred Term	失見当識
AE Onset Date / Rx Day	[redacted]20[redacted] / 799
Age at AE Onset	6[redacted]
Laboratory Testing	
[redacted]20[redacted] (RX DAY 799): Creatinine: 54 [64 - 111] UMOL/L; Erythrocytes: 4.3 [4.5 - 5.6] 10^12/L; Hematocrit: 0.4 [0.4 - 0.5] FRACTION OF 1; Leukocytes: 12.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST024-D-DIMER: 11.8 [0 - 0.7] UG/ML; NPTST054-TROPONIN: 18 [0 - 34] NG/L; Neutrophils: 10.6 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 800): NPTST054-TROPONIN: 31 [0 - 34] NG/L	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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 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	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Generated: [redacted]20[redacted]:09:11
Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は英国の 6[redacted] 歳男性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に失見当識及び非 ST 上昇型心筋梗塞（NSTEMI）を発現した。

Event 10 及び 11 の臨床経過：

関連する病歴は，パーキンソン病，片頭痛，多発ニューロパチー，非喫煙者，及び飲酒者（1 日 2–4 杯未満）であった。

投与 799 日目，被験者は失見当識及び非 ST 上昇型心筋梗塞（NSTEMI）を発現した。投与 800 日目，非 ST 上昇型心筋梗塞（NSTEMI）は消失した。失見当識（日時不明）は消失した。

投与 799 日目，被験者は選択的人工膝関節置換術を受けた。4 時間の手術中に，放散痛を含まない中心部胸痛が 15 分間持続した。ニトログリセリンの舌下投与により胸痛は治まった。しかし，被験者に新たに錯乱の徴候が認められた。運動性不全失語症の可能性，失見当識，場所及び時間の観念消失，左側顔面運動の減少を伴う左傾，並びに右側への注視優位性が認められた。四肢の脱力は認められなかった。グラスゴー昏睡尺度スコアは 13 であった。投与 800 日目，被験者は入院した。入院中，被験者の胸痛は持続し，non-dynamic troponin は正常な 31 であった。退院前，被験者に通常の下剤を用いた便秘の治療も実施し，便通があった。被験者が発現した錯乱は消失し，投与 806 日目，被験者は退院した。

被験者にアスピリン，ニトログリセリン，HARTMANN'S SOLUTION，酸素，及びアトルバスタチンが投与された。

The patient's past medications include:

OXFORD ASTRAZENECA COVID 19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

PFIZER COVID 19 BOOSTER VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Disorientation (10013395) (Disorientation (10013395)) [v.24.1] [10013395]

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

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

Dechallenge: Not Applicable

2) Non ST segment elevation myocardial infarction (10064347) (Acute myocardial infarction (10000891)) [v.24.1] [10064347]

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 DISORIENTATION

- Investigator: Not applicable

- AbbVie: The event is more likely in the clinical course of Non ST elevation myocardial infarction in the post Total knee replacement operation setting in a subject with Parkinson's disease, alcohol use and advanced age

Event of NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)

- Investigator: Possible vascular stenosis

- AbbVie: The event is more likely related to reported possible vascular stenosis in the post Total knee replacement operation setting in a subject with Parkinson's disease and advanced age

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] BODY WEIGHT:** 7[redacted].[redacted] KG

[redacted] **20[redacted] CREATININE:** 54 umol/L (normal 64 to 111)

[redacted] **20[redacted] CT ANGIOGRAM AORTA:** No evidence of acute aortic syndrome. There is moderate coronary artery calcification with stenosis in the mid lad. Flow limiting disease in the mid to distal rca cannot be excluded on this study. Left atrial dilation is noted. Normal opacification of the left atrial appendage.

[redacted] **20[redacted] CT HEAD:** No acute intracranial abnormality seen

[redacted] **20[redacted] D-DIMER:** 11.80 MCG/ML (normal 0 to 0.7)

20[redacted] GLASGOW COMA SCALE: 13 no units

[redacted] **20[redacted] HEMATOCRIT:** 0.396 L/L (normal 0.4 to 0.5)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.7 X10**9/L (normal 1 to 3.4)

[redacted] **20[redacted] NEUTROPHILS ABS:** 10.6 X10**9/L (normal 1.7 to 6.2)

[redacted] **20[redacted] RED BLOOD CELLS:** 4.3 X10**12/L (normal 4.5 to 5.6)

[redacted] **20[redacted] TROPONIN:** 18 NG/L (normal 0 to 34)

[redacted] **20[redacted] TROPONIN:** 31 NG/L (normal 0 to 34)

[redacted] **20[redacted] WHITE BLOOD CELLS**: 12.1 X10**9/L (normal 3.6 to 9.2)

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
急性腎障害	X			
関節痛				X
無症候性 COVID-19	X			
カテーテル留置部位内出血				X
挫傷				X
食欲減退				X
譫妄	X			
嚥下障害	X			X
転倒				X
ヘモグロビン減少	X			X
高ナトリウム血症	X			
痙攣発作	X			
敗血症	X			
外傷性頭蓋内出血	X			X
尿路感染	X			
尿路性敗血症	X			
膣脱	X			

Treatment Group	Age at M15-741 Study Start	Sex	Race
ABBV-951	5[redacted]	FEMALE	WHITE

Medical History	Onset Year
INSOMNIA	20[redacted]
CANDIDAS VULVOVAGINITIS	20[redacted]
SHINGLES	20[redacted]
IRRITABLE BOWEL SYNDROME	20[redacted]
INDIGESTION	20[redacted]
TENNIS ELBOW	20[redacted]
SWELLING TO BACK OF RIGHT KNEE	20[redacted]
MENOPAUSAL SYMPTOMS	20[redacted]

PARKINSON'S DISEASE	20[redacted]
VERTIGO	20[redacted]
ANKLE OEDEMA	20[redacted]
ACHILLES TENDONITIS LEFT LEG	20[redacted]
FREQUENT FALLS	20[redacted]
LUMP IN BREAST	20[redacted]
PILAR CYST OF SCALP	20[redacted]
VAGINAL PROLAPSE	20[redacted]
MENORRHGIA	20[redacted]
URINARY TRACT INFECTION	20[redacted]

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

Prior Procedures	Procedure Year
NOT REPORTED	

Tobacco Use	Status	Number/Day	Number of Years	Year Stopped
CHEWING TOBACCO	NEVER			
CIGARETTES	FORMER	5 CIGARETTE	5	19[redacted]
CIGARS	NEVER			
E-CIGARETTES	NEVER			
PIPES	NEVER			

Alcohol Use	Status	Number/Day
ALCOHOL	CURRENT	LESS THAN 2 DRINKS

Study Drug Prescription

Study Drug	Continuous Flow Rate 1 (mL/h)	Continuous Flow Rate 2 (mL/h)	Continuous Flow Rate 3 (mL/h)	Extra Dose Lockout (min)	Extra Dose Volume (mL)	Dose Date/Day
ABBV-951	0.44	0.45	0.43	60	0.19	[redacted]20[redacted] / 366
ABBV-951	0.45	0.46	0.44	60	0.19	[redacted]20[redacted] / 452

Daily Dose (mg LD) by Molecular Weight

Feeder Study /Study Drug	ABBV-951 Dose	ABBV-951 Extra Dose	Route (Subcutaneous)/Frequency	First Dose Date/Day	Last Dose Date/Day
M15-741 /ABBV-951		64.88	SC / ONCE	[redacted] / 1	
M15-741 /ABBV-951	829.67		SC / CONTINUOUS	[redacted] / 1	[redacted] / 1
M15-741 /ABBV-951	1688.71		SC / CONTINUOUS	[redacted] / 2	[redacted] / 2
M15-741 /ABBV-951	1762.14		SC / CONTINUOUS	[redacted] / 3	[redacted] / 3
M15-741 /ABBV-951	1737.21		SC / CONTINUOUS	[redacted] / 4	[redacted] / 4
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted] / 5	
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M15-741 /ABBV-951		97.32	SC / ONCE	[redacted]	20	[redacted]	/ 53			
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M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]	20	[redacted]	/ 54			
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M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]	20	[redacted]	/ 55			
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M15-741 /ABBV-951		129.77	SC / ONCE	[redacted]	20	[redacted]	/ 57			
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M15-741 /ABBV-951	1805.85		SC / CONTINUOUS	[redacted]20[redacted] / 362 [redacted]20[redacted] / 362
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 363
M15-741 /ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 363 [redacted]20[redacted] / 364
M15-741 /ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 364
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 368
ABBV-951	1850.93		SC / CONTINUOUS	[redacted]20[redacted] / 368 [redacted]20[redacted] / 368
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 369
ABBV-951	1823.95		SC / CONTINUOUS	[redacted]20[redacted] / 369 [redacted]20[redacted] / 369
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 370
ABBV-951	1830.26		SC / CONTINUOUS	[redacted]20[redacted] / 370 [redacted]20[redacted] / 370
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 371
ABBV-951	1825.82		SC / CONTINUOUS	[redacted]20[redacted] / 371 [redacted]20[redacted] / 371
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 372
ABBV-951	1825.31		SC / CONTINUOUS	[redacted]20[redacted] / 372 [redacted]20[redacted] / 372
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 373
ABBV-951	1833.68		SC / CONTINUOUS	[redacted]20[redacted] / 373 [redacted]20[redacted] / 373
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 378
ABBV-951	1840.51		SC / CONTINUOUS	[redacted]20[redacted] / 378 [redacted]20[redacted] / 378
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 379
ABBV-951	1820.36		SC / CONTINUOUS	[redacted]20[redacted] / 379 [redacted]20[redacted] / 379

ABBV-951		194.65	SC / ONCE	[redacted]20[redacted] / 380	
ABBV-951	1832.14		SC / CONTINUOUS	[redacted]20[redacted] / 380	[redacted]20[redacted] / 380
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 381	
ABBV-951	1814.21		SC / CONTINUOUS	[redacted]20[redacted] / 381	[redacted]20[redacted] / 381
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 382	
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 383	
ABBV-951	1818.48		SC / CONTINUOUS	[redacted]20[redacted] / 383	[redacted]20[redacted] / 383
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 384	
ABBV-951	1823.43		SC / CONTINUOUS	[redacted]20[redacted] / 384	[redacted]20[redacted] / 384
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 385	
ABBV-951	1840.00		SC / CONTINUOUS	[redacted]20[redacted] / 385	[redacted]20[redacted] / 385
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 386	
ABBV-951	1826.00		SC / CONTINUOUS	[redacted]20[redacted] / 386	[redacted]20[redacted] / 386
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 387	
ABBV-951	1820.36		SC / CONTINUOUS	[redacted]20[redacted] / 387	[redacted]20[redacted] / 387
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 388	
ABBV-951	1842.22		SC / CONTINUOUS	[redacted]20[redacted] / 388	[redacted]20[redacted] / 388
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 389	
ABBV-951	1828.90		SC / CONTINUOUS	[redacted]20[redacted] / 389	[redacted]20[redacted] / 389
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 390	
ABBV-951	1819.17		SC / CONTINUOUS	[redacted]20[redacted] / 390	[redacted]20[redacted] / 390

ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 391	
ABBV-951	1820.36		SC / CONTINUOUS	[redacted]20[redacted] / 391	[redacted]20[redacted] / 391
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 392	
ABBV-951	1823.26		SC / CONTINUOUS	[redacted]20[redacted] / 392	[redacted]20[redacted] / 392
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 393	
ABBV-951	1811.48		SC / CONTINUOUS	[redacted]20[redacted] / 393	[redacted]20[redacted] / 393
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 394	
ABBV-951	1803.12		SC / CONTINUOUS	[redacted]20[redacted] / 394	[redacted]20[redacted] / 394
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 395	
ABBV-951	1818.65		SC / CONTINUOUS	[redacted]20[redacted] / 395	[redacted]20[redacted] / 395
ABBV-951	1823.78		SC / CONTINUOUS	[redacted]20[redacted] / 396	[redacted]20[redacted] / 396
ABBV-951		162.21	SC / ONCE	[redacted]20[redacted] / 408	
ABBV-951	1843.41		SC / CONTINUOUS	[redacted]20[redacted] / 408	[redacted]20[redacted] / 408
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 409	
ABBV-951	1815.58		SC / CONTINUOUS	[redacted]20[redacted] / 409	[redacted]20[redacted] / 409
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 410	
ABBV-951	1821.21		SC / CONTINUOUS	[redacted]20[redacted] / 410	[redacted]20[redacted] / 410
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 411	
ABBV-951	1818.31		SC / CONTINUOUS	[redacted]20[redacted] / 411	[redacted]20[redacted] / 411
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 412	
ABBV-951	1820.36		SC / CONTINUOUS	[redacted]20[redacted] / 412	[redacted]20[redacted] / 412
ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 413	
ABBV-951	1832.31		SC / CONTINUOUS	[redacted]20[redacted] / 413	[redacted]20[redacted] / 413
ABBV-951		129.77	SC / ONCE	[redacted]20[redacted] / 414	
ABBV-951	1823.95		SC / CONTINUOUS	[redacted]20[redacted] / 414	[redacted]20[redacted] / 414
ABBV-951	1809.43		SC / CONTINUOUS	[redacted]20[redacted] / 415	[redacted]20[redacted] / 415
ABBV-951		32.44	SC / ONCE	[redacted]20[redacted] / 416	
ABBV-951		64.88	SC / ONCE	[redacted]20[redacted] / 417	
ABBV-951	1810.97		SC / CONTINUOUS	[redacted]20[redacted] / 417	[redacted]20[redacted] / 417

ABBV-951		97.32	SC / ONCE	[redacted]20[redacted] / 418
ABBV-951	1813.70		SC / CONTINUOUS	[redacted]20[redacted] / 418 [redacted]20[redacted] / 418
ABBV-951	1816.95		SC / CONTINUOUS	[redacted]20[redacted] / 419 [redacted]20[redacted] / 419
ABBV-951	1818.65		SC / CONTINUOUS	[redacted]20[redacted] / 420 [redacted]20[redacted] / 420

Previous Therapy - Prior to baseline/enrollment

Medication Name (WHO Drug)	Dose/Units	Frequency	Start Year-Month / RX Day
RASAGILINE	1.000 mg	QD	Y-M: 20[redacted]-[redacted]
CALCIUM CARBONATE;COLECALCIFEROL	150 mg	BID	Y-M: 20[redacted]-[redacted]
GLYCEROL	4 mg	QD	Y-M: 20[redacted]-[redacted] / -280
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	ONE OTHER: SACHET	QD	Y-M: 20[redacted]-[redacted] / 86
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 117
VITAMINS NOS	1 OTHER: TABLET	BID	Y-M: 20[redacted]-[redacted] / 197
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 200
PRUCALOPRIDE	1 mg	QD	Y-M: 20[redacted]-[redacted] / 285
SENNA ALEXANDRINA	7.5 mg	BID	Y-M: 20[redacted]-[redacted] / 306
ROTIGOTINE	3.000 mg	QD	Y-M: 20[redacted]-[redacted] / 339
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted]-[redacted] / 345

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 CARBONATE;COLECALCIFEROL	150 mg	BID	Y-M: 20[redacted]-[redacted]	NOT REPORTED
GLYCEROL	4 mg	QD	Y-M: 20[redacted]-[redacted] / -280	NOT REPORTED
MACROGOL 3350;POTASSIUM CHLORIDE;SODIUM BICARBONATE;SODIUM CHLORIDE	ONE OTHER: SACHET	QD	Y-M: 20[redacted]-[redacted] / 86	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 117	NOT REPORTED
VITAMINS NOS	1 OTHER: TABLET	BID	Y-M: 20[redacted]-[redacted] / 197	NOT REPORTED
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted]-[redacted] / 200	NOT REPORTED
PRUCALOPRIDE	1 mg	QD	Y-M: 20[redacted]-[redacted] / 285	NOT REPORTED
SENNA	7.5 mg	BID	Y-M: 20[redacted]-[redacted] / 306	NOT REPORTED

ALEXANDRINA				
PARACETAMOL	500 mg	PRN	Y-M: 20[redacted] / 345	Y-M: 20[redacted] / 465
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 368	Y-M: 20[redacted] / 375
MIRTAZAPINE	7.5 mg	QD	Y-M: 20[redacted] / 371	Y-M: 20[redacted] / 373
MIRTAZAPINE	15 mg	QD	Y-M: 20[redacted] / 374	Y-M: 20[redacted] / 430
TOZINAMERAN	NOT REPORTED	ONCE	Y-M: 20[redacted] / 394	NOT REPORTED
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 399	Y-M: 20[redacted] / 406
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: X2 STAT DOSES	Y-M: 20[redacted] / 422	Y-M: 20[redacted] / 423
SODIUM CHLORIDE	1000 mL	OTHER: X1 STAT DOSE	Y-M: 20[redacted] / 422	Y-M: 20[redacted] / 423
AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1000/200 mg	TID	Y-M: 20[redacted] / 422	Y-M: 20[redacted] / 425
GENTAMICIN	360/9 OTHER: MG/ML	OTHER: X1 STAT DOSE	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 423
POTASSIUM CHLORIDE;SODIUM CHLORIDE	1000 mL	OTHER: X1 STAT DOSE	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 423
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 423	Y-M: 20[redacted] / 430
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 425	Y-M: 20[redacted] / 431
MIRTAZAPINE	30 mg	QD	Y-M: 20[redacted] / 430	NOT REPORTED
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 430	Y-M: 20[redacted] / 433
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 444	Y-M: 20[redacted] / 445

AMOXICILLIN SODIUM;CLAVULANATE POTASSIUM	1000/200 mg	BID	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 445
ONDANSETRON	4 mg	TID	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 445
OXYCODONE	10 mg	OTHER: STAT DOSE	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 445
POTASSIUM CHLORIDE;SODIUM CHLORIDE	1000 mL	OTHER: STAT DOSE	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 446
SODIUM CHLORIDE	1000 mL	OTHER: STAT DOSE	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 446
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: STAT DOSE	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 447
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	4/500 OTHER: G/MG	BID	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 452
ENOXAPARIN SODIUM	20 mg	QD	Y-M: 20[redacted] / 445	Y-M: 20[redacted] / 455
SODIUM CHLORIDE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 448	Y-M: 20[redacted] / 449
MAGNESIUM	1 OTHER: SACHET	QD	Y-M: 20[redacted] / 452	Y-M: 20[redacted] / 455
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 452	Y-M: 20[redacted] / 465
POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	940/570 mg	TID	Y-M: 20[redacted] / 455	Y-M: 20[redacted] / 458
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 462	Y-M: 20[redacted] / 467
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 463	Y-M: 20[redacted] / 464
PARACETAMOL	1000 mg	QID	Y-M: 20[redacted] / 465	NOT REPORTED
PARECOXIB	40 mg	OTHER: STAT	Y-M: 20[redacted] / 465	NOT REPORTED
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 465	Y-M: 20[redacted] / 465
MORPHINE SULFATE	20 mg	PRN	Y-M: 20[redacted] / 465	Y-M: 20[redacted] / 465
AMOXICILLIN SODIUM;CLAVULAN	1200 mg	TID	Y-M: 20[redacted] / 465	Y-M: 20[redacted] / 466

ATE POTASSIUM				
ONDANSETRON	8 mg	PRN	Y-M: 20[redacted] / 466	Y-M: 20[redacted] / 466
POTASSIUM CHLORIDE;SODIUM CHLORIDE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 466	Y-M: 20[redacted] / 466
AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM	500/125 mg	TID	Y-M: 20[redacted] / 467	NOT REPORTED
ONDANSETRON	4 mg	PRN	Y-M: 20[redacted] / 467	NOT REPORTED
LAMOTRIGINE	25 mg	QD	Y-M: 20[redacted] / 470	Y-M: 20[redacted] / 473
TRIMETHOPRIM	200 mg	QD	Y-M: 20[redacted] / 470	Y-M: 20[redacted] / 477
LEVETIRACETAM	500 mg	OTHER: STAT	Y-M: 20[redacted] / 474	Y-M: 20[redacted] / 474
ACICLOVIR	800 mg	TID	Y-M: 20[redacted] / 474	Y-M: 20[redacted] / 478
LEVETIRACETAM	750 mg	BID	Y-M: 20[redacted] / 474	Y-M: 20[redacted] / 495
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 481	Y-M: 20[redacted] / 482
ENOXAPARIN SODIUM	40 mg	QD	Y-M: 20[redacted] / 483	NOT REPORTED
FOLIC ACID	5 mg	OTHER: OD	Y-M: 20[redacted] / 487	NOT REPORTED
RIVASTIGMINE	4.6 mg	QD	Y-M: 20[redacted] / 487	NOT REPORTED
LORAZEPAM	1 mg	PRN	Y-M: 20[redacted] / 489	NOT REPORTED
CALCIUM CHLORIDE DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 489	Y-M: 20[redacted] / 490
VALPROATE SODIUM	300 mg	TID	Y-M: 20[redacted] / 489	Y-M: 20[redacted] / 491
CLOBAZAM	20 mg	QD	Y-M: 20[redacted] / 489	Y-M: 20[redacted] / 499
MORPHINE SULFATE	5-10 mg	PRN	Y-M: 20[redacted] / 491	NOT REPORTED
CAFFEINE;CARBOHYDRATES NOS;CHOLINE;FATS NOS;MINERALS NOS;PROTEINS NOS;VITAMINS NOS	1 OTHER: BOTTLE	TID	Y-M: 20[redacted] / 492	NOT REPORTED
SODIUM CHLORIDE	1000 mL	QD	Y-M: 20[redacted] / 492	Y-M: 20[redacted] / 493
NYSTATIN	1 mL	QID	Y-M: 20[redacted] / 492	Y-M: 20[redacted] / 495
CALCIUM CHLORIDE DIHYDRATE;POTASS	1000 mL	QD	Y-M: 20[redacted] / 493	Y-M: 20[redacted] / 493

IUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE				
GLUCOSE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 493	Y-M: 20[redacted] / 494
GLUCOSE	1000 mL	OTHER: STAT	Y-M: 20[redacted] / 494	Y-M: 20[redacted] / 495
LEVETIRACETAM	1500 mg	BID	Y-M: 20[redacted] / 495	NOT REPORTED
PIPERACILLIN SODIUM;TAZOBACTAM SODIUM	4.5 g	TID	Y-M: 20[redacted] / 495	NOT REPORTED
GENTAMICIN	400 mg	QD	Y-M: 20[redacted] / 495	Y-M: 20[redacted] / 495
POTASSIUM CHLORIDE;SODIUM CHLORIDE	40 OTHER: MMOL/L	OTHER: STAT	Y-M: 20[redacted] / 495	Y-M: 20[redacted] / 495
SODIUM CHLORIDE	500 mL	OTHER: STAT	Y-M: 20[redacted] / 495	Y-M: 20[redacted] / 495
POTASSIUM BICARBONATE;POTASSIUM CHLORIDE	2 OTHER: TABLETS	QID	Y-M: 20[redacted] / 495	Y-M: 20[redacted] / 498
ASCORBIC ACID;GLUCOSE;NICOTINAMIDE;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN SODIUM PHOSPHATE;THIAMINE HYDROCHLORIDE	2 OTHER: AMPOULES	QD	Y-M: 20[redacted] / 497	Y-M: 20[redacted] / 499
CLOBAZAM	15 mg	QD	Y-M: 20[redacted] / 499	NOT REPORTED
THIAMINE HYDROCHLORIDE	100 mg	BID	Y-M: 20[redacted] / 499	NOT REPORTED

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

Event Description	BRUISE ON LEFT ELBOW
Preferred Term	挫傷
AE Onset Date / Rx Day	[redacted]20[redacted] / 384
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	391
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 #2: Event of Interest - Falls and Associated Injuries

Event Description	FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 384
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	384
Duration of AE	1 DAY
Severity	MODERATE
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #3: Serious Adverse Event

Event Description	UTI
Preferred Term	尿路感染
AE Onset Date / Rx Day	[redacted]20[redacted] / 418

Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 422): Leukocytes: 10.7 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.6 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 160 [0.1 - 5] MG/L; Neutrophils: 9.2 [1.7 - 6.2] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; [redacted]20[redacted] (RX DAY 423): Activated Partial Thromboplastin Time: 34 [26 - 34] SEC; Albumin: 32 [35 - 50] G/L; Calcium: 2.07 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.36 [0.37 - 0.46] FRACTION OF 1; Leukocytes: 13.1 [3.6 - 9.2] 10^9/L; Monocytes: 1.05 [0.2 - 0.8] 10^9/L; NPTST047-PHOSPHATE: 0.6 [0.8 - 1.5] MMOL/L; Neutrophils: 10.6 [1.7 - 6.2] 10^9/L; Potassium: 2.8 [3.4 - 4.5] MMOL/L; Prothrombin Time: 16 [13 - 16] SEC; [redacted]20[redacted] (RX DAY 424): Albumin: 27 [35 - 50] G/L; Calcium: 2.05 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.6 [3.9 - 5.1] 10^12/L; Hematocrit: 0.35 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 115 [120 - 155] G/L; Leukocytes: 10.2 [3.6 - 9.2] 10^9/L; Monocytes: 1 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 305 [0.1 - 5] MG/L; NPTST047-PHOSPHATE: 0.5 [0.8 - 1.5] MMOL/L; Neutrophils: 7.8 [1.7 - 6.2] 10^9/L; Platelets: 137 [140 - 400] 10^9/L; Protein: 52 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 426): Ery. Mean Corpuscular Hemoglobin: 33.4 [28 - 33] PG; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.37 [0.37 - 0.46] FRACTION OF 1; NPTST010-C-REACTIVE PROTEIN: 159 [0.1 - 5] MG/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; [redacted]20[redacted] (RX DAY 427): Albumin: 30 [35 - 50] G/L; Creatinine: 47 [50 - 98] UMOL/L; Ery. Mean Corpuscular Hemoglobin: 33.2 [28 - 33] PG; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 117 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 119 [0.1 - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 422): BLOOD BLOOD CULTURES (AER+ANAER): NEGATIVE; [redacted]20[redacted] (RX DAY 423): URINE URINE CULTURE: NEGATIVE; URINE URINE MICRO EPITHELIAL CELLS: POSITIVE-MODERATE/LARGE NUMBER (++/+++); URINE URINE MICRO WHITE CELLS: POSITIVE-+++ (IN LARGE NUMBERS); [redacted]20[redacted] (RX DAY 424): URINE URINE MICRO WHITE CELLS: POSITIVE-++ (IN MODERATE NUMBERS)

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	CURRENTLY UNKNOWN BACTERIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #4: Serious Adverse Event

Event Description	UROSEPSIS
Preferred Term	尿路性敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 422
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 422): Leukocytes: 10.7 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.6 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 160 [0.1 - 5] MG/L; Neutrophils: 9.2 [1.7 - 6.2] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; [redacted]20[redacted] (RX DAY 423): Activated Partial Thromboplastin Time: 34 [26 - 34] SEC; Albumin: 32 [35 - 50] G/L; Calcium: 2.07 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.36 [0.37 - 0.46] FRACTION OF 1; Leukocytes: 13.1 [3.6 - 9.2] 10^9/L; Monocytes: 1.05 [0.2 - 0.8] 10^9/L; NPTST047-PHOSPHATE: 0.6 [0.8 - 1.5] MMOL/L; Neutrophils: 10.6 [1.7 - 6.2] 10^9/L; Potassium: 2.8 [3.4 - 4.5] MMOL/L; Prothrombin Time: 16 [13 - 16] SEC; [redacted]20[redacted] (RX DAY 424): Albumin: 27 [35 - 50] G/L; Calcium: 2.05 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.6 [3.9 - 5.1] 10^12/L; Hematocrit: 0.35 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 115 [120 - 155] G/L; Leukocytes: 10.2 [3.6 - 9.2] 10^9/L; Monocytes: 1 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 305 [0.1 - 5] MG/L; NPTST047-PHOSPHATE: 0.5 [0.8 - 1.5] MMOL/L; Neutrophils: 7.8 [1.7 - 6.2] 10^9/L; Platelets: 137 [140 - 400] 10^9/L; Protein: 52 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 426): Ery. Mean Corpuscular Hemoglobin: 33.4 [28 - 33] PG; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.37 [0.37 - 0.46] FRACTION OF 1; NPTST010-C-REACTIVE PROTEIN: 159 [0.1 - 5] MG/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; [redacted]20[redacted] (RX DAY 427): Albumin: 30 [35 - 50] G/L; Creatinine: 47 [50 - 98] UMOL/L; Ery. Mean Corpuscular Hemoglobin: 33.2 [28 - 33] PG; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 117 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 119 [0.1 - 5] MG/L

Microbiology

[redacted]20[redacted] (RX DAY 422): BLOOD BLOOD CULTURES (AER+ANAER): NEGATIVE; [redacted]20[redacted] (RX DAY 423): URINE URINE CULTURE: NEGATIVE; URINE URINE MICRO EPITHELIAL CELLS: POSITIVE-MODERATE/LARGE NUMBER (++/+++); URINE URINE MICRO WHITE CELLS: POSITIVE-+++ (IN LARGE NUMBERS); [redacted]20[redacted] (RX DAY 424): URINE URINE MICRO WHITE CELLS: POSITIVE-++ (IN MODERATE NUMBERS)

AE Stopped Rx Day	430
Duration of AE	9 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	UNKNOWN BACTERIA
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #5: Event of Interest - Weight Loss

Event Description	REDUCED APPETITE
Preferred Term	食欲減退
AE Onset Date / Rx Day	[redacted]20[redacted] / 433
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

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

Event #6: Event of Interest - Weight Loss

Event Description	DIFFICULTY SWALLOWING
Preferred Term	嚥下障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 433
Age at AE Onset	5[redacted]

Laboratory Testing

NOT APPLICABLE

Microbiology

NOT APPLICABLE

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT 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	UROSEPSIS
Preferred Term	尿路性敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 444
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 445): Albumin: 25 [35 - 50] G/L; Alkaline Phosphatase: 232 [30 - 130] U/L; Calcium: 1.86 [2.1 - 2.5] MMOL/L; Creatinine: 401 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.33 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 107 [120 - 155] G/L; Leukocytes: 16.1 [3.6 - 9.2] 10^9/L; Monocytes: 0.81 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 596 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 10 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 2 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 24.2 [2.5 - 7.8] MMOL/L; Neutrophils: 14.1 [1.7 - 6.2] 10^9/L; Protein: 58 [60 - 80] G/L; Sodium: 132 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 446): Albumin: 22 [35 - 50] G/L; Alkaline Phosphatase: 234 [30 - 130] U/L; Calcium: 1.83 [2.1 - 2.5] MMOL/L; Creatinine: 269 [50 - 98] UMOL/L; Erythrocytes: 3.3 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 12.6 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 411 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 17 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 1.7 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 22.8 [2.5 - 7.8] MMOL/L; Neutrophils: 10.2 [1.7 - 6.2] 10^9/L; Protein: 49 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 447): Albumin: 21 [35 - 50] G/L; Alkaline Phosphatase: 257 [30 - 130] U/L; Calcium: 1.83 [2.1 - 2.5] MMOL/L; Creatinine: 176 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.33 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 107 [120 - 155] G/L; Leukocytes: 11.5 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 298 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 28 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 1.6 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 19.5 [2.5 - 7.8] MMOL/L; Neutrophils: 8.9 [1.7 - 6.2] 10^9/L; Protein: 47 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 448): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 243 [30 - 130] U/L; Calcium: 1.9 [2.1 - 2.5] MMOL/L; Creatinine: 104 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 113 [120 - 155] G/L; Leukocytes: 12.9 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 191 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 53 [90 - NOT REPORTED] mL/min/1.73m2; NPTST055-UREA: 14.7 [2.5 - 7.8] MMOL/L; Neutrophils: 10.2 [1.7 - 6.2] 10^9/L; Protein: 52 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 449): Eosinophils: 0.42 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 109 [120 - 155] G/L; Leukocytes: 11.1 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 152 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 86 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST055-UREA: 9.4 [2.5 - 7.8] MMOL/L; Neutrophils: 7.9 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 451): Albumin: 28 [35 - 50] G/L; Alkaline Phosphatase: 206 [30 - 130] U/L; Calcium: 2.04 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.35 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 111 [120 - 155] G/L; Leukocytes: 9.6 [3.6 - 9.2] 10^9/L; Magnesium: 0.65 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 107 [0.1 - 5] MG/L; NPTST047-PHOSPHATE: 0.7 [0.8 - 1.5] MMOL/L; Neutrophils: 7.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 453): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.32 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 106 [120 - 155] G/L; Leukocytes: 9.7 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 79 [0.1 - 5] MG/L; Neutrophils: 7.9 [1.7 - 6.2] 10^9/L; Potassium: 3.3 [3.5 - 5.3] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 445): OTHER SWAB CORONAVIRUS: NEGATIVE; [redacted]20[redacted] (RX DAY 447): OTHER SWAB MRSA SCREEN: NEGATIVE; URINE URINE CULTURE: NEGATIVE-NO BACTERIAL GROWTH

AE Stopped Rx Day	455

Duration of AE	12 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	VAGINAL PROLAPSE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #8: Serious Adverse Event

Event Description	ACUTE KIDNEY INJURY
Preferred Term	急性腎障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 445
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 445): Albumin: 25 [35 - 50] G/L; Alkaline Phosphatase: 232 [30 - 130] U/L; Calcium: 1.86 [2.1 - 2.5] MMOL/L; Creatinine: 401 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.33 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 107 [120 - 155] G/L; Leukocytes: 16.1 [3.6 - 9.2] 10^9/L; Monocytes: 0.81 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 596 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 10 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 2 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 24.2 [2.5 - 7.8] MMOL/L; Neutrophils: 14.1 [1.7 - 6.2] 10^9/L; Protein: 58 [60 - 80] G/L; Sodium: 132 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 446): Albumin: 22 [35 - 50] G/L; Alkaline Phosphatase: 234 [30 - 130] U/L; Calcium: 1.83 [2.1 - 2.5] MMOL/L; Creatinine: 269 [50 - 98] UMOL/L; Erythrocytes: 3.3 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 12.6 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 411 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 17 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 1.7 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 22.8 [2.5 - 7.8] MMOL/L; Neutrophils: 10.2 [1.7 - 6.2] 10^9/L; Protein: 49 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 447): Albumin: 21 [35 - 50] G/L; Alkaline Phosphatase: 257 [30 - 130] U/L; Calcium: 1.83 [2.1 - 2.5] MMOL/L; Creatinine: 176 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.33 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 107 [120 - 155] G/L; Leukocytes: 11.5 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 298 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 28 [90 - NOT REPORTED] mL/min/1.73m2; NPTST047-PHOSPHATE: 1.6 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 19.5 [2.5 - 7.8] MMOL/L; Neutrophils: 8.9 [1.7 - 6.2] 10^9/L; Protein: 47 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 448): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 243 [30 - 130] U/L; Calcium: 1.9 [2.1 - 2.5] MMOL/L; Creatinine: 104 [50 - 98] UMOL/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 113 [120 - 155] G/L; Leukocytes: 12.9 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 191 [0.1 - 5] MG/L; NPTST031-GLOMERULAR FILTRATION RATE: 53 [90 - NOT REPORTED] mL/min/1.73m2; NPTST055-UREA: 14.7 [2.5 - 7.8] MMOL/L; Neutrophils: 10.2 [1.7 - 6.2] 10^9/L; Protein: 52 [60 - 80] G/L; [redacted]20[redacted] (RX DAY 449): Eosinophils: 0.42 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.34 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 109 [120 - 155] G/L; Leukocytes: 11.1 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 152 [0.1 - 5] MG/L; NPTST031-GLOMERULAR

FILTRATION RATE: 86 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST055-UREA: 9.4 [2.5 - 7.8] MMOL/L; Neutrophils: 7.9 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 451): Albumin: 28 [35 - 50] G/L; Alkaline Phosphatase: 206 [30 - 130] U/L; Calcium: 2.04 [2.1 - 2.5] MMOL/L; Erythrocytes: 3.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.35 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 111 [120 - 155] G/L; Leukocytes: 9.6 [3.6 - 9.2] 10^9/L; Magnesium: 0.65 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 107 [0.1 - 5] MG/L; NPTST047-PHOSPHATE: 0.7 [0.8 - 1.5] MMOL/L; Neutrophils: 7.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 453): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.32 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 106 [120 - 155] G/L; Leukocytes: 9.7 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 79 [0.1 - 5] MG/L; Neutrophils: 7.9 [1.7 - 6.2] 10^9/L; Potassium: 3.3 [3.5 - 5.3] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 445): OTHER SWAB CORONAVIRUS: NEGATIVE; [redacted]20[redacted] (RX DAY 447): OTHER SWAB MRSA SCREEN: NEGATIVE; URINE URINE CULTURE: NEGATIVE-NO BACTERIAL GROWTH

AE Stopped Rx Day	455
Duration of AE	11 DAYS
Severity	SEVERE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	UROSEPSIS SECONDARY TO VAGINAL PROLAPSE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #9: Serious Adverse Event

Event Description	FURTHER WORSENING VAGINAL PROLAPSE
Preferred Term	膣脱
AE Onset Date / Rx Day	[redacted]20[redacted] / 462
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 464): Activated Partial Thromboplastin Time: 34 [26 - 34] SEC; Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 159 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.32 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 105 [120 - 155] G/L; Leukocytes: 3.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 21 [0.1 - 5] MG/L; NPTST055-UREA: 2.1 [2.5 - 7.8] MMOL/L; Neutrophils: 1.6 [1.7 - 6.2] 10^9/L

Microbiology

NOT REPORTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	WEAKENED MUSCLE FLOOR
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #10: Serious Adverse Event

Event Description	SEIZURE
Preferred Term	痙攣発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 469
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 473): Albumin: 31 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Eosinophils: 0.52 [0 - 0.4] 10^9/L; Erythrocytes: 3.4 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 100 [120 - 155] G/L; Magnesium: 0.69 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 51 [0.1 - 5] MG/L; NPTST050-SERUM FOLATE: 2.2 [3.1 - 20] UG/L; NPTST055-UREA: 2.4 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 474): Eosinophils: 0.46 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 6.5 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.8 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 40 [0.1 - 5] MG/L; NPTST055-UREA: 1.9 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 478): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; NPTST021-CSF GLUCOSE: 3.0 [NOT REPORTED - NOT REPORTED] mmol/L; NPTST022-CSF PROTEIN: 0.22 [0.15 - 0.45] G/L; [redacted]20[redacted] (RX DAY 479): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 153 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 104 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 66 [0.1 - 5] MG/L; [redacted]20[redacted] (RX DAY 480): Alkaline Phosphatase: 150 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 7.6 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 63 [0.1 - 5] MG/L; Neutrophils: 6.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 482): Albumin: 36 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Bilirubin: 9 [1 - 20] UMOL/L; Creatinine: 59 [50 - 98] UMOL/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.28 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 96 [120 - 155] G/L; Leukocytes: 8.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.5 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 70 [0.1 - 5] MG/L; Neutrophils: 7.2 [1.7 - 6.2] 10^9/L; Platelets: 196 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 474): BLOOD BLOOD CULTURE: NEGATIVE-BACTEC ANAEROBIC LYTIC BOTTLE NO GROWTH DETECTED AT 36 HRS BACTEC AEROBIC BOTTLE NO GROWTH DETECTED AT 36 HRS; [redacted]20[redacted] (RX DAY 477): OTHER SWAB CORONAVIRUS (COVID 19): POSITIVE-VARIANT RESULT NOT YET RECEIVED; [redacted]20[redacted] (RX DAY 478): CEREBROSPINAL FLUID STERILE FLUID/TISSUE MICROSCOPY: NEGATIVE-APPEARANCE: CLEAR CELL COUNT (X10^6/L): POLYMORPHS <1 LYMPHOCYTES 2 RED BLOOD CELLS 86 MONONUCLEAR CELLS <1 GRAM STAIN - NO ORGANISMS SEEN; [redacted]20[redacted] (RX DAY 479):

BLOOD COVID-19 PATIENT ANTIBODY SCREE: POSITIVE->2080.0 BAU/ML RESULT INTERPRETATION <33.8 - NOT DETECTED >33.8 = DETECTED

AE Stopped Rx Day	469
Duration of AE	1 DAY
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 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	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Event #11: Serious Adverse Event

Event Description	SEIZURE
Preferred Term	痙攣発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 472
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 473): Albumin: 31 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Eosinophils: 0.52 [0 - 0.4] 10^9/L; Erythrocytes: 3.4 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 100 [120 - 155] G/L; Magnesium: 0.69 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 51 [0.1 - 5] MG/L; NPTST050-SERUM FOLATE: 2.2 [3.1 - 20] UG/L; NPTST055-UREA: 2.4 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 474): Eosinophils: 0.46 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 6.5 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.8 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 40 [0.1 - 5] MG/L; NPTST055-UREA: 1.9 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 478): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; NPTST021-CSF GLUCOSE: 3.0 [NOT REPORTED - NOT REPORTED] mmol/L; NPTST022-CSF PROTEIN: 0.22 [0.15 - 0.45] G/L; [redacted]20[redacted] (RX DAY 479): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 153 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 104 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 66 [0.1 - 5] MG/L; [redacted]20[redacted] (RX DAY 480): Alkaline Phosphatase: 150 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 7.6 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 63 [0.1 - 5] MG/L; Neutrophils: 6.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 482): Albumin: 36 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Bilirubin: 9 [1 - 20] UMOL/L; Creatinine: 59 [50 - 98] UMOL/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.28 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 96 [120 - 155] G/L; Leukocytes: 8.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.5 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 70 [0.1 - 5] MG/L; Neutrophils: 7.2 [1.7 - 6.2] 10^9/L; Platelets: 196 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 474): BLOOD BLOOD CULTURE: NEGATIVE-BACTEC ANAEROBIC LYTIC BOTTLE NO GROWTH DETECTED AT 36 HRS BACTEC AEROBIC BOTTLE NO GROWTH DETECTED AT 36 HRS; [redacted]20[redacted] (RX DAY 477): OTHER SWAB CORONAVIRUS (COVID 19): POSITIVE-VARIANT RESULT NOT YET RECEIVED; [redacted]20[redacted] (RX DAY 478): CEREBROSPINAL FLUID STERILE FLUID/TISSUE MICROSCOPY: NEGATIVE-APPEARANCE: CLEAR CELL COUNT (X10^6/L): POLYMORPHS <1 LYMPHOCYTES 2 RED BLOOD CELLS 86 MONONUCLEAR CELLS <1 GRAM STAIN - NO ORGANISMS SEEN; [redacted]20[redacted] (RX DAY 479): BLOOD COVID-19 PATIENT ANTIBODY SCREE: POSITIVE->2080.0 BAU/ML RESULT INTERPRETATION <33.8 - NOT DETECTED >33.8 = DETECTED

AE Stopped Rx Day	472
Duration of AE	1 DAY
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 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	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Event #12: Serious Adverse Event, Event of Interest - Falls and Associated Injuries

Event Description	TRAUMATIC SUB-ARACHNOID HAEMORRHAGE
Preferred Term	外傷性頭蓋内出血
AE Onset Date / Rx Day	[redacted]20[redacted] / 473
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 473): Albumin: 31 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Eosinophils: 0.52 [0 - 0.4] 10^9/L; Erythrocytes: 3.4 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 100 [120 - 155] G/L; Magnesium: 0.69 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 51 [0.1 - 5] MG/L; NPTST050-SERUM FOLATE: 2.2 [3.1 - 20] UG/L; NPTST055-UREA: 2.4 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 474): Eosinophils: 0.46 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 6.5 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.8 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 40 [0.1 - 5] MG/L; NPTST055-UREA: 1.9 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 478): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; NPTST021-CSF GLUCOSE: 3.0 [NOT REPORTED - NOT REPORTED] mmol/L; NPTST022-CSF PROTEIN: 0.22 [0.15 - 0.45] G/L; [redacted]20[redacted] (RX DAY 479): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 153 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 104 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 66 [0.1 - 5] MG/L; [redacted]20[redacted] (RX DAY 480): Alkaline Phosphatase: 150 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 7.6 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L;

NPTST010-C-REACTIVE PROTEIN: 63 [0.1 - 5] MG/L; Neutrophils: 6.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 482): Albumin: 36 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Bilirubin: 9 [1 - 20] UMOL/L; Creatinine: 59 [50 - 98] UMOL/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.28 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 96 [120 - 155] G/L; Leukocytes: 8.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.5 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 70 [0.1 - 5] MG/L; Neutrophils: 7.2 [1.7 - 6.2] 10^9/L; Platelets: 196 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 474): BLOOD BLOOD CULTURE: NEGATIVE-BACTEC ANAEROBIC LYTIC BOTTLE NO GROWTH DETECTED AT 36 HRS BACTEC AEROBIC BOTTLE NO GROWTH DETECTED AT 36 HRS; [redacted]20[redacted] (RX DAY 477): OTHER SWAB CORONAVIRUS (COVID 19): POSITIVE-VARIANT RESULT NOT YET RECEIVED; [redacted]20[redacted] (RX DAY 478): CEREBROSPINAL FLUID STERILE FLUID/TISSUE MICROSCOPY: NEGATIVE-APPEARANCE: CLEAR CELL COUNT (X10^6/L): POLYMORPHS <1 LYMPHOCYTES 2 RED BLOOD CELLS 86 MONONUCLEAR CELLS <1 GRAM STAIN - NO ORGANISMS SEEN; [redacted]20[redacted] (RX DAY 479): BLOOD COVID-19 PATIENT ANTIBODY SCREE: POSITIVE->2080.0 BAU/ML RESULT INTERPRETATION <33.8 - NOT DETECTED >33.8 = DETECTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT 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	NOT REPORTED
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #13: Serious Adverse Event

Event Description	SEIZURE
Preferred Term	痙攣発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 474
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 473): Albumin: 31 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Eosinophils: 0.52 [0 - 0.4] 10^9/L; Erythrocytes: 3.4 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 100 [120 - 155] G/L; Magnesium: 0.69 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 51 [0.1 - 5] MG/L; NPTST050-SERUM FOLATE: 2.2 [3.1 - 20] UG/L; NPTST055-UREA: 2.4 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 474): Eosinophils: 0.46 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 6.5 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.8 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 40 [0.1 - 5] MG/L; NPTST055-UREA: 1.9 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 478): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102

[120 - 155] G/L; NPTST021-CSF GLUCOSE: 3.0 [NOT REPORTED - NOT REPORTED] mmol/L; NPTST022-CSF PROTEIN: 0.22 [0.15 - 0.45] G/L; [redacted]20[redacted] (RX DAY 479): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 153 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 104 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 66 [0.1 - 5] MG/L; [redacted]20[redacted] (RX DAY 480): Alkaline Phosphatase: 150 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 7.6 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 63 [0.1 - 5] MG/L; Neutrophils: 6.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 482): Albumin: 36 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Bilirubin: 9 [1 - 20] UMOL/L; Creatinine: 59 [50 - 98] UMOL/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.28 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 96 [120 - 155] G/L; Leukocytes: 8.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.5 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 70 [0.1 - 5] MG/L; Neutrophils: 7.2 [1.7 - 6.2] 10^9/L; Platelets: 196 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 474): BLOOD BLOOD CULTURE: NEGATIVE-BACTEC ANAEROBIC LYTIC BOTTLE NO GROWTH DETECTED AT 36 HRS BACTEC AEROBIC BOTTLE NO GROWTH DETECTED AT 36 HRS; [redacted]20[redacted] (RX DAY 477): OTHER SWAB CORONAVIRUS (COVID 19): POSITIVE-VARIANT RESULT NOT YET RECEIVED; [redacted]20[redacted] (RX DAY 478): CEREBROSPINAL FLUID STERILE FLUID/TISSUE MICROSCOPY: NEGATIVE-APPEARANCE: CLEAR CELL COUNT (X10^6/L): POLYMORPHS <1 LYMPHOCYTES 2 RED BLOOD CELLS 86 MONONUCLEAR CELLS <1 GRAM STAIN - NO ORGANISMS SEEN; [redacted]20[redacted] (RX DAY 479): BLOOD COVID-19 PATIENT ANTIBODY SCREE: POSITIVE->2080.0 BAU/ML RESULT INTERPRETATION <33.8 - NOT DETECTED >33.8 = DETECTED

AE Stopped Rx Day	474
Duration of AE	1 DAY
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 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	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #14: Serious Adverse Event

Event Description	DELIRIUM (FLUCTUATING SEVERITY)
Preferred Term	譫妄
AE Onset Date / Rx Day	[redacted]20[redacted] / 475
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 473): Albumin: 31 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Eosinophils: 0.52 [0 - 0.4] 10^9/L; Erythrocytes: 3.4 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 100

[120 - 155] G/L; Magnesium: 0.69 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 51 [0.1 - 5] MG/L; NPTST050-SERUM FOLATE: 2.2 [3.1 - 20] UG/L; NPTST055-UREA: 2.4 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 474): Eosinophils: 0.46 [0 - 0.4] 10^9/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 6.5 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.8 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 40 [0.1 - 5] MG/L; NPTST055-UREA: 1.9 [2.5 - 7.8] MMOL/L; [redacted]20[redacted] (RX DAY 478): Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; NPTST021-CSF GLUCOSE: 3.0 [NOT REPORTED - NOT REPORTED] mmol/L; NPTST022-CSF PROTEIN: 0.22 [0.15 - 0.45] G/L; [redacted]20[redacted] (RX DAY 479): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 153 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 104 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 66 [0.1 - 5] MG/L; [redacted]20[redacted] (RX DAY 480): Alkaline Phosphatase: 150 [30 - 130] U/L; Erythrocytes: 3.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.31 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 102 [120 - 155] G/L; Leukocytes: 7.6 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 63 [0.1 - 5] MG/L; Neutrophils: 6.3 [1.7 - 6.2] 10^9/L; [redacted]20[redacted] (RX DAY 482): Albumin: 36 [35 - 50] G/L; Alkaline Phosphatase: 154 [30 - 130] U/L; Bilirubin: 9 [1 - 20] UMOL/L; Creatinine: 59 [50 - 98] UMOL/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.28 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 96 [120 - 155] G/L; Leukocytes: 8.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.5 [1 - 3.4] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 70 [0.1 - 5] MG/L; Neutrophils: 7.2 [1.7 - 6.2] 10^9/L; Platelets: 196 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L

Microbiology

[redacted]20[redacted] (RX DAY 474): BLOOD BLOOD CULTURE: NEGATIVE-BACTEC ANAEROBIC LYTIC BOTTLE NO GROWTH DETECTED AT 36 HRS BACTEC AEROBIC BOTTLE NO GROWTH DETECTED AT 36 HRS; [redacted]20[redacted] (RX DAY 477): OTHER SWAB CORONAVIRUS (COVID 19): POSITIVE-VARIANT RESULT NOT YET RECEIVED; [redacted]20[redacted] (RX DAY 478): CEREBROSPINAL FLUID STERILE FLUID/TISSUE MICROSCOPY: NEGATIVE-APPEARANCE: CLEAR CELL COUNT (X10^6/L): POLYMORPHS <1 LYMPHOCYTES 2 RED BLOOD CELLS 86 MONONUCLEAR CELLS <1 GRAM STAIN - NO ORGANISMS SEEN; [redacted]20[redacted] (RX DAY 479): BLOOD COVID-19 PATIENT ANTIBODY SCREE: POSITIVE->2080.0 BAU/ML RESULT INTERPRETATION <33.8 - NOT DETECTED >33.8 = DETECTED

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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 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	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #15: Event of Interest - Infusion Site Related Non Infection Reactions

Event Description	BRUISE AT CANNULA SITE
Preferred Term	カテーテル留置部位内出血

AE Onset Date / Rx Day	[redacted]20[redacted] / 476
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	CAUSAL RELATIONSHIP
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #16: Serious Adverse Event

Event Description	ASYMPTOMATIC COVID-19
Preferred Term	無症候性 COVID-19
AE Onset Date / Rx Day	[redacted]20[redacted] / 477
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	493
Duration of AE	17 DAYS
Severity	MILD
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED

Other Cause of Event	SARS-COV-2 (OMICRON VARIANT)
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

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

Event Description	FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 481
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	481
Duration of AE	1 DAY
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 RELATED
SAE: Investigator Opinion of Relationship 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: Serious Adverse Event

Event Description	SEIZURE
Preferred Term	痙攣発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 482
Age at AE Onset	5[redacted]
Laboratory Testing	

[redacted]20[redacted] (RX DAY 484): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 156 [30 - 130] U/L; Bilirubin: 12 [1 - 20] UMOL/L; Creatinine: 60000 [50000 - 98000] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 82 [120 - 155] G/L; Leukocytes: 5.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.9 [1 - 3.4] 10^9/L; Monocytes: 0.25 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST009-C- REACTIVE PROTEIN: 117 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1079 [10 - 204] UG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT

REPORTED] ML/MIN/1.73*2; NPTST050-SERUM FOLATE: 2.4 [3.1 - 20] UG/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 401 [187 - 883] NG/L; Platelets: 161 [140 - 400] 10^9/L; Protein: 71 [60 - 80] G/L; Sodium: 142 [133 - 146] MMOL/L; [redacted] (RX DAY 485): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 142 [30 - 130] U/L; Bilirubin: 10 [1 - 20] UMOL/L; Creatinine: 53 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 81 [120 - 155] G/L; Leukocytes: 3.9 [3.6 - 9.2] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 94 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 33 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.24 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.5 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.2 [2.5 - 7.8] MMOL/L; Platelets: 193 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 66 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L; [redacted] (RX DAY 486): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 143 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 860 [1200 - 1550] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 76 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1065 [10 - 204] UG/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST038-IRON: 27 [9 - 30] UMOL/L; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST050-SERUM FOLATE: 1.5 [3.1 - 20] UG/L; NPTST052-TRANSFERRIN: 1.4 [1.8 - 3.82] G/L; NPTST053-TRANSFERRIN SATURATION: 76.47 [16 - 45] %; NPTST061-VITAMIN B12 (SERUM): 367 [187 - 883] NG/L; Platelets: 230 [140 - 400] 10^9/L; Potassium: 3.5 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 139 [133 - 146] MMOL/L; [redacted] (RX DAY 489): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 139 [30 - 130] U/L; Creatinine: 49 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 80 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; Magnesium: 0.77 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 54 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.17 [2.1 - 2.5] MMOL/L; NPTST028-ESOINOPHILS: 0.16 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.21 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.4 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; Platelets: 262 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Sodium: 142 [133 - 146] MMOL/L; [redacted] (RX DAY 490): Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 138 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 75 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 44 [0.1 - 5] MG/L; NPTST026-EOSINOPHILS: 0.22 [0 - 0.4] 10^9/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.26 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 1.9 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; Platelets: 276 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted] (RX DAY 491): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 133 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 73 [120 - 155] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 35 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 30 [18 - 36] G/L; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST045-NEUTROPHILS: 3.3 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.1 [2.5 - 7.8] MMOL/L; Platelets: 286 [140 - 400] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; Protein: 63 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted] (RX DAY 492): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 130 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Calcium: 2.21 [2.1 - 2.5] MMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 79 [120 - 155] G/L; Leukocytes: 3.1 [3.6 - 9.2] 10^9/L; Magnesium: 0.89 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 29 [0.1 - 5] MG/L; NPTST027-EOSIONPHILS: 0.12 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.22 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 8.6 [2.5 - 7.8] MMOL/L; Platelets: 132 [140 - 400] 10^9/L; Sodium: 149 [133 - 146] MMOL/L; [redacted] (RX DAY 493): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 141 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Chloride: 116 [95 - 108] MMOL/L; Creatinine: 54 [50 - 98]

UMOL/L; Eosinophils: 0.1 [0 - 0.4] 10^9/L; Erythrocytes: 2.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 3.7 [3.6 - 9.2] 10^9/L; Magnesium: 0.84 [0.7 - 1] MMOL/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 25 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.24 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.7 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.17 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.7 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1.1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 9.2 [2.5 - 7.8] MMOL/L; Platelets: 145 [140 - 400] 10^9/L; Potassium: 4.1 [3.5 - 5.3] MMOL/L; Protein: 70 [60 - 80] G/L; Sodium: 154 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 494): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 136 [30 - 130] U/L; Bilirubin: 7 [1 - 20] UMOL/L; Chloride: 114 [95 - 108] MMOL/L; Creatinine: 48 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 4.9 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; Magnesium: 0.81 [0.7 - 1] MMOL/L; Monocytes: 0.3 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 22 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; Neutrophils: 3.8 [1.7 - 6.2] 10^9/L; Platelets: 232 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 151 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 495): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 103 [30 - 130] U/L; Alkaline Phosphatase: 107 [30 - 130] U/L; Basophils: 0.01 [0 - 0.1] 10^9/L; Bilirubin: 10 [1 - 20] UMOL/L; Bilirubin: 7 [1 - 20] UMOL/L; Creatine Kinase: 30 [25 - 200] U/L; Creatinine: 40 [50 - 98] UMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Eosinophils: 0.47 [0 - 0.4] 10^9/L; Erythrocytes: 0 [0 - 0] 10^12/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.19 [0.37 - 0.46] FRACTION OF 1; Hematocrit: 0.27 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 64 [120 - 155] G/L; Hemoglobin: 91 [120 - 155] G/L; Leukocytes: 4.4 [3.6 - 9.2] 10^9/L; Leukocytes: 7.8 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.7 [1 - 3.4] 10^9/L; Magnesium: 0.75 [0.7 - 1] MMOL/L; Magnesium: 0.63 [0.7 - 1] MMOL/L; Monocytes: 0.47 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 18 [0.1 - 5] MG/L; NPTST010-C-REACTIVE PROTEIN: 21 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 1.94 [2.1 - 2.5] MMOL/L; NPTST012-CALCIUM (SERUM): 1.9 [2.1 - 2.5] MMOL/L; NPTST029-FERRITIN: 1100 [10 - 204] UG/L; NPTST030-GLOBULIN: 25 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1.1 [1 - 3.4] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST050-SERUM FOLATE: 3.8 [3.1 - 20] UG/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 407 [187 - 883] NG/L; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.4 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Platelets: 164 [140 - 400] 10^9/L; Platelets: 140 [140 - 400] 10^9/L; Potassium: 2.9 [3.5 - 5.3] MMOL/L; Potassium: 3 [3.5 - 5.3] MMOL/L; Protein: 51 [60 - 80] G/L; Protein: 51 [60 - 80] G/L; Sodium: 148 [133 - 146] MMOL/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 496): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 113 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Eosinophils: 0.74 [0 - 0.4] 10^9/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.26 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 89 [120 - 155] G/L; Leukocytes: 7.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.5 [1.3 - 4] 10^9/L; Magnesium: 0.86 [0.7 - 1] MMOL/L; Monocytes: 0.38 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 32 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.02 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 23 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 5.4 [2.5 - 7.8] MMOL/L; Neutrophils: 4.6 [1.7 - 6.2] 10^9/L; Platelets: 151 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 49 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 497): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 102 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Magnesium: 0.74 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 26 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2 [2.1 - 2.5] MMOL/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.9 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 4.1 [2.5 - 7.8] MMOL/L; Potassium: 4.2 [3.5 - 5.3] MMOL/L; Protein: 45 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 498): Albumin: 24 [35 - 50] G/L; Creatinine: 43 [50 - 98] UMOL/L; Erythrocytes: 2.9 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46]

FRACTION OF 1; Hemoglobin: 84 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 14 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.07 [2.1 - 2.5] MMOL/L; Platelets: 118 [140 - 400] 10^9/L; Protein: 51 [60 - 80] G/L

Microbiology

[redacted]20[redacted] (RX DAY 495): BLOOD BLOOD CULTURE (AER+ANAER): NEGATIVE-BACTEC AEROBIC BOTTLE- NO GROWTH DETECTED AT 36 HRS. BACTEC ANAEROBIC LYTIC BOTTLE- NO GROWTH DETECTED AT 36 HRS.; OTHER SWAB MRSA: NEGATIVE-TRIPLE SWAB FOR MRSA MRSA SCREEN: NEGATIVE.; URINE ROUTINE URINE SCREEN (CATHETER: POSITIVE-URINE MICRO EPITHELIAL CELLS- SPECIMEN TYPE: CATHETER SPECIMEN URINE. NOT SEEN OR SMALL NUMBERS. URINE MICRO WHITE CELLS +++ (IN LARGE NUMBERS).; URINE URINE CULTURE (CATHETER SPECIME: NEGATIVE-SPECIMEN TYPE: CATHETER SPECIMEN URINE. URINE CULTURE : NO SIGNIFICANT GROWTH.

AE Stopped Rx Day	482
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 RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	SURMISED CAUSED BY FALL, WHICH CAUSED THE SUB-ARACHNOID HAEMORRHAGE WHICH CAUSED THE SEIZURE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

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

Event Description	FALL
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 483
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	483
Duration of AE	1 DAY
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 RELATED
SAE: Investigator Opinion of Relationship 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: Serious Adverse Event

Event Description	SEIZURES
Preferred Term	痙攣発作
AE Onset Date / Rx Day	[redacted]20[redacted] / 485
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 484): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 156 [30 - 130] U/L; Bilirubin: 12 [1 - 20] UMOL/L; Creatinine: 60000 [50000 - 98000] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 82 [120 - 155] G/L; Leukocytes: 5.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.9 [1 - 3.4] 10^9/L; Monocytes: 0.25 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST009-C- REACTIVE PROTEIN: 117 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1079 [10 - 204] UG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73*2; NPTST050-SERUM FOLATE: 2.4 [3.1 - 20] UG/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 401 [187 - 883] NG/L; Platelets: 161 [140 - 400] 10^9/L; Protein: 71 [60 - 80] G/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 485): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 142 [30 - 130] U/L; Bilirubin: 10 [1 - 20] UMOL/L; Creatinine: 53 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 81 [120 - 155] G/L; Leukocytes: 3.9 [3.6 - 9.2] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 94 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 33 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.24 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.5 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.2 [2.5 - 7.8] MMOL/L; Platelets: 193 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 66 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 486): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 143 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 860 [1200 - 1550] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 76 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1065 [10 - 204] UG/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST038-IRON: 27 [9 - 30] UMOL/L; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST050-SERUM FOLATE: 1.5 [3.1 - 20] UG/L; NPTST052-TRANSFERRIN: 1.4 [1.8 - 3.82] G/L; NPTST053-TRANSFERRIN SATURATION: 76.47 [16 - 45] %; NPTST061-VITAMIN B12 (SERUM): 367 [187 - 883] NG/L; Platelets: 230 [140 - 400] 10^9/L; Potassium: 3.5 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 139 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 489): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 139 [30 - 130] U/L; Creatinine: 49 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 80 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; Magnesium: 0.77 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 54 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.17 [2.1 - 2.5] MMOL/L; NPTST028-ESOINOPHILS: 0.16 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.21 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.4 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST055-UREA:

6.7 [2.5 - 7.8] MMOL/L; Platelets: 262 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 490): Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 138 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 75 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 44 [0.1 - 5] MG/L; NPTST026-EOSINOPHILS: 0.22 [0 - 0.4] 10^9/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.26 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 1.9 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; Platelets: 276 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 491): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 133 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 73 [120 - 155] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 35 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 30 [18 - 36] G/L; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST045-NEUTROPHILS: 3.3 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.1 [2.5 - 7.8] MMOL/L; Platelets: 286 [140 - 400] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; Protein: 63 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 492): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 130 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Calcium: 2.21 [2.1 - 2.5] MMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 79 [120 - 155] G/L; Leukocytes: 3.1 [3.6 - 9.2] 10^9/L; Magnesium: 0.89 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 29 [0.1 - 5] MG/L; NPTST027-EOSIONPHILS: 0.12 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.22 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 8.6 [2.5 - 7.8] MMOL/L; Platelets: 132 [140 - 400] 10^9/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 493): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 141 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Chloride: 116 [95 - 108] MMOL/L; Creatinine: 54 [50 - 98] UMOL/L; Eosinophils: 0.1 [0 - 0.4] 10^9/L; Erythrocytes: 2.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 3.7 [3.6 - 9.2] 10^9/L; Magnesium: 0.84 [0.7 - 1] MMOL/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 25 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.24 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.7 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.17 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.7 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1.1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 9.2 [2.5 - 7.8] MMOL/L; Platelets: 145 [140 - 400] 10^9/L; Potassium: 4.1 [3.5 - 5.3] MMOL/L; Protein: 70 [60 - 80] G/L; Sodium: 154 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 494): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 136 [30 - 130] U/L; Bilirubin: 7 [1 - 20] UMOL/L; Chloride: 114 [95 - 108] MMOL/L; Creatinine: 48 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 4.9 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; Magnesium: 0.81 [0.7 - 1] MMOL/L; Monocytes: 0.3 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 22 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; Neutrophils: 3.8 [1.7 - 6.2] 10^9/L; Platelets: 232 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 151 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 495): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 103 [30 - 130] U/L; Alkaline Phosphatase: 107 [30 - 130] U/L; Basophils: 0.01 [0 - 0.1] 10^9/L; Bilirubin: 10 [1 - 20] UMOL/L; Bilirubin: 7 [1 - 20] UMOL/L; Creatine Kinase: 30 [25 - 200] U/L; Creatinine: 40 [50 - 98] UMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Eosinophils: 0.47 [0 - 0.4] 10^9/L; Erythrocytes: 0 [0 - 0] 10^12/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.19 [0.37 - 0.46] FRACTION OF 1; Hematocrit: 0.27 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 64 [120 - 155] G/L; Hemoglobin: 91 [120 - 155] G/L; Leukocytes: 4.4 [3.6 - 9.2] 10^9/L; Leukocytes: 7.8 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.7 [1 - 3.4] 10^9/L; Magnesium: 0.75 [0.7 - 1] MMOL/L; Magnesium: 0.63 [0.7 - 1] MMOL/L; Monocytes: 0.47 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 18 [0.1 - 5] MG/L; NPTST010-C-REACTIVE PROTEIN: 21 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 1.94 [2.1 - 2.5] MMOL/L; NPTST012-CALCIUM (SERUM): 1.9 [2.1 - 2.5] MMOL/L; NPTST029-FERRITIN: 1100 [10 - 204] UG/L; NPTST030-GLOBULIN: 25 [18 - 36]

G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1.1 [1 - 3.4] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST050-SERUM FOLATE: 3.8 [3.1 - 20] UG/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 407 [187 - 883] NG/L; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.4 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Platelets: 164 [140 - 400] 10^9/L; Platelets: 140 [140 - 400] 10^9/L; Potassium: 2.9 [3.5 - 5.3] MMOL/L; Potassium: 3 [3.5 - 5.3] MMOL/L; Protein: 51 [60 - 80] G/L; Protein: 51 [60 - 80] G/L; Sodium: 148 [133 - 146] MMOL/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 496): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 113 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Eosinophils: 0.74 [0 - 0.4] 10^9/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.26 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 89 [120 - 155] G/L; Leukocytes: 7.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.5 [1.3 - 4] 10^9/L; Magnesium: 0.86 [0.7 - 1] MMOL/L; Monocytes: 0.38 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 32 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.02 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 23 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 5.4 [2.5 - 7.8] MMOL/L; Neutrophils: 4.6 [1.7 - 6.2] 10^9/L; Platelets: 151 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 49 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 497): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 102 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Magnesium: 0.74 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 26 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2 [2.1 - 2.5] MMOL/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.9 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 4.1 [2.5 - 7.8] MMOL/L; Potassium: 4.2 [3.5 - 5.3] MMOL/L; Protein: 45 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 498): Albumin: 24 [35 - 50] G/L; Creatinine: 43 [50 - 98] UMOL/L; Erythrocytes: 2.9 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 84 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 14 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.07 [2.1 - 2.5] MMOL/L; Platelets: 118 [140 - 400] 10^9/L; Protein: 51 [60 - 80] G/L

Microbiology

[redacted]20[redacted] (RX DAY 495): BLOOD BLOOD CULTURE (AER+ANAER): NEGATIVE-BACTEC AEROBIC BOTTLE- NO GROWTH DETECTED AT 36 HRS. BACTEC ANAEROBIC LYTIC BOTTLE- NO GROWTH DETECTED AT 36 HRS.; OTHER SWAB MRSA: NEGATIVE-TRIPLE SWAB FOR MRSA MRSA SCREEN: NEGATIVE.; URINE ROUTINE URINE SCREEN (CATHETER: POSITIVE-URINE MICRO EPITHELIAL CELLS- SPECIMEN TYPE: CATHETER SPECIMEN URINE. NOT SEEN OR SMALL NUMBERS. URINE MICRO WHITE CELLS +++ (IN LARGE NUMBERS).; URINE URINE CULTURE (CATHETER SPECIME: NEGATIVE-SPECIMEN TYPE: CATHETER SPECIMEN URINE. URINE CULTURE : NO SIGNIFICANT GROWTH.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	SURMISED THIS ORIGINATED FROM FALL, WHICH LED TO SUB-ARACHNOID HAEMORRHAGE, WHICH LED TO

	SEIZURES
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #21: Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	BILATERAL HIP PAIN
Preferred Term	関節痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 487
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MILD
Relation to Study Drug by Investigator	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 APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

Event #22: Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	BILATERAL SHOULDER PAIN
Preferred Term	関節痛
AE Onset Date / Rx Day	[redacted]20[redacted] / 487
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED

Severity	MILD
Relation to Study Drug by Investigator	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 APPLICABLE
Other Cause of Event	NOT APPLICABLE
Discontinued Study Drug Due to the Event	NO
SAE Criteria	NONE

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

Event Description	FALLS
Preferred Term	転倒
AE Onset Date / Rx Day	[redacted]20[redacted] / 487
Age at AE Onset	5[redacted]
Laboratory Testing	
NOT APPLICABLE	
Microbiology	
NOT APPLICABLE	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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 RELATED
SAE: Investigator Opinion of Relationship 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: Serious Adverse Event, Event of Interest - Concurrent Events of Falls and Associated Injuries

Event Description	LOW HAEMOGLOBIN
Preferred Term	ヘモグロビン減少
AE Onset Date / Rx Day	[redacted]20[redacted] / 487

Age at AE Onset	5[redacted]
Laboratory Testing	
NOT REPORTED	
Microbiology	
NOT REPORTED	
AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to Infusion Pump	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT RELATED
SAE: Investigator Opinion of Relationship to [redacted] Infusion Set	NOT REPORTED
Other Cause of Event	WORSENING ANAEMIA. CAUSE UNCERTAIN.
Discontinued Study Drug Due to the Event	NO
SAE Criteria	IMPORTANT MEDICAL OR SURGICAL INTERVENTION

Event #25: Serious Adverse Event, Event of Interest - Weight Loss

Event Description	DIFFICULTY SWALLOWING
Preferred Term	嚥下障害
AE Onset Date / Rx Day	[redacted]20[redacted] / 493
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 484): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 156 [30 - 130] U/L; Bilirubin: 12 [1 - 20] UMOL/L; Creatinine: 60000 [50000 - 98000] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 82 [120 - 155] G/L; Leukocytes: 5.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.9 [1 - 3.4] 10^9/L; Monocytes: 0.25 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST009-C- REACTIVE PROTEIN: 117 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1079 [10 - 204] UG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73*2; NPTST050-SERUM FOLATE: 2.4 [3.1 - 20] UG/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 401 [187 - 883] NG/L; Platelets: 161 [140 - 400] 10^9/L; Protein: 71 [60 - 80] G/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 485): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 142 [30 - 130] U/L; Bilirubin: 10 [1 - 20] UMOL/L; Creatinine: 53 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 81 [120 - 155] G/L; Leukocytes: 3.9 [3.6 - 9.2] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 94 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 33 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.24 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.5 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.2 [2.5 - 7.8] MMOL/L; Platelets: 193 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 66 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 486): Albumin: 34 [35 - 50] G/L;

Alkaline Phosphatase: 143 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 860 [1200 - 1550] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 76 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1065 [10 - 204] UG/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST038-IRON: 27 [9 - 30] UMOL/L; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST050-SERUM FOLATE: 1.5 [3.1 - 20] UG/L; NPTST052-TRANSFERRIN: 1.4 [1.8 - 3.82] G/L; NPTST053-TRANSFERRIN SATURATION: 76.47 [16 - 45] %; NPTST061-VITAMIN B12 (SERUM): 367 [187 - 883] NG/L; Platelets: 230 [140 - 400] 10^9/L; Potassium: 3.5 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 139 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 489): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 139 [30 - 130] U/L; Creatinine: 49 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 80 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; Magnesium: 0.77 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 54 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.17 [2.1 - 2.5] MMOL/L; NPTST028-ESOINOPHILS: 0.16 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.21 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.4 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; Platelets: 262 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 490): Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 138 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 75 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 44 [0.1 - 5] MG/L; NPTST026-EOSINOPHILS: 0.22 [0 - 0.4] 10^9/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.26 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 1.9 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; Platelets: 276 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 491): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 133 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 73 [120 - 155] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 35 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 30 [18 - 36] G/L; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST045-NEUTROPHILS: 3.3 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.1 [2.5 - 7.8] MMOL/L; Platelets: 286 [140 - 400] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; Protein: 63 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 492): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 130 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Calcium: 2.21 [2.1 - 2.5] MMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 79 [120 - 155] G/L; Leukocytes: 3.1 [3.6 - 9.2] 10^9/L; Magnesium: 0.89 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 29 [0.1 - 5] MG/L; NPTST027-EOSIONPHILS: 0.12 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.22 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 8.6 [2.5 - 7.8] MMOL/L; Platelets: 132 [140 - 400] 10^9/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 493): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 141 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Chloride: 116 [95 - 108] MMOL/L; Creatinine: 54 [50 - 98] UMOL/L; Eosinophils: 0.1 [0 - 0.4] 10^9/L; Erythrocytes: 2.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 3.7 [3.6 - 9.2] 10^9/L; Magnesium: 0.84 [0.7 - 1] MMOL/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 25 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.24 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.7 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.17 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.7 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1.1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 9.2 [2.5 - 7.8] MMOL/L; Platelets: 145 [140 - 400] 10^9/L; Potassium: 4.1 [3.5 - 5.3] MMOL/L; Protein: 70 [60 - 80] G/L; Sodium: 154 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 494): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 136 [30 - 130] U/L; Bilirubin: 7 [1 - 20] UMOL/L; Chloride: 114 [95 - 108] MMOL/L; Creatinine: 48 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76

[120 - 155] G/L; Leukocytes: 4.9 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; Magnesium: 0.81 [0.7 - 1] MMOL/L; Monocytes: 0.3 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 22 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; Neutrophils: 3.8 [1.7 - 6.2] 10^9/L; Platelets: 232 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 151 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 495): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 103 [30 - 130] U/L; Alkaline Phosphatase: 107 [30 - 130] U/L; Basophils: 0.01 [0 - 0.1] 10^9/L; Bilirubin: 10 [1 - 20] UMOL/L; Bilirubin: 7 [1 - 20] UMOL/L; Creatine Kinase: 30 [25 - 200] U/L; Creatinine: 40 [50 - 98] UMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Eosinophils: 0.47 [0 - 0.4] 10^9/L; Erythrocytes: 0 [0 - 0] 10^12/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.19 [0.37 - 0.46] FRACTION OF 1; Hematocrit: 0.27 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 64 [120 - 155] G/L; Hemoglobin: 91 [120 - 155] G/L; Leukocytes: 4.4 [3.6 - 9.2] 10^9/L; Leukocytes: 7.8 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.7 [1 - 3.4] 10^9/L; Magnesium: 0.75 [0.7 - 1] MMOL/L; Magnesium: 0.63 [0.7 - 1] MMOL/L; Monocytes: 0.47 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 18 [0.1 - 5] MG/L; NPTST010-C-REACTIVE PROTEIN: 21 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 1.94 [2.1 - 2.5] MMOL/L; NPTST012-CALCIUM (SERUM): 1.9 [2.1 - 2.5] MMOL/L; NPTST029-FERRITIN: 1100 [10 - 204] UG/L; NPTST030-GLOBULIN: 25 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1.1 [1 - 3.4] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST050-SERUM FOLATE: 3.8 [3.1 - 20] UG/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 407 [187 - 883] NG/L; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.4 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Platelets: 164 [140 - 400] 10^9/L; Platelets: 140 [140 - 400] 10^9/L; Potassium: 2.9 [3.5 - 5.3] MMOL/L; Potassium: 3 [3.5 - 5.3] MMOL/L; Protein: 51 [60 - 80] G/L; Protein: 51 [60 - 80] G/L; Sodium: 148 [133 - 146] MMOL/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 496): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 113 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Eosinophils: 0.74 [0 - 0.4] 10^9/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.26 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 89 [120 - 155] G/L; Leukocytes: 7.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.5 [1.3 - 4] 10^9/L; Magnesium: 0.86 [0.7 - 1] MMOL/L; Monocytes: 0.38 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 32 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.02 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 23 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 5.4 [2.5 - 7.8] MMOL/L; Neutrophils: 4.6 [1.7 - 6.2] 10^9/L; Platelets: 151 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 49 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 497): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 102 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Magnesium: 0.74 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 26 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2 [2.1 - 2.5] MMOL/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.9 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 4.1 [2.5 - 7.8] MMOL/L; Potassium: 4.2 [3.5 - 5.3] MMOL/L; Protein: 45 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 498): Albumin: 24 [35 - 50] G/L; Creatinine: 43 [50 - 98] UMOL/L; Erythrocytes: 2.9 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 84 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 14 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.07 [2.1 - 2.5] MMOL/L; Platelets: 118 [140 - 400] 10^9/L; Protein: 51 [60 - 80] G/L

Microbiology

[redacted]20[redacted] (RX DAY 495): BLOOD BLOOD CULTURE (AER+ANAER): NEGATIVE-BACTEC AEROBIC BOTTLE- NO GROWTH DETECTED AT 36 HRS. BACTEC ANAEROBIC LYTIC BOTTLE- NO GROWTH DETECTED AT 36 HRS.; OTHER SWAB MRSA: NEGATIVE-TRIPLE SWAB FOR MRSA MRSA SCREEN: NEGATIVE.; URINE ROUTINE URINE SCREEN (CATHETER: POSITIVE-URINE MICRO EPITHELIAL CELLS- SPECIMEN TYPE: CATHETER SPECIMEN URINE. NOT SEEN OR SMALL NUMBERS. URINE MICRO WHITE CELLS +++ (IN LARGE NUMBERS).; URINE URINE CULTURE (CATHETER SPECIME: NEGATIVE-SPECIMEN TYPE: CATHETER SPECIMEN URINE. URINE CULTURE : NO SIGNIFICANT GROWTH.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	INVESTIGATIONS STILL ONGOING
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #26: Serious Adverse Event

Event Description	HYPERNATREMIA (151)
Preferred Term	高ナトリウム血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 494
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 484): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 156 [30 - 130] U/L; Bilirubin: 12 [1 - 20] UMOL/L; Creatinine: 60000 [50000 - 98000] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 82 [120 - 155] G/L; Leukocytes: 5.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.9 [1 - 3.4] 10^9/L; Monocytes: 0.25 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST009-C- REACTIVE PROTEIN: 117 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1079 [10 - 204] UG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73*2; NPTST050-SERUM FOLATE: 2.4 [3.1 - 20] UG/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 401 [187 - 883] NG/L; Platelets: 161 [140 - 400] 10^9/L; Protein: 71 [60 - 80] G/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 485): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 142 [30 - 130] U/L; Bilirubin: 10 [1 - 20] UMOL/L; Creatinine: 53 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 81 [120 - 155] G/L; Leukocytes: 3.9 [3.6 - 9.2] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 94 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 33 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.24 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.5 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.2 [2.5 - 7.8] MMOL/L; Platelets: 193 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 66 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 486): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 143 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 860 [1200 - 1550] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 76 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1065 [10 - 204] UG/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST038-IRON: 27 [9 - 30] UMOL/L; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST050-SERUM FOLATE: 1.5 [3.1 - 20] UG/L; NPTST052-TRANSFERRIN: 1.4 [1.8 - 3.82] G/L; NPTST053-TRANSFERRIN SATURATION: 76.47 [16 - 45] %; NPTST061-VITAMIN B12 (SERUM): 367 [187 - 883] NG/L; Platelets: 230 [140 - 400]

10^9/L; Potassium: 3.5 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 139 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 489): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 139 [30 - 130] U/L; Creatinine: 49 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 80 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; Magnesium: 0.77 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 54 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.17 [2.1 - 2.5] MMOL/L; NPTST028-ESOINOPHILS: 0.16 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.21 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.4 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; Platelets: 262 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 490): Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 138 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 75 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 44 [0.1 - 5] MG/L; NPTST026-EOSINOPHILS: 0.22 [0 - 0.4] 10^9/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.26 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 1.9 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; Platelets: 276 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 491): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 133 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 73 [120 - 155] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 35 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 30 [18 - 36] G/L; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST045-NEUTROPHILS: 3.3 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.1 [2.5 - 7.8] MMOL/L; Platelets: 286 [140 - 400] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; Protein: 63 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 492): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 130 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Calcium: 2.21 [2.1 - 2.5] MMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 79 [120 - 155] G/L; Leukocytes: 3.1 [3.6 - 9.2] 10^9/L; Magnesium: 0.89 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 29 [0.1 - 5] MG/L; NPTST027-EOSIONPHILS: 0.12 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.22 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 8.6 [2.5 - 7.8] MMOL/L; Platelets: 132 [140 - 400] 10^9/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 493): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 141 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Chloride: 116 [95 - 108] MMOL/L; Creatinine: 54 [50 - 98] UMOL/L; Eosinophils: 0.1 [0 - 0.4] 10^9/L; Erythrocytes: 2.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 3.7 [3.6 - 9.2] 10^9/L; Magnesium: 0.84 [0.7 - 1] MMOL/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 25 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.24 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.7 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.17 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.7 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1.1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 9.2 [2.5 - 7.8] MMOL/L; Platelets: 145 [140 - 400] 10^9/L; Potassium: 4.1 [3.5 - 5.3] MMOL/L; Protein: 70 [60 - 80] G/L; Sodium: 154 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 494): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 136 [30 - 130] U/L; Bilirubin: 7 [1 - 20] UMOL/L; Chloride: 114 [95 - 108] MMOL/L; Creatinine: 48 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 4.9 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; Magnesium: 0.81 [0.7 - 1] MMOL/L; Monocytes: 0.3 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 22 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; Neutrophils: 3.8 [1.7 - 6.2] 10^9/L; Platelets: 232 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 151 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 495): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 103 [30 - 130] U/L; Alkaline Phosphatase: 107 [30 - 130] U/L; Basophils: 0.01 [0 - 0.1] 10^9/L; Bilirubin: 10 [1 - 20] UMOL/L; Bilirubin: 7 [1 - 20] UMOL/L; Creatine Kinase: 30 [25 - 200] U/L;

Creatinine: 40 [50 - 98] UMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Eosinophils: 0.47 [0 - 0.4] 10^9/L; Erythrocytes: 0 [0 - 0] 10^12/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.19 [0.37 - 0.46] FRACTION OF 1; Hematocrit: 0.27 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 64 [120 - 155] G/L; Hemoglobin: 91 [120 - 155] G/L; Leukocytes: 4.4 [3.6 - 9.2] 10^9/L; Leukocytes: 7.8 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.7 [1 - 3.4] 10^9/L; Magnesium: 0.75 [0.7 - 1] MMOL/L; Magnesium: 0.63 [0.7 - 1] MMOL/L; Monocytes: 0.47 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 18 [0.1 - 5] MG/L; NPTST010-C-REACTIVE PROTEIN: 21 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 1.94 [2.1 - 2.5] MMOL/L; NPTST012-CALCIUM (SERUM): 1.9 [2.1 - 2.5] MMOL/L; NPTST029-FERRITIN: 1100 [10 - 204] UG/L; NPTST030-GLOBULIN: 25 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1.1 [1 - 3.4] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST050-SERUM FOLATE: 3.8 [3.1 - 20] UG/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 407 [187 - 883] NG/L; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.4 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Platelets: 164 [140 - 400] 10^9/L; Platelets: 140 [140 - 400] 10^9/L; Potassium: 2.9 [3.5 - 5.3] MMOL/L; Potassium: 3 [3.5 - 5.3] MMOL/L; Protein: 51 [60 - 80] G/L; Protein: 51 [60 - 80] G/L; Sodium: 148 [133 - 146] MMOL/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 496): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 113 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Eosinophils: 0.74 [0 - 0.4] 10^9/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.26 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 89 [120 - 155] G/L; Leukocytes: 7.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.5 [1.3 - 4] 10^9/L; Magnesium: 0.86 [0.7 - 1] MMOL/L; Monocytes: 0.38 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 32 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.02 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 23 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 5.4 [2.5 - 7.8] MMOL/L; Neutrophils: 4.6 [1.7 - 6.2] 10^9/L; Platelets: 151 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 49 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 497): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 102 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Magnesium: 0.74 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 26 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2 [2.1 - 2.5] MMOL/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.9 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 4.1 [2.5 - 7.8] MMOL/L; Potassium: 4.2 [3.5 - 5.3] MMOL/L; Protein: 45 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 498): Albumin: 24 [35 - 50] G/L; Creatinine: 43 [50 - 98] UMOL/L; Erythrocytes: 2.9 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 84 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 14 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.07 [2.1 - 2.5] MMOL/L; Platelets: 118 [140 - 400] 10^9/L; Protein: 51 [60 - 80] G/L

Microbiology

[redacted]20[redacted] (RX DAY 495): BLOOD BLOOD CULTURE (AER+ANAER): NEGATIVE-BACTEC AEROBIC BOTTLE- NO GROWTH DETECTED AT 36 HRS. BACTEC ANAEROBIC LYTIC BOTTLE- NO GROWTH DETECTED AT 36 HRS.; OTHER SWAB MRSA: NEGATIVE-TRIPLE SWAB FOR MRSA MRSA SCREEN: NEGATIVE.; URINE ROUTINE URINE SCREEN (CATHETER: POSITIVE-URINE MICRO EPITHELIAL CELLS- SPECIMEN TYPE: CATHETER SPECIMEN URINE. NOT SEEN OR SMALL NUMBERS. URINE MICRO WHITE CELLS +++ (IN LARGE NUMBERS).; URINE URINE CULTURE (CATHETER SPECIME: NEGATIVE-SPECIMEN TYPE: CATHETER SPECIMEN URINE. URINE CULTURE : NO SIGNIFICANT GROWTH.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
Severity	MODERATE
Relation to Study Drug by Investigator	NO REASONABLE POSSIBILITY
SAE: Investigator Opinion of Relationship to	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	LOW SODIUM LEVELS
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION

Event #27: Serious Adverse Event

Event Description	SEPSIS
Preferred Term	敗血症
AE Onset Date / Rx Day	[redacted]20[redacted] / 495
Age at AE Onset	5[redacted]

Laboratory Testing

[redacted]20[redacted] (RX DAY 484): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 156 [30 - 130] U/L; Bilirubin: 12 [1 - 20] UMOL/L; Creatinine: 60000 [50000 - 98000] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 82 [120 - 155] G/L; Leukocytes: 5.1 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.9 [1 - 3.4] 10^9/L; Monocytes: 0.25 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST009-C- REACTIVE PROTEIN: 117 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1079 [10 - 204] UG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73*2; NPTST050-SERUM FOLATE: 2.4 [3.1 - 20] UG/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 401 [187 - 883] NG/L; Platelets: 161 [140 - 400] 10^9/L; Protein: 71 [60 - 80] G/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 485): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 142 [30 - 130] U/L; Bilirubin: 10 [1 - 20] UMOL/L; Creatinine: 53 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 81 [120 - 155] G/L; Leukocytes: 3.9 [3.6 - 9.2] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 94 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 33 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.24 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.5 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.2 [2.5 - 7.8] MMOL/L; Platelets: 193 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 66 [60 - 80] G/L; Sodium: 137 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 486): Albumin: 34 [35 - 50] G/L; Alkaline Phosphatase: 143 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.25 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 860 [1200 - 1550] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 76 [0.1 - 5] MG/L; NPTST029-FERRITIN: 1065 [10 - 204] UG/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2; NPTST038-IRON: 27 [9 - 30] UMOL/L; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST050-SERUM FOLATE: 1.5 [3.1 - 20] UG/L; NPTST052-TRANSFERRIN: 1.4 [1.8 - 3.82] G/L; NPTST053-TRANSFERRIN SATURATION: 76.47 [16 - 45] %; NPTST061-VITAMIN B12 (SERUM): 367 [187 - 883] NG/L; Platelets: 230 [140 - 400] 10^9/L; Potassium: 3.5 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 139 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 489): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 139 [30 - 130] U/L; Creatinine: 49 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 80 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; Magnesium: 0.77 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 54 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.17 [2.1 - 2.5] MMOL/L; NPTST028-ESOINOPHILS: 0.16 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [90 - NOT REPORTED] ML/MIN/1.73M*2;

NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.21 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.4 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 6.7 [2.5 - 7.8] MMOL/L; Platelets: 262 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Sodium: 142 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 490): Albumin: 32 [35 - 50] G/L; Alkaline Phosphatase: 138 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 75 [120 - 155] G/L; Leukocytes: 3.4 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 44 [0.1 - 5] MG/L; NPTST026-EOSINOPHILS: 0.22 [0 - 0.4] 10^9/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.26 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 1.9 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; Platelets: 276 [140 - 400] 10^9/L; Potassium: 3.7 [3.5 - 5.3] MMOL/L; Protein: 67 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 491): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 133 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Creatinine: 52 [50 - 98] UMOL/L; Erythrocytes: 0 [0 - 0] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 73 [120 - 155] G/L; Leukocytes: 4.3 [3.6 - 9.2] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 35 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 30 [18 - 36] G/L; NPTST039-LYMPHOCYTES: 0.6 [1 - 3.4] 10^9/L; NPTST045-NEUTROPHILS: 3.3 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 6.1 [2.5 - 7.8] MMOL/L; Platelets: 286 [140 - 400] 10^9/L; Potassium: 3.4 [3.5 - 5.3] MMOL/L; Protein: 63 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 492): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 130 [30 - 130] U/L; Bilirubin: 5 [1 - 20] UMOL/L; Calcium: 2.21 [2.1 - 2.5] MMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Erythrocytes: 2.8 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 79 [120 - 155] G/L; Leukocytes: 3.1 [3.6 - 9.2] 10^9/L; Magnesium: 0.89 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 29 [0.1 - 5] MG/L; NPTST027-EOSIONPHILS: 0.12 [0 - 0.4] 10^9/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.8 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.22 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2 [1.7 - 6.2] 10^9/L; NPTST055-UREA: 8.6 [2.5 - 7.8] MMOL/L; Platelets: 132 [140 - 400] 10^9/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 493): Albumin: 35 [35 - 50] G/L; Alkaline Phosphatase: 141 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Chloride: 116 [95 - 108] MMOL/L; Creatinine: 54 [50 - 98] UMOL/L; Eosinophils: 0.1 [0 - 0.4] 10^9/L; Erythrocytes: 2.5 [3.9 - 5.1] 10^12/L; Hematocrit: 0.22 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 3.7 [3.6 - 9.2] 10^9/L; Magnesium: 0.84 [0.7 - 1] MMOL/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 25 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.24 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 35 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73M*2; NPTST039-LYMPHOCYTES: 0.7 [1 - 3.4] 10^9/L; NPTST042-MONOCYTES: 0.17 [0.2 - 0.8] 10^9/L; NPTST045-NEUTROPHILS: 2.7 [1.7 - 6.2] 10^9/L; NPTST047-PHOSPHATE: 1.1 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 9.2 [2.5 - 7.8] MMOL/L; Platelets: 145 [140 - 400] 10^9/L; Potassium: 4.1 [3.5 - 5.3] MMOL/L; Protein: 70 [60 - 80] G/L; Sodium: 154 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 494): Albumin: 33 [35 - 50] G/L; Alkaline Phosphatase: 136 [30 - 130] U/L; Bilirubin: 7 [1 - 20] UMOL/L; Chloride: 114 [95 - 108] MMOL/L; Creatinine: 48 [50 - 98] UMOL/L; Erythrocytes: 2.7 [3.9 - 5.1] 10^12/L; Hematocrit: 0.23 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 76 [120 - 155] G/L; Leukocytes: 4.9 [3.6 - 9.2] 10^9/L; Lymphocytes: 0.7 [1 - 3.4] 10^9/L; Magnesium: 0.81 [0.7 - 1] MMOL/L; Monocytes: 0.3 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 22 [0.1 - 5] MG/L; NPTST030-GLOBULIN: 36 [18 - 36] G/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; Neutrophils: 3.8 [1.7 - 6.2] 10^9/L; Platelets: 232 [140 - 400] 10^9/L; Potassium: 3.8 [3.5 - 5.3] MMOL/L; Protein: 69 [60 - 80] G/L; Sodium: 151 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 495): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 103 [30 - 130] U/L; Alkaline Phosphatase: 107 [30 - 130] U/L; Basophils: 0.01 [0 - 0.1] 10^9/L; Bilirubin: 10 [1 - 20] UMOL/L; Bilirubin: 7 [1 - 20] UMOL/L; Creatine Kinase: 30 [25 - 200] U/L; Creatinine: 40 [50 - 98] UMOL/L; Creatinine: 56 [50 - 98] UMOL/L; Eosinophils: 0.47 [0 - 0.4] 10^9/L; Erythrocytes: 0 [0 - 0] 10^12/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.19 [0.37 - 0.46] FRACTION OF 1; Hematocrit: 0.27 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 64 [120 - 155] G/L; Hemoglobin: 91 [120 - 155] G/L; Leukocytes: 4.4 [3.6 - 9.2] 10^9/L; Leukocytes: 7.8 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.7 [1 - 3.4] 10^9/L; Magnesium: 0.75 [0.7 - 1] MMOL/L; Magnesium: 0.63 [0.7 - 1] MMOL/L; Monocytes: 0.47 [0.2 - 0.8] 10^9/L; NPTST001-ALANINE TRANSAMINASE: 6 [1 - 55] IU/L; NPTST010-C-REACTIVE PROTEIN: 18 [0.1 - 5] MG/L; NPTST010-C-REACTIVE

PROTEIN: 21 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 1.94 [2.1 - 2.5] MMOL/L; NPTST012-CALCIUM (SERUM): 1.9 [2.1 - 2.5] MMOL/L; NPTST029-FERRITIN: 1100 [10 - 204] UG/L; NPTST030-GLOBULIN: 25 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST039-LYMPHOCYTES: 1.1 [1 - 3.4] 10^9/L; NPTST047-PHOSPHATE: 1 [0.8 - 1.5] MMOL/L; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST050-SERUM FOLATE: 3.8 [3.1 - 20] UG/L; NPTST055-UREA: 8.7 [2.5 - 7.8] MMOL/L; NPTST055-UREA: 6.6 [2.5 - 7.8] MMOL/L; NPTST061-VITAMIN B12 (SERUM): 407 [187 - 883] NG/L; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.4 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; NPTST062-WARFARIN ANTICOAGULATION CONTRO: 1.5 [NOT REPORTED - NOT REPORTED] UNIT NOT REPORTED; Platelets: 164 [140 - 400] 10^9/L; Platelets: 140 [140 - 400] 10^9/L; Potassium: 2.9 [3.5 - 5.3] MMOL/L; Potassium: 3 [3.5 - 5.3] MMOL/L; Protein: 51 [60 - 80] G/L; Protein: 51 [60 - 80] G/L; Sodium: 148 [133 - 146] MMOL/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 496): Albumin: 26 [35 - 50] G/L; Alkaline Phosphatase: 113 [30 - 130] U/L; Bilirubin: 8 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Eosinophils: 0.74 [0 - 0.4] 10^9/L; Erythrocytes: 3.1 [3.9 - 5.1] 10^12/L; Hematocrit: 0.26 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 89 [120 - 155] G/L; Leukocytes: 7.3 [3.6 - 9.2] 10^9/L; Lymphocytes: 1.5 [1.3 - 4] 10^9/L; Magnesium: 0.86 [0.7 - 1] MMOL/L; Monocytes: 0.38 [0.2 - 0.8] 10^9/L; NPTST010-C-REACTIVE PROTEIN: 32 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.02 [2.1 - 2.5] MMOL/L; NPTST030-GLOBULIN: 23 [18 - 36] G/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.8 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 5.4 [2.5 - 7.8] MMOL/L; Neutrophils: 4.6 [1.7 - 6.2] 10^9/L; Platelets: 151 [140 - 400] 10^9/L; Potassium: 3.6 [3.5 - 5.3] MMOL/L; Protein: 49 [60 - 80] G/L; Sodium: 149 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 497): Albumin: 23 [35 - 50] G/L; Alkaline Phosphatase: 102 [30 - 130] U/L; Bilirubin: 6 [1 - 20] UMOL/L; Creatinine: 42 [50 - 98] UMOL/L; Magnesium: 0.74 [0.7 - 1] MMOL/L; NPTST010-C-REACTIVE PROTEIN: 26 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2 [2.1 - 2.5] MMOL/L; NPTST031-GLOMERULAR FILTRATION RATE: >90 [NOT REPORTED - NOT REPORTED] ML/MIN/1.73*2; NPTST047-PHOSPHATE: 0.9 [0.8 - 1.5] MMOL/L; NPTST055-UREA: 4.1 [2.5 - 7.8] MMOL/L; Potassium: 4.2 [3.5 - 5.3] MMOL/L; Protein: 45 [60 - 80] G/L; Sodium: 145 [133 - 146] MMOL/L; [redacted]20[redacted] (RX DAY 498): Albumin: 24 [35 - 50] G/L; Creatinine: 43 [50 - 98] UMOL/L; Erythrocytes: 2.9 [3.9 - 5.1] 10^12/L; Hematocrit: 0.24 [0.37 - 0.46] FRACTION OF 1; Hemoglobin: 84 [120 - 155] G/L; NPTST010-C-REACTIVE PROTEIN: 14 [0.1 - 5] MG/L; NPTST012-CALCIUM (SERUM): 2.07 [2.1 - 2.5] MMOL/L; Platelets: 118 [140 - 400] 10^9/L; Protein: 51 [60 - 80] G/L

Microbiology

[redacted]20[redacted] (RX DAY 495): BLOOD BLOOD CULTURE (AER+ANAER): NEGATIVE-BACTEC AEROBIC BOTTLE- NO GROWTH DETECTED AT 36 HRS. BACTEC ANAEROBIC LYTIC BOTTLE- NO GROWTH DETECTED AT 36 HRS.; OTHER SWAB MRSA: NEGATIVE-TRIPLE SWAB FOR MRSA MRSA SCREEN: NEGATIVE.; URINE ROUTINE URINE SCREEN (CATHETER: POSITIVE-URINE MICRO EPITHELIAL CELLS- SPECIMEN TYPE: CATHETER SPECIMEN URINE. NOT SEEN OR SMALL NUMBERS. URINE MICRO WHITE CELLS +++ (IN LARGE NUMBERS).; URINE URINE CULTURE (CATHETER SPECIME: NEGATIVE-SPECIMEN TYPE: CATHETER SPECIMEN URINE. URINE CULTURE : NO SIGNIFICANT GROWTH.

AE Stopped Rx Day	NOT REPORTED
Duration of AE	NOT REPORTED
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	BACTERIAL INFECTION
Discontinued Study Drug Due to the Event	NO
SAE Criteria	HOSPITALIZATION OR PROLONGED HOSPITALIZATION, LIFE THREATENING

Generated: [redacted]20[redacted]:09:11

Program Source Code: [redacted]

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に尿路感染及び尿路性敗血症を発現した。

Event 3 及び 4 の臨床経過：

関連する病歴は，元喫煙者（1 日 5 本を 5 年間），過敏性腸症候群，閉経症状，パーキンソン病，膣脱，月経過多，尿路感染，及び飲酒者（1 日 2 杯未満）であった。

投与 418 日目被験者は尿路感染を発現した。投与 422 日目，被験者は尿路性敗血症を発現した。投与 430 日目，尿路性敗血症は消失した。

投与 422 日目，被験者は全身の倦怠感，疲労の増加，及び錯乱が 4 日間続いたため入院した。また，被験者は尿失禁が 2 週間続き，恥骨上部の不快感を伴って頻尿及び排尿障害が数日間続いていると訴えた。

被験者に膀胱のスキャンを実施し，カテーテルを留置した。被験者に静脈内輸液及び抗生物質を投与したところ，治療から 24 時間で血圧などの症状及びグラスゴー昏睡尺度は改善した。投与 430 日目，被験者は抗生物質の経口投与を継続し，退院した。

治験責任医師によると，被験者には膣脱，尿閉，及び慢性便秘の病歴があり，これらは上記の有害事象に関連するリスク因子であった。

被験者に 0.3%塩化カリウム / 0.9%塩化ナトリウム，エノキサパリンナトリウム，アモキシシリン / クラブラン酸，0.9%塩化ナトリウム，HARTMANN'S SOLUTION，及びゲンタマイシンが投与された。

The patient's past medications include:

PFIZER BIONTECH COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) UTI (10046848) (Urinary tract infection (10046571)) [v.24.1] [10046848]

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

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

Dechallenge: Not Applicable

2) Urosepsis (10048709) (Urosepsis (10048709)) [v.24.1] [10048709]

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 UTI

- Investigator: Currently unknown bacteria

- **AbbVie:** More likely related to risk factors of reported urinary retention and chronic constipation and history of Parkinson's disease and vaginal prolapse in this 5[redacted] year old subject.

Event of UROSEPSIS

- Investigator: Unknown bacteria

- **AbbVie:** More likely related to risk factors of reported urinary retention and chronic constipation and history of Parkinson's disease and vaginal prolapse in this 5[redacted] year old subject.

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ACTIVATED PARTIAL THROMBOPLASTIN TIME:** 34.1 SEC (normal 25.5 to 34)

[redacted] **20[redacted] ALBUMIN:** 32 G/L (normal 35 to 50)

[redacted] **20[redacted] BLADDER SCAN:** 670ML RESIDUAL

[redacted] **20[redacted] BLOOD CULTURE:** Anaerobes and Aerobes-Negative

[redacted] **20[redacted] BLOOD PRESSURE:** 88/48 MMHG

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 160 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 305 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 119 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] CALCIUM:** 2.07 MMOL/L (normal 2.1 to 2.5)

[redacted] **20[redacted] CALCIUM:** 2.05 MMOL/L (normal 2.1 to 2.5)

[redacted] **20[redacted] CHEST X-RAY:** NO LOBAR COLLAPSE OR FOCAL CONSOLIDATION

[redacted] **20[redacted] CREATININE:** 47 umol/L (normal 50 to 98)

[redacted] **20[redacted] CT HEAD:** THE VENTRICULAR SYSTEM IS NORMAL IN SIZE AND POSITION. THE BASAL AND CORTICAL SUBARACHNOID CISTERNS OUTLINE NORMALLY. THERE IS MILD DIFFUSE CEREBRAL ATROPHY. NO ABNORMAL AREAS OF PARENCHYMAL ATTENUATION SEEN. NO EXTRA-AXIAL COLLECTIONS IDENTIFIED. NO EVIDENCE OF RECENT INTRACRANIAL BLEEDING

[redacted] **20[redacted] GCS (GLASGOW COMA SCALE) SCORE:** 12 No Units

[redacted] **20[redacted] GCS (GLASGOW COMA SCALE) SCORE:** 15 No units

[redacted] **20[redacted] HEART RATE:** 107 /min

[redacted] **20[redacted] HEMATOCRIT:** 0.361 L/L (normal 0.37 to 0.46)

[redacted] **20[redacted] HEMOGLOBIN:** 115 G/L (normal 120 to 155)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.6 X10**9/L (normal 1 to 3.4)

[redacted] **20[redacted] MONOCYTES ABS:** 1.05 X10**9/L (normal 0.2 to 0.8)

[redacted] **20[redacted] MONOCYTES ABS:** 1.00 X10**9/L (normal 0.2 to 0.8)

[redacted] **20[redacted] NEUTROPHIL ABS:** 7.8 X10**9/L (normal 1.7 to 6.2)

[redacted] **20[redacted] NEUTROPHILS ABS:** 9.2 X10**9/L (normal 1.7 to 6.2)

[redacted] **20[redacted] NEUTROPHILS ABS:** 10.6 X10**9/L (normal 1.7 to 6.2)

[redacted] **20[redacted] PHOSPHATE:** 0.6 MMOL/L (normal 0.8 to 1.5)

[redacted] **20[redacted] PHOSPHATE:** 0.5 MMOL/L (normal 0.8 to 1.5)

[redacted] **20[redacted] PLATELET COUNT:** 137 X10**9/L (normal 140 to 400)

[redacted] **20[redacted] POTASSIUM:** 3.4 MMOL/L (normal 3.5 to 5.3)

[redacted] **20[redacted] POTASSIUM:** 2.8 MMOL/L (normal 3.4 to 4.5)

[redacted] **20[redacted] PROTHROMBIN TIME:** 16.3 SEC (normal 12.5 to 15.5)

[redacted] **20[redacted] RED BLOOD CELL:** 3.7 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] RED BLOOD COUNT:** 3.6 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] RESPIRATORY RATE:** 17 /min

[redacted] **20[redacted] SATS ON 3L OXYGEN:** 100%

[redacted] **20[redacted] TEMPERATURE:** 40.2 Degrees C

[redacted] **20[redacted] TOTAL PROTEIN:** 52 G/L (normal 60 to 80)

[redacted] **20[redacted] URINE CULTURE:** Negative

[redacted] **20[redacted] URINE MICRO EPITHELIAL CELLS:** Positive: Moderate/Large number (++/+++)

[redacted] **20[redacted] URINE MICRO WHITE CELLS:** Positive:+++ (in large numbers)

[redacted] **20[redacted] URINE URINE MICRO WHITE CELLS:** Positive: ++ (in moderate numbers)

[redacted] **20[redacted] US URINARY TRACT:** The kidneys are normal in size (right 10.8cm, left 11.5cm) with good parenchymal thickness and there is no hydronephrosis. A 14mm diameter septated cyst in the interpolar region of the right kidney is unchanged, no other renal mass identified. The urinary bladder is catheterized and was empty at the time of the examination, small echogenic nodules within the bladder lumen are likely to represent gas and may be secondary to catheterization.

[redacted] **20[redacted] WHITE BLOOD CELL:** 10.7 X10**9/L (normal 3.6 to 9.2)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 13.1 X10**9/L (normal 3.6 to 9.2)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 10.2 X10**9/L (normal 3.6 to 9.2)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に尿路性敗血症及び急性腎障害を発現した。

Event 7 及び 8 の臨床経過：

関連する病歴は，元喫煙者（1 日 5 本を 5 年間），カンジダ外陰膣炎，帯状疱疹，過敏性腸症候群，パーキンソン病，閉経症状，膣脱，月経過多，尿路感染，及び飲酒者（1 日 2 杯未満）であった。

投与 444 日目，被験者は尿路性敗血症を発現した。投与 445 日目，被験者は急性腎障害を発現した。投与 455 日目，尿路性敗血症及び急性腎障害は消失した。

投与 445 日目，被験者は尿失禁及び腸失禁，錯乱，運動機能の低下，発熱，及び浮動性めまいを発現した。被験者は手すりを使っても歩行できなかった。同日，被験者は自宅から救急車で搬送され入院した。入院時の血液検査では炎症性マーカーの上昇及び急性腎障害が認められた。被験者に抗生物質及び輸液が投与され，臨床状態は改善した。被験者にカテーテルが留置された（日時不明）。投与 448 日目，膣脱は減退し，ペッサリーが挿入された。投与 455 日目，被験者は退院した。

治験責任医師によると，被験者には関連するリスク因子として顕著な膣脱があった。

被験者にアモキシシリン / クラブラン酸，オンダンセトロン，オキシコドン，ピペラシリン / タゾバクタム，0.15%塩化カリウム / 0.9%塩化ナトリウム，塩化ナトリウム，SANDO-K，及び HARTMANN'S SOLUTION が投与された。

The patient's past medications include:

PFIZER COVID-19 VACCINATION for PROPHYLAXIS (Started [redacted] 20[redacted], Started [redacted] 20[redacted], Started [redacted] 20[redacted])

CO-AMOXICLAV for DIAGNOSIS OF UTI FOR THIS TIME PERIOD, UTI and SEPTIC UTI ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Urosepsis (10048709) (Urosepsis (10048709)) [v.24.1] [10048709]

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

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

Dechallenge: Not Applicable

2) Acute kidney injury (10069339) (Acute kidney injury (10069339)) [v.24.1] [10069339]

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 UROSEPSIS

- Investigator: Vaginal prolapse

- AbbVie: More likely related to history of vaginal prolapse and Parkinson's disease

Event of ACUTE KIDNEY INJURY

- Investigator: Urosepsis secondary to vaginal prolapse

- AbbVie: More likely related to reported urosepsis and history of Parkinson's disease

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALBUMIN:** 25 G/L (normal 35 to 50)

[redacted] **20[redacted] ALBUMIN:** 23 G/L (normal 35 to 50)

[redacted] **20[redacted] ALBUMIN:** 28 G/L (normal 35 to 50)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 232 IU/L (normal 30 to 130)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 243 MCMOL/L (normal 30 to 130)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 206 MCMOL/L (normal 30 to 130)

[redacted] **20[redacted] BLOOD PRESSURE:** 75/55 mmhg

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 596 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 191 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 79 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] CALCIUM:** 1.86 MMOL/L (normal 2.1 to 2.5)

[redacted] **20[redacted] CALCIUM:** 1.90 MMOL/L (normal 2.1 to 2.5)

[redacted] **20[redacted] CALCIUM:** 2.04 MMOL/L (normal 2.1 to 2.5)

[redacted] **20[redacted] CHEST XRAY:** THERE IS A FAINT PATCHY OPACIFICATION IN THE LEFT LOWER ZONE, SOME OF WHICH ARE PROJECTED BEHIND THE HEART - THESE NAY BE INFECTIVE IN NATURE.

[redacted] **20[redacted] COVID-19 TEST:** Negative

[redacted] **20[redacted] CREATININE:** 401 MCMOL/L (normal 50 to 98)

[redacted] **20[redacted] CREATININE:** 104 MCMOL/L (normal 50 to 98)

[redacted] **20[redacted] CT HEAD:** NO EVIDENCE OF INTRACRANIAL HAEMORRHAGE OR SPACE OCCUPYING LESION. SMALL PARTIALLY CALCIFIED SOFT TISSUE LESION OVERLYING THE RIGHT PARIETAL BONE IN KEEPING WITH TRICHILEMMAL CYST. NO ACUTE INTRACRANIAL PATHOLOGY.

[redacted] **20[redacted] CT URINARY TRACT:** THERE IS BILATERAL HYDRONEPHROSIS AND HYDROURETER DOWN TO THE BLADDER BUT NO EVIDENCE OF CALCIFIED RENAL OR URETERIC STONE. THE DISTAL URETERS HAVE DESCENDED THROUGH THE PELVIC FLOOR TO FOLLOW THE INCOMPLETELY IMAGED VAGINAL PROLAPSE.

[redacted] **20[redacted] ERYTHROCYTE:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] ERYTHROCYTE:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] ERYTHROCYTE:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] GFR:** 10

[redacted] **20**[redacted] **GFR:** 86 ML/MIN/1.73M*2 (normal >90)

[redacted] **20**[redacted] **GLOMERULAR FILTRATION RATE:** 10 ML/MIN/1.73M*2 (normal 10 to 90)

[redacted] **20**[redacted] **GLOMERULAR FILTRATION RATE:** 53 ML/MIN/1.73M*2 (normal 10 to 90)

[redacted] **20**[redacted] **HEART RATE:** 107 /min

[redacted] **20**[redacted] **HEMATOCRIT:** 0.329 L/L (normal 0.37 to 0.46)

[redacted] **20**[redacted] **HEMATOCRIT:** 0.335 L/L (normal 0.37 to 0.46)

[redacted] **20**[redacted] **HEMATOCRIT:** 0.322 L/L (normal 0.37 to 0.46)

[redacted] **20**[redacted] **HEMOGLOBIN:** 107 G/L (normal 120 to 155)

[redacted] **20**[redacted] **HEMOGLOBIN:** 106 G/L (normal 120 to 155)

[redacted] **20**[redacted] **LEUKOCYTE:** 16.1 X10**9/L (normal 3.6 to 9.2)

[redacted] **20**[redacted] **LEUKOCYTE:** 12.9 X10**9/L (normal 3.6 to 9.2)

[redacted] **20**[redacted] **LEUKOCYTE:** 9.7 X10**9/L (normal 3.6 to 9.2)

[redacted] **20**[redacted] **MAGNESIUM:** 0.65 MMOL/L (normal 0.7 to 1)

[redacted] **20**[redacted] **MONOCYTES ABS:** 0.81 X10**9/L (normal 0.2 to 0.8)

[redacted] **20**[redacted] **MRSA SREEN:** Negative

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 14.1 X10**9/L (normal 1.7 to 6.2)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 10.2 X10**9/L (normal 1.7 to 6.2)

[redacted] **20**[redacted] **NEUTROPHILS ABS:** 7.9 X10**9/L (normal 1.7 to 6.2)

[redacted] **20**[redacted] **PHOSPHATE:** 2.0 MMOL/L (normal 0.8 to 1.5)

[redacted] **20**[redacted] **PHOSPHATE:** 0.7 MMOL/L (normal 0.8 to 1.5)

[redacted] **20**[redacted] **POTASSIUM:** 3.3 MMOL/L (normal 3.5 to 5.3)

[redacted] **20**[redacted] **PROTEIN:** 58 G/L (normal 60 to 80)

[redacted] **20**[redacted] **PROTEIN:** 52 G/L (normal 60 to 80)

[redacted] **20**[redacted] **RED BLOOD CELLS:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] 20[redacted] **RED BLOOD CELLS:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] 20[redacted] **SODIUM:** 132 MMOL/L (normal 133 to 146)

[redacted] 20[redacted] **TOTAL PROTEIN:** 58 G/L (normal 60 to 80)

[redacted] 20[redacted] **TOTAL PROTEIN:** 52 G/L (normal 60 to 80)

[redacted] 20[redacted] **UREA:** 24.2 MMOL/L (normal 2.5 to 7.8)

[redacted] 20[redacted] **UREA:** 14.7 MMOL/L (normal 2.5 to 7.8)

[redacted] 20[redacted] **UREA:** 9.4 MMOL/L (normal 2.5 to 7.8)

[redacted] 20[redacted] **URINE CULTURE:** No bacterial growth

[redacted] 20[redacted] **US URINARY TRACT:** BILATERAL HYDRONEPHROSIS AND HYDROURETER, NOT PRESENT ONTHE PREVIOUS SCAN IN [redacted] 20[redacted]. CAUSE NOT ESTABLISHED ON THIS EXAMINATION. IN THE CONTEXT OF SEPSIS, TURBIDITY OF FLUID WITHIN THE LEFT COLLECTING SYSTEM RAISES THE POSSIBILITY OF AN INFECTED HYDRONEPHROSIS.

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 16.1 X10**9/L (normal 3.6 to 9.2)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 12.9 X10**9/L (normal 3.6 to 9.2)

[redacted] 20[redacted] **WHITE BLOOD CELLS:** 9.7 X10**9/L (normal 3.6 to 9.2)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に膣脱の更なる悪化を発現した。

Event 9 の臨床経過：

関連する病歴は，元喫煙者（1 日 5 本を 5 年間），カンジダ外陰膣炎，帯状疱疹，過敏性腸症候群，閉経症状，パーキンソン病，膣脱，月経過多，尿路感染，及び飲酒者（1 日 2 杯未満）であった。

投与 462 日目，被験者は膣脱の更なる悪化を発現した。

本事象の発現前，被験者は投与の約 2 ヵ月後に非重篤な膣脱の悪化を発現した。

投与 462 日目，被験者は膣脱が更に悪化し入院した。投与 465 日目，被験者に腹腔鏡下仙骨子宮摘出術及び右卵管切除術を実施し，成功した。

The patient's past medications include:

PFIZER BIONTECH COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Vaginal prolapse (10046940) (Vaginal prolapse (10046940)) [v.24.1] [10046940]

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 FURTHER WORSENING VAGINAL PROLAPSE

- Investigator: Weakened muscle floor

- AbbVie: More likely related to reported weakened muscle floor and history of vaginal prolapse and menopausal symptoms.

Relevant Laboratory & OtherDiagnostic Tests

[redacted] **20[redacted] ACTIVATED PARTIAL THROMBOPLASTIN TIME:** 34.2 SEC (normal 25.5 to 34)

[redacted] **20[redacted] ALBUMIN:** 32 G/L (normal 35 to 50)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 159 IU/L (normal 30 to 130)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 21 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] HEMATOCRIT:** 0.318 L/L (normal 0.37 to 0.46)

[redacted] **20[redacted] HEMOGLOBIN:** 105 G/L (normal 120 to 155)

[redacted] **20[redacted] NEUTROPHILS ABS:** 1.6 X10**9/L (normal 1.7 to 6.2)

[redacted] **20[redacted] RED BLOOD CELLS:** 3.5 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] UREA:** 2.1 MMOL/L (normal 2.5 to 7.8)

[redacted] **20[redacted] US PELVIS TRANSVAGINAL:** Enlarged postmenopausal uterus, cervical length 51 mm, approx. 34mm posterior wall fibroid just above the cervix.

[redacted] **20[redacted] WHITE BLOOD CELLS:** 3.3 X10**9/L (normal 3.6 to 9.2)

Investigator No.: [redacted]

Subject Number: [redacted]

Protocol Number: M15-737

治験責任医師からの報告。本被験者は英国の 5[redacted] 歳女性であり，アッヴィ社の ABBV-951（Foscarbidopa/Foslevodopa）の治験で ABBV-951 を投与中に敗血症，外傷性くも膜下出血，譫妄（重症度の変更），痙攣発作（投与 474 日目，投与 472 日目，投与 469 日目，投与 482 日目），ヘモグロビン低値，嚥下困難，高ナトリウム血症，及び無症候性 COVID-19 を発現した。

Event 10，11，12，13，14，16，18，20，24，25，26，及び 27 の臨床経過：

関連する病歴は，元喫煙者（1 日 5 本を 5 年間），回転性めまい，パーキンソン病，度重なる転倒，尿路感染，及び現飲酒者（1 日 2 杯未満）であった。

投与 469 日目，被験者は痙攣発作を発現した。投与 469 日目，痙攣発作は消失した。投与 472 日目，被験者は痙攣発作を発現した。投与 472 日目，痙攣発作は消失した。投与 473 日目，被験者は外傷性くも膜下出血を発現した。投与 474 日目，被験者は痙攣発作を発現した。投与 474 日目，痙攣発作は消失した。投与 475 日目，被験者は譫妄（重症度の変更）を発現した。投与 477 日目，被験者は無症候性 COVID-19 を発現した。投与 482 日目，被験者は痙攣発作を発現した。投与 482 日目痙攣発作は消失した。投与 485 日目，被験者は痙攣発作を発現した。投与 487 日目，被験者はヘモグロビン低値を発現した。投与 493 日目，被験者は嚥下困難を発現した。投与 493 日目，無症候性 COVID-19 は消失した。投与 494 日目，被験者は高ナトリウム血症を発現した。投与 495 日目，被験者は敗血症を発現した。

治験責任医師によると，投与の約 14 ヵ月後から被験者は食欲が減退し，時に吐き戻しを伴う嚥下困難が増加した。投与の約 15 ヵ月後，被験者は非重篤な低カリウム血症及び低マグネシウム血症を発現した。

本事象の発現前，投与 465 日目に被験者に膣脱に対する処置として腹腔鏡下手術を実施した（AER#[redacted]）。

投与 469 日目，被験者は発作後錯乱を伴う全身性強直性間代性発作を発現したが，回復した。被験者は緊急治療室に来院し，ラモトリギン投与が開始され，外来での頭部画像検査が予定された。

投与 470 日目，被験者は非重篤な尿路感染を発現した。

投与 472 日目，被験者は持続する発作後錯乱を伴う別の痙攣発作のため入院した。投与 473 日目，MRI 検査により左前頭部のくも膜下出血が認められた。治験責任医師によると，被験者はこの数週間転倒する頻度が増加していた。投与 474 日目，被験者は 3 回目の痙攣発作を発現した。投与 475 日目，被験者は譫妄を発現した。

投与 477 日目，被験者は COVID-19 検査陽性となった。治験責任医師によると，被験者は COVID-19 検査陽性となった後に，錯乱の重症度が増加していることが分かった。また，被験者は変動する錯乱を伴った幻覚を発現した。

被験者にクロバザム，ロラゼパム，バルプロ酸ナトリウム，レベチラセタム，ラモトリギン，ゲンタマイシン，及びピペラシリン / タゾバクタムが投与された。

The patient's past medications include:

PFIZER BIONTECH COVID-19 VACCINE for PROPHYLAXIS ([redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted], [redacted] 20[redacted] - [redacted] 20[redacted])

Causality for ABBV-951 (Open Label)

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1) Sepsis (10040047) (Sepsis (10040047)) [v.24.1] [10040047]

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

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

Dechallenge: Not Applicable

2) Cerebral hemorrhage traumatic (10055236) (Traumatic intracranial haemorrhage (10061387)) [v.24.1] [10055236]

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

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

Dechallenge: Not Applicable

3) Delirium (10012218) (Delirium (10012218)) [v.24.1] [10012218]

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

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

Dechallenge: Not Applicable

4) Seizure (10039906) (Seizure (10039906)) [v.24.1] [10039906]

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

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

Dechallenge: Not Applicable

5) Seizure (10039906) (Seizure (10039906)) [v.24.1] [10039906]

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

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

Dechallenge: Not Applicable

6) Seizure (10039906) (Seizure (10039906)) [v.24.1] [10039906]

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

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

Dechallenge: Not Applicable

7) Seizure (10039906) (Seizure (10039906)) [v.24.1] [10039906]

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

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

Dechallenge: Not Applicable

8) Seizures (10039910) (Seizure (10039906)) [v.24.1] [10039910]

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

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

Dechallenge: Not Applicable

9) Hemoglobin low (10055600) (Haemoglobin decreased (10018884)) [v.24.1] [10055600]

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

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

Dechallenge: Not Applicable

10) Swallowing difficult (10042645) (Dysphagia (10013950)) [v.24.1] [10042645]

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

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

Dechallenge: Not Applicable

11) Hypernatremia (10020680) (Hypernatraemia (10020679)) [v.24.1] [10020680]

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

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

Dechallenge: Not Applicable

12) Asymptomatic COVID-19 (10084459) (Asymptomatic COVID-19 (10084459)) [v.24.1] [10084459]

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

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

Dechallenge: Not Applicable

Alternative Etiology for ABBV-951 (Open Label)

Event of SEPSIS

- Investigator: Bacterial infection

- AbbVie: This event is more likely related to reported bacterial infection in this 5[redacted] year old with Parkinson's disease with recent hospitalization and frequent urinary tract infections.

Event of TRAUMATIC SUB-ARACHNOID HAEMORRHAGE

- Investigator: Not applicable

- AbbVie: This event is more likely related to reported traumatic nature of the event in this 5[redacted] year old with history of Parkinson's and frequent falls and recent use of Clexane.

Event of DELIRIUM (FLUCTUATING SEVERITY)

- Investigator: Not applicable

- AbbVie: This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, seizures, UTI and hypomagnesaemia in this 5[redacted] year old with Parkinson's disease and frequent falls and recent laparoscopic surgery.

Event of SEIZURE

- Investigator: Not applicable

- AbbVie: This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, recent hypomagnesaemia and laparoscopic procedure in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections.

Event of SEIZURE

- **Investigator:** Not applicable

- **AbbVie:** This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, recent hypomagnesaemia and laparoscopic procedure in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections.

Event of SEIZURE

- **Investigator:** Not applicable

- **AbbVie:** This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, recent hypomagnesaemia and laparoscopic procedure in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections.

Event of SEIZURE

- **Investigator:** Surmised caused by fall, which caused the sub-arachnoid hemorrhage which caused the seizure.

- **AbbVie:** This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, recent hypomagnesaemia in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections.

Event of SEIZURES

- **Investigator:** Surmised this originated from fall, which led to sub-arachnoid hemorrhage, which led to seizures

- **AbbVie:** This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage, recent hypomagnesaemia in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections.

Event of LOW HAEMOGLOBIN

- **Investigator:** Worsening anemia, cause uncertain

- **AbbVie:** This event is more likely related to reported worsening anemia within the clinical course of a traumatic subarachnoid hemorrhage, and swallowing difficulty in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections

Event of DIFFICULTY SWALLOWING

- Investigator: Not reported

- AbbVie: This event is more likely within the clinical course of a traumatic subarachnoid hemorrhage and seizures in this 5[redacted] year old with Parkinson's disease and frequent falls.

Event of HYPERNATREMIA

- Investigator: Low sodium levels

- AbbVie: This event is more likely reported swallowing difficulty within the clinical course of a traumatic subarachnoid hemorrhage, seizures and sepsis in this 5[redacted] year old with Parkinson's disease and frequent falls and frequent urinary tract infections

Event of ASYMPTOMATIC COVID-19

- Investigator: SARS-COV-2 (OMICRON VARIANT)

- AbbVie: Event is more likely related to a pandemic outbreak

Relevant Laboratory & Other Diagnostic Tests

[redacted] **20[redacted] ALBUMIN:** 31 G/L (normal 31 to 50)

[redacted] **20[redacted] ALBUMIN:** 34 G/L (normal 31 to 50)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 154 IU/L (normal 30 to 130)

[redacted] **20[redacted] ALKALINE PHOSPHATASE:** 154 IU/L (normal 30 to 130)

[redacted] **20[redacted] BLOOD CULTURE:** Negative. Bactec anaerobic lytic bottle: no growth detected at 36 hrs. Bactec aerobic bottle: no growth detected at 36 hrs.

[redacted] **20[redacted] BLOOD CULTURE:** Aerobic and Anaerobic - Negative - No growth detected at 36 hrs

[redacted] **20[redacted] BODY WEIGHT:** 8[redacted] KG

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 51 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 40 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 63 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] C-REACTIVE PROTEIN:** 70 MG/L (normal 0.1 to 5)

[redacted] **20[redacted] CEREBROSPINAL FLUID ANALYSIS:** Appearance: clear cell count (x10^6/l): polymorphs <1 lymphocytes 2 red blood cells 86 mononuclear cells <1 gram stain - no organisms seen

[redacted] **20[redacted] CHEST X-RAY:** Portable ap erect with rotation and suboptimal inspiration. Grossly unchanged cardiomediastinal contours and pleural recesses. No confluent consolidation or collapse, the previously demonstrated left lower zone patchy opacification appears to have improved.

[redacted] **20[redacted] CHEST X-RAY:** NGT inserted for feeding today, no aspirate - CXR for NGT position XR For NGT position : NG tube is correctly sited. However the NG tube may be advanced as the tip is only marginally past the GOJ

[redacted] **20[redacted] CHEST X-RAY:** Rotated AP semierect. The NG tube has been removed. No focal consolidation or lobar collapse

[redacted] **20[redacted] COVID-19 PATIENT ANTIBODY SCREEN:** >2080.0 BAU/ML. RESULT INTERPRETATION: Result <33.8 = NOT DETECTED. Result >33.8 = DETECTED

[redacted] **20[redacted] COVID-19 PCR TEST:** Positive. Variant result not yet received.

[redacted] **20[redacted] CSF GLUCOSE:** 3.0 No units

[redacted] **20[redacted] CSF PROTEIN:** 0.22 G/L (normal 0.15 to 0.45)

[redacted] **20[redacted] CT ABDOMEN AND PELVIS WITH CONTRAST:** Low attenuation lesion laterally in the liver. This has a slightly heterogenous appearance and is of uncertain significance, possibly representing some focal fat or a small contusion. Even if contusion this is unlikely to be responsible for the haemoglobin drop. Clarification with ultrasound ultrasound may be appropriate. No convincing cause for haemorrhage leading to hypotension demonstrated

[redacted] **20[redacted] CT HEAD:** No change in the left frontal acute subarachnoid hemorrhage.

[redacted] **20[redacted] CT HEAD:** There is a persisting small focus of acute subarachnoid haemorrhage in the left frontal lobe (axial image 52/128). There is no evidence of extension of the haemorrhage, substantial mass-effect or surrounding oedema, no new intracranial haemorrhagic focus is identified. The ventricular system and sulci are commensurate with age. No focal parenchymal abnormality in the cerebrum, cerebellum or brainstem. Normal appearances of the skull base and calvarium. There is mucosal thickening in the ethmoidal air cells and right maxillary antrum. Stable intracranial appearances.

[redacted] **20[redacted] CT HEAD:** Comparison made with previous CT imaging. Normal ventricular system and CSF spaces. No CT signs of raised intracranial pressure. Previously reported subarachnoid bleed is poorly demonstrated on the current scan and there is no evidence of new subarachnoid haemorrhage. No evidence

of ischaemia, infarction, space-occupying lesion or surface haematoma. Posterior fossa structures are within normal limits. Summary: No new bleed. Consider MRI as appropriate

[redacted] **20[redacted] CT HEAD:** The subtle left frontal subarachnoid haemorrhage in the CT dated [redacted] is hardly seen on the present study. No new haemorrhages. Probable mild small vessel ischaemic changes and mild generalised cerebral atrophy. No calvarial fractures identified. Conclusion/recommendations: No new intracranial haemorrhage identified. If there is is significant clinical concern consider MRI.

[redacted] **20[redacted] CT HEAD AND CEREBRAL ANGIOGRAM:** There is no vascular malformation such as an aneurysm or AVM.

[redacted] **20[redacted] EOSINOPHILS ABS:** 0.52 L (normal 0 to 0.4)

[redacted] **20[redacted] EOSINOPHILS ABS:** 0.46 L (normal 0 to 0.4)

[redacted] **20[redacted] HEMATOCRIT:** 0.306% (normal 0.37 to 0.46)

[redacted] **20[redacted] HEMATOCRIT:** 0.312% (normal 0.37 to 0.46)

[redacted] **20[redacted] HEMATOCRIT:** 0.28% (normal 0.37 to 0.46)

[redacted] **20[redacted] HEMOGLOBIN:** 100 G/L (normal 120 to 155)

[redacted] **20[redacted] HEMOGLOBIN:** 102 G/L (normal 120 to 155)

[redacted] **20[redacted] HEMOGLOBIN:** 104 G/L (normal 120 to 155)

[redacted] **20[redacted] HEMOGLOBIN:** 96 G/L (normal 120 to 155)

[redacted] **20[redacted] LYMPHOCYTES ABS:** 0.8 L (normal 1 to 3.4)

[redacted] **20[redacted] MAGNESIUM:** 0.65 MMOL/L (normal 0.7 to 1)

[redacted] **20[redacted] MAGNESIUM:** 0.69 MMOL/L (normal 0.7 to 1)

[redacted] **20[redacted] MRI HEAD:** Left frontal subarachnoid hemorrhage. No associated edema or mass-effect. No features to suggest an underlying mass or vascular abnormality.

[redacted] **20[redacted] MRI HEAD:** No intracranial mass, extra-axial collection or hydrocephalus. No focal cerebral parenchymal abnormality. Slight prominence of the cerebellar sulcal spaces in keeping with a degree of atrophy. No evidence of previous intracranial haemorrhage or territorial infarct. No diffusion-weighted abnormality. No cortical malformation, heterotopia or cortical dysplasia. No significant hippocampal abnormality. No pathological brain parenchymal or meningeal enhancement. Mucosal congestion within the paranasal sinuses. Comment: No substrate for seizures is identified.

[redacted] **20[redacted] MRSA SWAB:** Negative

[redacted] **20[redacted] RED BLOOD CELLS:** 3.4 X10**12/L (normal 3.9 to 5.1)

[redacted] **20[redacted] RED BLOOD CELLS:** 3.5 L (normal 3.9 to 5.1)

[redacted] **20[redacted] SERUM:** 31 G/L (normal 35 to 50)

[redacted] **20[redacted] SERUM FOLATE:** 2.2 MCG/L (normal 3.1 to 20)

[redacted] **20[redacted] SODIUM:** 132 MMOL/L (normal 133 to 146)

[redacted] **20[redacted] UREA:** 2.4 MMOL/L (normal 2.5 to 7.8)

[redacted] **20[redacted] UREA:** 1.9 MMOL/L (normal 2.5 to 7.8)

[redacted] **20[redacted] URINE CULTURE:** Catheter specimen - Negative - no significant growth

[redacted] **20[redacted] URINE SCREEN:** Catheter specimen - Positive - Urine Micro Epithelial Cells- Specimen type: Catheter Specimen Urine. Not seen or small numbers. Urine Micro White Cells +++ (in large numbers)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 6.5 X10**9/L (normal 3.6 to 9.2)

[redacted] **20[redacted] WHITE BLOOD CELLS:** 8.3 X10**9/L (normal 3.6 to 9.2)

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

Subject experienced temporal events of reduced appetite, difficulty swallowing, and regurgitation. Etiolology not determined.