APPENDIX 1 PERI-INFUSIONAL AEに含めたMEDDRA PT（1702 試験）

急性呼吸不全
アレルギー性咳嗽
アレルギー性浮腫
アレルギー性呼吸器症状
アナフィラキシー反応
アナフィラキシーショック
アナフィラキシー様反応
アナフィラキシー様ショック
血管浮腫
無呼吸
血圧低下
拡張期血圧低下
血圧測定不能
収縮期血圧低下
徐脈
気管支浮腫
気管支痙攣
心停止
急性心不全
心肺停止
心肺機能窮迫
心血管不全
胸部不快感
悪寒
息詰まり感
循環虚脱
口周囲浮腫
咳嗽
拡張期低血圧
浮動性めまい
薬物過敏症
呼吸困難
紅斑
眼球浮腫
眼部腫脹
眼瞼浮腫
顔面浮腫
初回透析症候群
固定疹
潮紅
全身紅斑
頭痛
心拍数増加
嗄声

ほてり
多汗症
異常高熱
過敏症
過換気
低血圧
低酸素症
インフルエンザ様疾患
注入に伴う反応
コーニス症候群
喉頭障害による呼吸困難
咽頭浮腫
咽頭痙攣
咽頭気管浮腫
口唇浮腫
口唇腫脹
心筋梗塞
悪心
浮腫
口腔浮腫
口腔咽頭痙攣
口腔咽頭腫脹
酸素飽和度低下
動悸
眼窩周囲浮腫
咽頭浮腫
そう痒症
アレルギー性そう痒症
全身性そう痒症
発熱
発疹
紅斑性皮疹
全身性皮疹
斑状皮疹
斑状丘疹状皮疹
斑水疱性皮疹
そう痒性皮疹
膿疱性皮疹
呼吸停止
呼吸窮迫
呼吸不全
呼吸数増加
可逆性気道閉塞
異物感
ショック
洞性頻脈
皮膚反応

皮膚腫脹
くしゃみ
上気道性喘鳴
腫脹
顔面腫脹
舌腫脹
失神
頻脈
頻呼吸
咽喉刺激感
咽喉絞扼感
舌浮腫
気管閉塞
気管浮腫
１型過敏症
２型過敏症
４型過敏症
上気道閉塞
蕁麻疹
丘疹状蕁麻疹
血管炎性皮疹
血管炎
嘔吐
喘鳴

APPENDIX 2 PERI-INFUSIONAL AEに含めたMEDDRA PT（1703 試験）

1 急性呼吸不全
2 アレルギー性咳嗽
3 アレルギー性浮腫
4 アレルギー性呼吸器症状
5 アナフィラキシー反応
6 アナフィラキシーショック
7 アナフィラキシー様反応
8 アナフィラキシー様ショック
9 血管浮腫
10 無呼吸
11 血圧低下
12 拡張期血圧低下
13 血圧測定不能
14 収縮期血圧低下
15 徐脈
16 気管支浮腫
17 気管支痙攣
18 心停止
19 急性心不全
20 心肺停止
21 心肺機能窮迫
22 心血管不全
23 胸部不快感
24 悪寒
25 息詰まり感
26 循環虚脱
27 口周囲浮腫
28 咳嗽
29 拡張期低血圧
30 浮動性めまい
31 薬物過敏症
32 呼吸困難
33 紅斑
34 眼球浮腫
35 眼部腫脹
36 眼瞼浮腫
37 顔面浮腫
38 初回透析症候群
39 固定疹
40 潮紅
41 全身紅斑
42 頭痛
43 心拍数増加
44 嗄声
45 ほてり

多汗症
異常高熱
過敏症
過換気
低血圧
低酸素症
インフルエンザ様疾患
注入に伴う反応
コーニス症候群
喉頭障害による呼吸困難
喉頭浮腫
喉頭痙攣
喉頭気管浮腫
口唇浮腫
口唇腫脹
心筋梗塞
悪心
浮腫
口腔浮腫
口腔咽頭痙攣
口腔咽頭腫脹
酸素飽和度低下
動悸
眼窩周囲浮腫
咽頭浮腫
そう痒症
アレルギー性そう痒症
全身性そう痒症
発熱
発疹
紅斑性皮疹
全身性皮疹
斑状皮疹
斑状丘疹状皮疹
斑水疱性皮疹
そう痒性皮疹
膿疱性皮疹
呼吸停止
呼吸窮迫
呼吸不全
呼吸数増加
可逆性気道閉塞
異物感
ショック
洞性頻脈
皮膚反応
皮膚腫脹

93 くしゃみ
94 上気道性喘鳴
95 腫脹
96 顔面腫脹
97 舌腫脹
98 失神
99 頻脈
100 頻呼吸
101 咽喉刺激感
102 咽喉絞扼感
103 舌浮腫
104 気管閉塞
105 気管浮腫
106 １型過敏症
107 ２型過敏症
108 ４型過敏症
109 上気道閉塞
110 蕁麻疹
111 丘疹状蕁麻疹
112 血管炎性皮疹
113 血管炎
114 嘔吐
115 喘鳴

APPENDIX 3　　日和見感染に含めた基本語（004 試験及び 009 試験）

- ニューモシスチス・イロベチイ肺炎
- 真菌性肺炎
- 帯状疱疹
- 口腔ヘルペス
- ヘルペスウイルス感染
- 陰部ヘルペス
- 単純ヘルペス
- 眼部単純ヘルペス
- 眼帯状疱疹
- アスペルギルス感染
- 気管支肺アスペルギルス症
- 脳アスペルギルス症
- サイトメガロウイルス感染
- 口腔カンジダ症
- カンジダ感染
- 食道カンジダ症
- 消化器カンジダ症
- 真菌感染
- 皮膚真菌感染
- 口腔真菌感染
- 真菌性耳感染
- 真菌性尿路感染

APPENDIX 4　　治験薬別の投与期間（004 試験及び統合E-LD群、治験薬投与例）

	CA204-004				
	E-Ld N = 318			Ld N = 317	
	Elotuzumab	Lenalidomide	Dexamethasone	Lenalidomide	Dexamethasone
ALL TREATED SUBJECTS					
DURATION OF TREATMENT (MONTHS)					
N	318	317	318	316	317
MEAN	17.05	17.06	17.21	13.82	13.59
MEDIAN	17.03	17.02	17.02	12.45	11.99
MIN , MAX	<0.1 , 37.7	0.2 , 37.5	<0.1 , 37.7	0.2 , 35.6	<0.1 , 35.9
Q1 , Q3	7.39 , 25.33	7.82 , 24.67	7.82 , 25.33	5.29 , 22.77	5.29 , 22.31
STANDARD DEVIATION	10.030	9.825	9.970	9.350	9.287
SUBJECTS STILL ON-TREATMENT					
DURATION OF TREATMENT (MONTHS)					
N	113	113	113	66	66
MEAN	27.36	27.04	27.49	26.77	26.49
MEDIAN	26.25	26.48	26.51	25.53	25.53
MIN , MAX	15.6 , 37.7	2.6 , 37.5	15.6 , 37.7	22.8 , 35.6	18.2 , 35.9
Q1 , Q3	23.95 , 30.39	24.15 , 30.13	23.98 , 30.42	23.69 , 29.24	23.72 , 29.24
STANDARD DEVIATION	4.056	4.425	3.968	3.536	3.663

Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ex-drug-dot.sas　　13FEB2015:01:15:54

Protocol: Elotuzumab - SCS

Duration of Treatment by Drug Summary
All Treated Subjects

	Pooled E-Ld		
	E-Ld N = 451		
	Elotuzumab	Lenalidomide	Dexamethasone
ALL TREATED SUBJECTS			
DURATION OF TREATMENT (MONTHS)			
N	451	449	451
MEAN	17.28	17.28	17.24
MEDIAN	15.67	16.10	15.70
MIN , MAX	<0.1 , 58.9	0.2 , 58.6	<0.1 , 57.5
Q1 , Q3	6.47 , 25.79	6.87 , 25.53	6.93 , 25.56
STANDARD DEVIATION	11.962	11.776	11.666
SUBJECTS STILL ON-TREATMENT			
DURATION OF TREATMENT (MONTHS)			
N	144	144	144
MEAN	28.99	28.50	28.83
MEDIAN	27.22	26.51	27.20
MIN , MAX	8.1 , 58.9	2.6 , 58.6	8.1 , 57.5
Q1 , Q3	23.95 , 31.75	23.69 , 31.10	23.95 , 31.54
STANDARD DEVIATION	8.278	8.500	7.993

Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ex-drug-dot.sas 13FEB2015:01:15:54

APPENDIX 5　　本薬を投与延期した被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE DELAY	186 (58.5)
NUMBER OF DELAYED ADMINISTRATIONS	
1	83 (26.1)
2	38 (11.9)
3	31 (9.7)
>=4	34 (10.7)
REASON FOR DELAY	
HEMATOLOGIC TOXICITY	2 (0.6)
NON-HEMATOLOGIC TOXICITY	3 (0.9)
ADVERSE EVENT	52 (16.4)
DOSING ERROR	3 (0.9)
OTHER	156 (49.1)
UNKNOWN	18 (5.7)

Reason UNKNOWN is reported when there is a derived delay and no reason is being reported on the CRF.
Subjects may have more than one reason for delay.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-doir.sas　　10MAR2015:14:28:59

APPENDIX 6　　本薬の投与延期期間（004 試験、治験薬投与例）

	E-Ld N = 12851
NUMBER OF ADMINISTRATIONS DELAYED (1)	409 (3.2)
DURATION OF DELAY (DAYS) (2)	
2-3	186 (45.5)
4-7	223 (54.5)

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of delayed administrations.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-dur.sas　　10MAR2015:14:30:12

APPENDIX 7　　本薬を投与スキップした被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE OMISSION	176 (55.3)
NUMBER OF OMITTED ADMINISTRATIONS	
1	87 (27.4)
2	48 (15.1)
3	21 (6.6)
>=4	20 (6.3)
REASON FOR OMISSION	
HEMATOLOGIC TOXICITY	4 (1.3)
NON-HEMATOLOGIC TOXICITY	8 (2.5)
ADVERSE EVENT	132 (41.5)
DOSING ERROR	5 (1.6)
OTHER	59 (18.6)
UNKNOWN	9 (2.8)

Reason UNKNOWN is reported when there is a derived omission and no reason is being reported on the CRF.
Subjects may have more than one reason for omission.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-doir.sas　　10MAR2015:14:29:14

APPENDIX 8　　本薬の投与スキップ期間（004 試験、治験薬投与例）

	E-Ld N = 12851
NUMBER OF ADMINISTRATIONS OMITTED (1)	358 (2.8)
DURATION OF OMISSION (DAYS) (2)	
11-14	40 (11.2)
15-21	21 (5.9)
22-27	40 (11.2)
>=28	257 (71.8)

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of omissions.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-dur.sas　　10MAR2015:14:30:30

APPENDIX 9　　本薬の投与中の中断時間（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF ADMINISTRATIONS WITH INTERRUPTION	59
DURATION OF INTERRUPTIONS (MIN)	
N	47
MEAN	31.7
MEDIAN	15.0
MIN , MAX	1 , 162
Q1 , Q3	5.0 , 45.0
STANDARD DEVIATION	39.96

Duration of interruption was reported only when IV was resumed after interruption.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-dur-interr.sas　　10MAR2015:14:31:04

APPENDIX 10　　本薬の投与速度を下げた被験者の割合及び理由

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE IV RATE REDUCED	13 (4.1)
NUMBER OF TIMES IV RATE REDUCED	
1	11 (3.5)
2	2 (0.6)
3	0
>=4	0
REASON FOR REDUCTION OF IV RATE	
INFUSION REACTION	6 (1.9)
INFUSION ADMINISTRATION ISSUES	0
OTHER	8 (2.5)

Subjects may have more than one reason for IV rate reduction.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-elo-doir.sas　　10MAR2015:14:29:43

APPENDIX 11　　レナリドミドを減量した被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318	Ld N = 317
NUMBER OF SUBJECTS STARTING AT STANDARD DOSE LEVEL 25 MG	264	266
NUMBER OF SUBJECTS WITH AT LEAST ONE REDUCTION	117 (44.3)	103 (38.7)
LOWEST DOSE LEVEL REACHED		
15 MG	50 (18.9)	46 (17.3)
10 MG	50 (18.9)	42 (15.8)
15 MG (48 HRS)	0	0
5 MG	17 (6.4)	15 (5.6)
NUMBER OF SUBJECTS STARTING AT < 25 MG DOSE LEVEL	53	50
NUMBER OF SUBJECTS WITH AT LEAST ONE REDUCTION	20 (37.7)	19 (38.0)
LOWEST DOSE LEVEL REACHED		
10 MG	10 (18.9)	6 (12.0)
15 MG (48 HRS)	0	1 (2.0)
5 MG	10 (18.9)	12 (24.0)
REASON FOR REDUCTION		
HEMATOLOGIC TOXICITY	26 (8.2)	30 (9.5)
NON-HEMATOLOGIC TOXICITY	18 (5.7)	13 (4.1)
ADVERSE EVENT	93 (29.2)	76 (24.0)
DOSING ERROR	2 (0.6)	0
OTHER	19 (6.0)	16 (5.0)
UNKNOWN	5 (1.6)	2 (0.6)

Starting dose level for subjects with moderate renal impairment is reduced (per protocol 10 MG).
Reason UNKNOWN is reported when there is a derived reduction and no reason is being reported on the CRF.
Subjects may have more than one reason for reduction.
For reductions percentages are computed separately for the group of subjects treated at 25 mg or at < 25 mg. For the reduction reason percentages are out of all treated subjects.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-len-red.sas　　10MAR2015:14:32:15

APPENDIX 12　　レナリドミドを投与スキップした被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318	Ld N = 317
NUMBER OF SUBJECTS WITH AT LEAST ONE INTERRUPTION	220 (69.2)	200 (63.1)
NUMBER OF INTERRUPTIONS		
1	77 (24.2)	63 (19.9)
2	41 (12.9)	47 (14.8)
3	37 (11.6)	34 (10.7)
>=4	65 (20.4)	56 (17.7)
REASON FOR INTERRUPTION		
HEMATOLOGIC TOXICITY	34 (10.7)	41 (12.9)
NON-HEMATOLOGIC TOXICITY	14 (4.4)	15 (4.7)
ADVERSE EVENT	167 (52.5)	161 (50.8)
DOSING ERROR	38 (11.9)	28 (8.8)
OTHER	74 (23.3)	46 (14.5)
UNKNOWN	6 (1.9)	5 (1.6)

Reason UNKNOWN is reported when there is a derived interruption and no reason is being reported on the CRF.
Subjects may have more than one reason for interruption.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-len-inter.sas　　10MAR2015:14:32:28

APPENDIX 13　　デキサメタゾン（静脈内投与）を投与延期した被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE DELAY	208 (65.4)
NUMBER OF DELAYED ADMINISTRATIONS	
1	83 (26.1)
2	42 (13.2)
3	33 (10.4)
>=4	50 (15.7)
REASON FOR DELAY	
HEMATOLOGIC TOXICITY	5 (1.6)
NON-HEMATOLOGIC TOXICITY	5 (1.6)
ADVERSE EVENT	83 (26.1)
DOSING ERROR	6 (1.9)
OTHER	165 (51.9)

Subjects may have more than one reason for delay.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-dex-dor.sas　　10MAR2015:14:32:45

APPENDIX 14　　デキサメタゾン（静脈内投与）を投与スキップした被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE OMISSION	181 (56.9)
NUMBER OF OMITTED ADMINISTRATIONS	
1	71 (22.3)
2	40 (12.6)
3	24 (7.5)
>=4	46 (14.5)
REASON FOR OMISSION	
HEMATOLOGIC TOXICITY	4 (1.3)
NON-HEMATOLOGIC TOXICITY	14 (4.4)
ADVERSE EVENT	138 (43.4)
DOSING ERROR	11 (3.5)
OTHER	61 (19.2)

Subjects may have more than one reason for omission.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-dex-dor.sas　　10MAR2015:14:32:57

APPENDIX 15　　デキサメタゾン（静脈内投与）を減量した被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318
NUMBER OF SUBJECTS WITH AT LEAST ONE REDUCTION	5 (1.6)
NUMBER OF REDUCED ADMINISTRATIONS	
1	5 (1.6)
2	0
3	0
>=4	0
REASON FOR REDUCTION	
HEMATOLOGIC TOXICITY	0
NON-HEMATOLOGIC TOXICITY	1 (0.3)
ADVERSE EVENT	2 (0.6)
DOSING ERROR	1 (0.3)
OTHER	1 (0.3)

Subjects may have more than one reason for reduction.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-dex-dor.sas　　10MAR2015:14:33:11

APPENDIX 16　　デキサメタゾン（経口投与）の用量が調整された被験者の割合及び理由（004 試験、治験薬投与例）

	E-Ld N = 318	Ld N = 317
NUMBER OF SUBJECTS WITH AT LEAST ONE DOSE MODIFICATION	267 (84.0)	242 (76.3)
NUMBER OF DOSE MODIFICATIONS		
1	33 (10.4)	48 (15.1)
2	38 (11.9)	40 (12.6)
3	18 (5.7)	28 (8.8)
>=4	178 (56.0)	126 (39.7)
REASON FOR DOSE MODIFICATION		
HEMATOLOGIC TOXICITY	9 (2.8)	13 (4.1)
NON-HEMATOLOGIC TOXICITY	34 (10.7)	25 (7.9)
ADVERSE EVENT	209 (65.7)	194 (61.2)
DOSING ERROR	89 (28.0)	47 (14.8)
OTHER	167 (52.5)	116 (36.6)
NOT REPORTED	1 (0.3)	0

Subjects may have more than one reason for dose modification.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ex-dex-dosmod.sas　　10MAR2015:14:33:23

APPENDIX 17　　レナリドミドのRELATIVE DOSE INTENSITY（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31	Ld N = 29
SUBJECTS STARTING AT 25 MG	21	18
DOSE INTENSITY (MG/WEEK)		
N	21	18
MEAN	84.75	103.15
MEDIAN	81.43	110.26
MIN , MAX	32.4 , 129.4	53.0 , 130.2
Q1 , Q3	54.78 , 117.75	86.89 , 123.22
STANDARD DEVIATION	32.463	23.375
RELATIVE DOSE INTENSITY		
>= 90%	5 (23.8)	8 (44.4)
80% TO < 90%	2 (9.5)	2 (11.1)
70% TO < 80%	2 (9.5)	2 (11.1)
60% TO < 70%	3 (14.3)	3 (16.7)
< 60%	9 (42.9)	3 (16.7)
SUBJECTS STARTING AT < 25 MG	10	11
DOSE INTENSITY (MG/WEEK)		
N	10	11
MEAN	53.06	50.07
MEDIAN	47.82	46.88
MIN , MAX	35.4 , 121.4	24.6 , 123.0
Q1 , Q3	41.41 , 50.26	26.78 , 52.50
STANDARD DEVIATION	24.548	27.727
RELATIVE DOSE INTENSITY		
>= 90%	5 (50.0)	5 (45.5)
80% TO < 90%	2 (20.0)	2 (18.2)
70% TO < 80%	2 (20.0)	1 (9.1)
60% TO < 70%	1 (10.0)	0
< 60%	0	3 (27.3)

Starting dose level for subjects with moderate renal impairment is reduced (per protocol 10 MG).
For relative dose intensity percentages are computed separately for the group of subjects treated at 25 mg or at <25 mg (10 mg is used for the planned DI).
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-len-di.sas　　14JAN2015:08:37:25

APPENDIX 18　　デキサメタゾンのRELATIVE DOSE INTENSITY（004 試験の日本人部分集団、治験薬投与例）

	E-Ld N = 31	Ld N = 29
CYCLE 1 AND 2		
DOSE INTENSITY (MG/WEEK)		
N	31	29
MEAN	35.43	36.75
MEDIAN	38.56	40.00
MIN , MAX	19.9 , 40.5	20.0 , 40.7
Q1 , Q3	33.74 , 38.56	39.30 , 40.00
STANDARD DEVIATION	5.861	6.424
CYCLE 3 AND BEYOND		
DOSE INTENSITY (MG/WEEK)		
N	30	29
MEAN	29.89	28.78
MEDIAN	30.74	32.00
MIN , MAX	7.0 , 39.3	9.0 , 40.0
Q1 , Q3	27.31 , 36.82	22.08 , 37.50
STANDARD DEVIATION	8.142	10.263
RELATIVE DOSE INTENSITY		
>= 90%	10 (32.3)	11 (37.9)
80% TO < 90%	5 (16.1)	6 (20.7)
70% TO < 80%	8 (25.8)	1 (3.4)
60% TO < 70%	4 (12.9)	3 (10.3)
< 60%	4 (12.9)	8 (27.6)

IV dexamethasone is converted to its equivalent oral dose by treating each mg of IV dexamethasone as 1.32 mg of oral dexamethasone.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-dex-di.sas 14JAN2015:08:36:59

APPENDIX 19　　本薬を投与延期した被験者の割合及び理由（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31
NUMBER OF SUBJECTS WITH AT LEAST ONE DELAY	23 (74.2)
NUMBER OF DELAYED ADMINISTRATIONS	
1	7 (22.6)
2	4 (12.9)
3	6 (19.4)
>=4	6 (19.4)
REASON FOR DELAY	
HEMATOLOGIC TOXICITY	0
NON-HEMATOLOGIC TOXICITY	2 (6.5)
ADVERSE EVENT	6 (19.4)
DOSING ERROR	0
OTHER	19 (61.3)
UNKNOWN	3 (9.7)

Reason UNKNOWN is reported when there is a derived delay and no reason is being reported on the CRF.
Subjects may have more than one reason for delay.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-doir.sas　　14JAN2015:08:37:17

APPENDIX 20　　本薬の投与延期期間（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 1362
NUMBER OF ADMINISTRATIONS DELAYED (1)	61 (4.5)
DURATION OF DELAY (DAYS) (2)	
2-3	25 (41.0)
4-7	36 (59.0)

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of delayed administrations.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-dur.sas　　14JAN2015:08:37:21

APPENDIX 21　　本薬を投与スキップした被験者の割合及び理由（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31
NUMBER OF SUBJECTS WITH AT LEAST ONE OMISSION	18 (58.1)
NUMBER OF OMITTED ADMINISTRATIONS	
1	9 (29.0)
2	3 (9.7)
3	5 (16.1)
>=4	1 (3.2)
REASON FOR OMISSION	
HEMATOLOGIC TOXICITY	3 (9.7)
NON-HEMATOLOGIC TOXICITY	6 (19.4)
ADVERSE EVENT	9 (29.0)
DOSING ERROR	0
OTHER	5 (16.1)
UNKNOWN	2 (6.5)

Reason UNKNOWN is reported when there is a derived omission and no reason is being reported on the CRF.
Subjects may have more than one reason for omission.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-doir.sas　　14JAN2015:08:37:18

APPENDIX 22　　本薬の投与スキップ期間（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 1362
NUMBER OF ADMINISTRATIONS OMITTED (1)	34 (2.5)
DURATION OF OMISSION (DAYS) (2)	
11-14	3 (8.8)
15-21	4 (11.8)
22-27	2 (5.9)
>=28	25 (73.5)

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of omissions.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-dur.sas　　14JAN2015:08:37:22

APPENDIX 23　　本薬の投与中の中断時間（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31
NUMBER OF ADMINISTRATIONS WITH INTERRUPTION	7
DURATION OF INTERRUPTIONS (MIN)	
N	6
MEAN	22.5
MEDIAN	22.5
MIN , MAX	4 , 44
Q1 , Q3	12.0 , 30.0
STANDARD DEVIATION	14.02

Duration of interruption was reported only when IV was resumed after interruption.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-dur-interr.sas　　14JAN2015:08:37:24

APPENDIX 24　　本薬の投与速度を下げた被験者の割合及び理由（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31
NUMBER OF SUBJECTS WITH AT LEAST ONE IV RATE REDUCED	5 (16.1)
NUMBER OF TIMES IV RATE REDUCED	
1	4 (12.9)
2	1 (3.2)
3	0
>=4	0
REASON FOR REDUCTION OF IV RATE	
INFUSION REACTION	2 (6.5)
INFUSION ADMINISTRATION ISSUES	0
OTHER	3 (9.7)

Subjects may have more than one reason for IV rate reduction.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ex-elo-doir.sas　　14JAN2015:08:37:20

APPENDIX 25　　本薬を投与延期した被験者の割合及び理由（009 試験、治験薬投与例）

	E-Bd N = 75
NUMBER OF SUBJECTS WITH AT LEAST ONE DELAY	32 (42.7)
NUMBER OF DELAYED ADMINISTRATIONS	
1	15 (20.0)
2	6 (8.0)
3	7 (9.3)
>=4	4 (5.3)
REASON FOR DELAY	
HEMATOLOGIC TOXICITY	0
NON-HEMATOLOGIC TOXICITY	0
ADVERSE EVENT	5 (6.7)
DOSING ERROR	1 (1.3)
OTHER	21 (28.0)
UNKNOWN	12 (16.0)

Reason UNKNOWN is reported when there is a derived delay and no reason is being reported on the CRF.
Subjects may have more than one reason for delay.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-doir.sas　　29APR2[redacted]:05:54:39

APPENDIX 26　　本薬の投与延期期間（009 試験、治験薬投与例）

	E-Bd N = 1931
NUMBER OF ADMINISTRATIONS DELAYED (1)	69 (3.6)
DURATION OF DELAY (DAYS) (2)	
2-3	58 (84.1)
4-7	11 (15.9)
8-14	0

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of delayed administrations.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-dur.sas　　29APR2[redacted]:05:55:06

APPENDIX 27　　本薬を投与スキップした被験者の割合及び理由（009 試験、治験薬投与例）

	E-Bd N = 75
NUMBER OF SUBJECTS WITH AT LEAST ONE OMISSION	46 (61.3)
NUMBER OF OMITTED ADMINISTRATIONS	
1	29 (38.7)
2	12 (16.0)
3	5 (6.7)
>=4	0
REASON FOR OMISSION	
HEMATOLOGIC TOXICITY	3 (4.0)
NON-HEMATOLOGIC TOXICITY	2 (2.7)
ADVERSE EVENT	26 (34.7)
DOSING ERROR	0
OTHER	14 (18.7)
UNKNOWN	11 (14.7)

Reason UNKNOWN is reported when there is a derived omission and no reason is being reported on the CRF.
Subjects may have more than one reason for omission.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-doir.sas　　29APR2[redacted]:05:54:47

APPENDIX 28　　本薬の投与スキップ期間（009 試験、治験薬投与例）

	E-Bd N = 1931
NUMBER OF ADMINISTRATIONS OMITTED (1)	68 (3.5)
DURATION OF OMISSION (DAYS) (2)	
11-14	9 (13.2)
15-21	25 (36.8)
22-27	12 (17.6)
>=28	22 (32.4)

(1) Percentage is based on total number of Elotuzumab infusions.
(2) Percentages are computed out of the total number of omissions.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-dur.sas　　29APR2[redacted]:05:55:11

APPENDIX 29　　本薬を投与中に中断した被験者の割合及び理由（009 試験、治験薬投与例）

	E-Bd N = 75
NUMBER OF SUBJECTS WITH AT LEAST ONE INFUSION INTERRUPTION	2 (2.7)
NUMBER OF INFUSION INTERRUPTIONS	
1	1 (1.3)
2	1 (1.3)
3	0
>=4	0
REASON FOR INFUSION INTERRUPTION	
INFUSION REACTION	1 (1.3)
INFUSION ADMINISTRATION ISSUES	0
OTHER	2 (2.7)

Subjects may have more than one reason for infusion interruption.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-doir.sas　　29APR2[redacted]:05:54:56

APPENDIX 30　　本薬の投与中の中断時間（009 試験、治験薬投与例）

	E-Bd N = 75
NUMBER OF ADMINISTRATIONS WITH INTERRUPTION	3
DURATION OF INTERRUPTIONS (MIN)	
N	3
MEAN	29.3
MEDIAN	30.0
MIN , MAX	18 , 40
Q1 , Q3	18.0 , 40.0
STANDARD DEVIATION	11.02

Duration of interruption was reported only when IV was resumed after interruption.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-ex-elo-dur-interr.sas　　29APR2[redacted]:05:55:20

APPENDIX 31　被験者の内訳（1702試験、登録例）

TABLE 14.1 1.1
SUBJECT DISPOSITION
ALL SUBJECTS ENROLLED

SUBJECTS ENROLLED	COHORT 1 2.5 MG/KG (N 3)	COHORT 2 5 MG/KG (N 3)	COHORT 3 10 MG/KG (N 3)	COHORT 4 20 MG/KG (N 19)	TOTAL (N 28)
SUBJECTS INCLUDED IN ITT POPULATION	3 (100.0%)	3 (100.0%)	3 (100.0%)	19 (100.0%)	28 (100.0%)
SUBJECTS INCLUDED IN SAFETY POPULATION	3 (100.0%)	3 (100.0%)	3 (100.0%)	19 (100.0%)	28 (100.0%)
SUBJECTS INCLUDED IN DLT EVAUABLE POPULATION	3 (100.0%)	3 (100.0%)	3 (100.0%)	17 (89.5 %)	26 (92.9 %)
SUBJECTS INCLUDED IN EFFICACY EVALUABLE POPULATION	3 (100.0%)	3 (100.0%)	3 (100.0%)	18 (94.7 %)	27 (96.4 %)
SUBJECTS RECEIVED STUDY DRUG	3 (100.0%)	3 (100.0%)	3 (100.0%)	19 (100.0%)	28 (100.0%)
COMPLETED TREATMENT CYCLE 1	3 (100.0%)	3 (100.0%)	3 (100.0%)	18 (94.7 %)	27 (96.4 %)
ENTERED TREATMENT CYCLE 2	3 (100.0%)	3 (100.0%)	3 (100.0%)	17 (89.5 %)	26 (92.9 %)
COMPLETED TREATMENT CYCLE 2	3 (100.0%)	3 (100.0%)	3 (100.0%)	17 (89.5 %)	26 (92.9 %)
ENTERED TREATMENT CYCLE 3	3 (100.0%)	3 (100.0%)	3 (100.0%)	16 (84.2 %)	25 (89.3 %)
COMPLETED TREATMENT CYCLE 3	3 (100.0%)	3 (100.0%)	3 (100.0%)	15 (78.9 %)	24 (85.7 %)
ENTERED TREATMENT CYCLE 4	3 (100.0%)	2 (66.7 %)	3 (100.0%)	14 (73.7 %)	22 (78.6 %)
COMPLETED TREATMENT CYCLE 4	3 (100.0%)	2 (66.7 %)	3 (100.0%)	12 (63.2 %)	20 (71.4 %)
ENTERED TREATMENT CYCLE 5-10	3 (100.0%)	2 (66.7 %)	3 (100.0%)	10 (52.6 %)	18 (64.3 %)
COMPLETED TREATMENT CYCLE 5-10	2 (66.7 %)	0	3 (100.0%)	4 (21.1 %)	9 (32.1 %)
ENTERED TREATMENT CYCLE 11-15	2 (66.7 %)	0	3 (100.0%)	3 (15.8 %)	8 (28.6 %)
COMPLETED TREATMENT CYCLE 11-15	0	0	2 (66.7 %)	3 (15.8 %)	5 (17.9 %)
ENTERED TREATMENT CYCLE 16-20	0	0	2 (66.7 %)	3 (15.8 %)	5 (17.9 %)
COMPLETED TREATMENT CYCLE 16-20	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
ENTERED TREATMENT CYCLE 21-25	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
COMPLETED TREATMENT CYCLE 21-25	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
ENTERED TREATMENT CYCLE 26-30	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
COMPLETED TREATMENT CYCLE 26-30	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)

[1] ONLY SUBJECTS WHO RECEIVED AT LEAST ONE STUDY DOSE WERE INCLUDED.
NOTE: ALL PERCENTAGES ARE CALCULATED BASED ON THE NUMBER OF SUBJECTS ENROLLED.

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Abbott Biotherapeutics Corp.
ABT-081
Protocol: HuLuc63-1702 (Clinical Study Report)

TABLE 14.1 1.1
SUBJECT DISPOSITION
ALL SUBJECTS ENROLLED

SUBJECTS ENROLLED	COHORT 1 2.5 MG/KG (N 3)	COHORT 2 5 MG/KG (N 3)	COHORT 3 10 MG/KG (N 3)	COHORT 4 20 MG/KG (N 19)	TOTAL (N 28)
ENTERED TREATMENT CYCLE 31-35	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
COMPLETED TREATMENT CYCLE 31-35	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
ENTERED TREATMENT CYCLE 36-40	0	0	1 (33.3 %)	1 (5.3 %)	2 (7.1 %)
COMPLETED TREATMENT CYCLE 36-40	0	0	1 (33.3 %)	0	1 (3.6 %)
ENTERED TREATMENT CYCLE 41-45	0	0	1 (33.3 %)	0	1 (3.6 %)
COMPLETED TREATMENT CYCLE 41-45	0	0	1 (33.3 %)	0	1 (3.6 %)
ENTERED TREATMENT CYCLE 46-50	0	0	1 (33.3 %)	0	1 (3.6 %)
COMPLETED TREATMENT CYCLE 46-50	0	0	1 (33.3 %)	0	1 (3.6 %)
ENTERED TREATMENT CYCLE 51-55	0	0	1 (33.3 %)	0	1 (3.6 %)
COMPLETED TREATMENT CYCLE 51-55	0	0	0	0	0
COMPLETED FOLLOW-UP 30 DAYS	1 (33.3 %)	1 (33.3 %)	3 (100.0%)	10 (52.6 %)	15 (53.6 %)
EARLY TERMINATED PRIOR TO RECEIVING TREATMENT CYCLE 1	0	0	0	0	0
EARLY TERMINATED PRIOR TO COMPLETING TREATMENT CYCLE 1 [1]	0	0	0	0	0
EARLY TERMINATED PRIOR TO COMPLETING TREATMENT CYCLE 4 [1]	0	1 (33.3 %)	0	7 (36.8 %)	8 (28.6 %)
PRIMARY REASON FOR TREATMENT CESSATION	3 (100.0%)	3 (100.0%)	3 (100.0%)	19 (100.0%)	28 (100.0%)
ADVERSE EVENT(S)	0	2	1	6	9
COMMENCEMENT OF ALTERNATIVE TREATMENT FOR MM	0	0	0	0	0
DEATH	0	0	0	0	0
DISEASE PROGRESSION	1	1	2	8	12
INVESTIGATOR'S DECISION	1	0	0	0	1
NON-COMPLIANCE WITH STUDY PROCEDURES	0	0	0	0	0
NON-COMPLIANCE WITH STUDY DRUG	0	0	0	0	0
PREGNANCY	0	0	0	0	0
SPONSOR'S DECISION	0	0	0	0	0
SUBJECT'S DECISION	1	0	0	5	6

[1] ONLY SUBJECTS WHO RECEIVED AT LEAST ONE STUDY DOSE WERE INCLUDED.
NOTE: ALL PERCENTAGES ARE CALCULATED BASED ON THE NUMBER OF SUBJECTS ENROLLED.

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Abbott Biotherapeutics Corp.
ABT-081
Protocol: HuLuc63-1702 (Clinical Study Report)

TABLE 14.1 1.1
SUBJECT DISPOSITION
ALL SUBJECTS ENROLLED

SUBJECTS ENROLLED	COHORT 1 2.5 MG/KG (N 3)	COHORT 2 5 MG/KG (N 3)	COHORT 3 10 MG/KG (N 3)	COHORT 4 20 MG/KG (N 19)	TOTAL (N 28)
SUBJECT LOST TO FOLLOW-UP	0	0	0	0	0
OTHER	0	0	0	0	0
EARLY WITHDRAWAL FROM THE STUDY	2 (66.7 %)	2 (66.7 %)	0	9 (47.4 %)	13 (46.4 %)
ADVERSE EVENT(S)	0	1	0	1	2
DEATH	0	0	0	0	0
INVESTIGATOR'S DECISION	0	0	0	1	1
PREGNANCY	0	0	0	0	0
SPONSOR'S DECISION	0	0	0	0	0
SUBJECT'S DECISION	1	0	0	4	5
SUBJECT LOST TO FOLLOW-UP	0	1	0	1	2
OTHER	1	0	0	2	3
PROTOCOL VERSION					
AMENDMENT A	3 (100.0%)	3 (100.0%)	1 (33.3 %)	0	7 (25.0 %)
AMENDMENT B	0	0	2 (66.7 %)	6 (31.6 %)	8 (28.6 %)
AMENDMENT C	0	0	0	1 (5.3 %)	1 (3.6 %)
AMENDMENT D	0	0	0	12 (63.2 %)	12 (42.9 %)

[1] ONLY SUBJECTS WHO RECEIVED AT LEAST ONE STUDY DOSE WERE INCLUDED.
NOTE: ALL PERCENTAGES ARE CALCULATED BASED ON THE NUMBER OF SUBJECTS ENROLLED.

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APPENDIX 32　　全身療法の前治療歴（004 試験、日本人部分集団、ランダム割付例）

	E-Ld N = 31	Ld N = 29	Total N = 60
NUMBER OF SUBJECTS WITH AT LEAST ONE PRIOR SYSTEMIC THERAPY	31 (100.0)	29 (100.0)	60 (100.0)
REGIMEN			
MELPHALAN/PREDNISOLONE	8 (25.8)	10 (34.5)	18 (30.0)
BORTEZOMIB/DEXAMETHASONE	5 (16.1)	9 (31.0)	14 (23.3)
CYCLOPHOSPHAMIDE/DEXAMETHASONE/DOXORUBICIN/MELPHALAN/VINCRISTINE	4 (12.9)	6 (20.7)	10 (16.7)
BORTEZOMIB/MELPHALAN/PREDNISOLONE	6 (19.4)	3 (10.3)	9 (15.0)
THALIDOMIDE	3 (9.7)	2 (6.9)	5 (8.3)
BORTEZOMIB/DEXAMETHASONE/DOXORUBICIN	3 (9.7)	1 (3.4)	4 (6.7)
DEXAMETHASONE/DOXORUBICIN/VINCRISTINE	2 (6.5)	2 (6.9)	4 (6.7)
BORTEZOMIB/CYCLOPHOSPHAMIDE/DEXAMETHASONE	0	3 (10.3)	3 (5.0)
DEXAMETHASONE/MELPHALAN/RANIMUSTINE/VINCRISTINE	3 (9.7)	0	3 (5.0)
MELPHALAN/PREDNISOLONE/THALIDOMIDE	1 (3.2)	2 (6.9)	3 (5.0)
OTHER	15 (48.4)	11 (37.9)	26 (43.3)
DRUGS			
ANTINEOPLASTIC & IMMUNOMODULATING AGENT	31 (100.0)	29 (100.0)	60 (100.0)
ANTINEOPLASTIC AGENTS	31 (100.0)	29 (100.0)	60 (100.0)
MELPHALAN	28 (90.3)	26 (89.7)	54 (90.0)
BORTEZOMIB	21 (67.7)	16 (55.2)	37 (61.7)
VINCRISTINE	14 (45.2)	13 (44.8)	27 (45.0)
DOXORUBICIN	13 (41.9)	13 (44.8)	26 (43.3)
CYCLOPHOSPHAMIDE	9 (29.0)	14 (48.3)	23 (38.3)
ETOPOSIDE	2 (6.5)	1 (3.4)	3 (5.0)
RANIMUSTINE	3 (9.7)	0	3 (5.0)
FLUDARABINE	1 (3.2)	0	1 (1.7)
INVESTIGATIONAL ANTINEOPLASTIC	1 (3.2)	0	1 (1.7)
METHOTREXATE	1 (3.2)	0	1 (1.7)
IMMUNOMODULATING AGENT	1 (3.2)	1 (3.4)	2 (3.3)
INTERFERON ALFA	1 (3.2)	1 (3.4)	2 (3.3)

Regimens with < 5% frequency are grouped in the OTHER category.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-th.sas　　21JAN2015:04:45:24

	E-Ld N = 31	Ld N = 29	Total N = 60
SYSTEMIC HORMONAL PREP, EXCL SEX HORMONE	31 (100.0)	29 (100.0)	60 (100.0)
CORTICOSTEROID FOR SYSTEMIC USE	31 (100.0)	29 (100.0)	60 (100.0)
DEXAMETHASONE	20 (64.5)	20 (69.0)	40 (66.7)
PREDNISOLONE	16 (51.6)	14 (48.3)	30 (50.0)
PREDNISONE	1 (3.2)	0	1 (1.7)
NERVOUS SYSTEM	6 (19.4)	6 (20.7)	12 (20.0)
PSYCHOLEPTIC	6 (19.4)	6 (20.7)	12 (20.0)
THALIDOMIDE	6 (19.4)	6 (20.7)	12 (20.0)
VARIOUS	2 (6.5)	1 (3.4)	3 (5.0)
ALL OTHER THERAPEUTIC PRODUCT	2 (6.5)	1 (3.4)	3 (5.0)
INVESTIGATIONAL DRUG	2 (6.5)	1 (3.4)	3 (5.0)
BLOOD & BLOOD FORMING ORGAN	1 (3.2)	0	1 (1.7)
PLASMA SUBSTITUTE & PERFUSION SOLUTION	1 (3.2)	0	1 (1.7)
STEM CELL RESCUE	1 (3.2)	0	1 (1.7)

Regimens with < 5% frequency are grouped in the OTHER category.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-th.sas 21JAN2015:04:45:24

APPENDIX 33　　ベースラインの人口統計学的特性（005 試験、治験薬投与例）

	BMS 10mg/kg + Ld N = 3	BMS 20mg/kg + Ld N = 3	Total N = 6
AGE			
N	3	3	6
MEAN	59.7	67.0	63.3
MEDIAN	61.0	66.0	63.5
MIN , MAX	52 , 66	60 , 75	52 , 75
Q1 , Q3	52.0 , 66.0	60.0 , 75.0	60.0 , 66.0
STANDARD DEVIATION	7.09	7.55	7.69
AGE CATEGORIZATION (%)			
< 65	2 (66.7)	1 (33.3)	3 (50.0)
65 - <75	1 (33.3)	1 (33.3)	2 (33.3)
>= 75	0	1 (33.3)	1 (16.7)
NOT REPORTED	0	0	0
GENDER (%)			
MALE	2 (66.7)	1 (33.3)	3 (50.0)
FEMALE	1 (33.3)	2 (66.7)	3 (50.0)
NOT REPORTED	0	0	0
RACE (%)			
JAPANESE	3 (100.0)	3 (100.0)	6 (100.0)
NOT REPORTED	0	0	0

APPENDIX 34　　ベースラインの疾患特性（005 試験、治験薬投与例）

Treatment Group: BMS 10mg/kg + Ld

Subject ID (Age/Gender/Race)	Serum M-Protein (g/dL)	Urine M-Protein (mg/day)	M Protein Classification	
			Serum	Urine
CA20_005-2-101 (6[redacted] M/JA)	2.0	0	IGGK	
CA20_005-2-102 (5[redacted] M/JA)	2.2	0	IGGK	IGGK
CA20_005-3-103 (6[redacted] F/JA)	4.1	0	IGGL	IGGL

IGGN = IgG without an associated light chain, IGAN = IgA without an associated light chain,
IGMN = IgM without an associated light chain, IGDN = IgD without an associated light chain,
IGEN = IgE without an associated light chain
K LC = Kappa light chains, L LC = Lambda light chains, IGGK = IgG Kappa, IGAK = IgA Kappa, IGMK = IgM Kappa, IGDK = IgD Kappa,
IGEK = IgE Kappa, IGGL = IgG Lambda, IGAL = IgA Lambda, IGML = IgM Lambda, IGDL = IgD Lambda, IGEL = IgE Lambda
Program Source: /gbs/prod/clin/programs/ca/204/005/csr01/rpt/rl-dm-myel-charac-v02.sas　　21MAY2[redacted]:07:49:46

Treatment Group: BMS 20mg/kg + Ld

Subject ID (Age/Gender/Race)	Serum M-Protein (g/dL)	Urine M-Protein (mg/day)	M Protein Classification	
			Serum	Urine
CA20_005-1-201 (6[redacted] M/JA)	0.6	1125.21		K LC
CA20_005-1-203 (6[redacted] F/JA)	1.2	2102.55	K LC	K LC
CA20_005-3-204 (7[redacted] F/JA)	1.5	0	IGAL	

IGGN = IgG without an associated light chain, IGAN = IgA without an associated light chain,
IGMN = IgM without an associated light chain, IGDN = IgD without an associated light chain,
IGEN = IgE without an associated light chain
K LC = Kappa light chains, L LC = Lambda light chains, IGGK = IgG Kappa, IGAK = IgA Kappa, IGMK = IgM Kappa, IGDK = IgD Kappa,
IGEK = IgE Kappa, IGGL = IgG Lambda, IGAL = IgA Lambda, IGML = IgM Lambda, IGDL = IgD Lambda, IGEL = IgE Lambda
Program Source: /gbs/prod/clin/programs/ca/204/005/csr01/rpt/rl-dm-myel-charac-v02.sas 21MAY2[redacted]:07:49:46

APPENDIX 35　　ベースラインの細胞遺伝学的リスク（FISH法）を含むリスク分類（009 試験、ランダム割付例）

	E-Bd N = 77	Bd N = 75	Total N = 152
RISK CATEGORY			
HIGH RISK	0	5 (6.7)	5 (3.3)
LOW RISK	0	3 (4.0)	3 (2.0)
STANDARD RISK	36 (46.8)	25 (33.3)	61 (40.1)
NOT EVALUABLE	41 (53.2)	42 (56.0)	83 (54.6)
DEL 17P			
YES	3 (3.9)	6 (8.0)	9 (5.9)
NO	29 (37.7)	33 (44.0)	62 (40.8)
NOT REPORTED	45 (58.4)	36 (48.0)	81 (53.3)
1Q21			
YES	2 (2.6)	6 (8.0)	8 (5.3)
NO	18 (23.4)	19 (25.3)	37 (24.3)
NOT REPORTED	57 (74.0)	50 (66.7)	107 (70.4)
T(14;16)			
YES	1 (1.3)	4 (5.3)	5 (3.3)
NO	28 (36.4)	26 (34.7)	54 (35.5)
NOT REPORTED	48 (62.3)	45 (60.0)	93 (61.2)
T(14;20)			
YES	1 (1.3)	1 (1.3)	2 (1.3)
NO	22 (28.6)	27 (36.0)	49 (32.2)
NOT REPORTED	54 (70.1)	47 (62.7)	101 (66.4)
T(4;14)			
YES	2 (2.6)	6 (8.0)	8 (5.3)
NO	31 (40.3)	32 (42.7)	63 (41.4)
NOT REPORTED	44 (57.1)	37 (49.3)	81 (53.3)

High risk: ISS stage II or III and t(4;14) or del(17p) abnormality.
Low risk: ISS stage I or II and absence of t(4;14), del(17p) and 1q21 abnormalities and age <55.
Standard risk: subjects not meeting the definition of high or low risk.
Not Evaluable: subjects having missing data preventing the classification in the other 3 categories.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-dm-risk.sas　　29APR2[redacted]:05:54:02

Protocol: CA204009

Baseline Myeloma Risk Factors Summary
All Randomized Subjects

	E-Bd N = 77	Bd N = 75	Total N = 152
DEL 13			
YES	3 (3.9)	1 (1.3)	4 (2.6)
NO	18 (23.4)	25 (33.3)	43 (28.3)
NOT REPORTED	56 (72.7)	49 (65.3)	105 (69.1)
HYPODIPLOIDY			
YES	2 (2.6)	1 (1.3)	3 (2.0)
NO	16 (20.8)	20 (26.7)	36 (23.7)
NOT REPORTED	59 (76.6)	54 (72.0)	113 (74.3)

High risk: ISS stage II or III and t(4;14) or del(17p) abnormality.
Low risk: ISS stage I or II and absence of t(4;14), del(17p) and 1q21 abnormalities and age <55.
Standard risk: subjects not meeting the definition of high or low risk.
Not Evaluable: subjects having missing data preventing the classification in the other 3 categories.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-dm-risk.sas 29APR2[redacted]:05:54:02

APPENDIX 36　　多発性骨髄腫に対する前治療歴（009 試験、治験薬投与例）

	E-Bd N = 77	Bd N = 75	Total N = 152
NUMBER OF SUBJECTS WITH AT LEAST ONE PRIOR SYSTEMIC THERAPY	77 (100.0)	75 (100.0)	152 (100.0)
NUMBER OF REGIMENS			
MEDIAN	1.0	1.0	1.0
MIN , MAX	1 , 3	1 , 3	1 , 3
NUMBER OF REGIMENS			
1	50 (64.9)	51 (68.0)	101 (66.4)
2	25 (32.5)	18 (24.0)	43 (28.3)
3	2 (2.6)	6 (8.0)	8 (5.3)
PRIOR THERAPY			
STEM CELL TRANSPLANT	39 (50.6)	41 (54.7)	80 (52.6)
RADIOTHERAPY	16 (20.8)	13 (17.3)	29 (19.1)
SURGERY	12 (15.6)	9 (12.0)	21 (13.8)
TYPE OF SURGERY			
KYPHOPLASTY	4 (5.2)	1 (1.3)	5 (3.3)
ORTHOPEDIC SURGERY	3 (3.9)	2 (2.7)	5 (3.3)
DEBULKING SURGERY	2 (2.6)	0	2 (1.3)
OTHER	5 (6.5)	6 (8.0)	11 (7.2)

Program Source: /projects/bms209459/stats/primary/prog/tables/rt-th.sas　　29APR2[redacted]:05:54:12

APPENDIX 37 ベースラインの人口統計学的特性（1702試験、治験薬投与例）

Abbott Biotherapeutics Corp. Page 1 of 1
ABT 081
Protocol: HuLuc63 1702 (Clinical Study Report)

TABLE 14.1 2.1
SUMMARY OF DEMOGRAPHICS
ITT POPULATION

		COHORT 1 2.5 MG/KG (N=3)	COHORT 2 5 MG/KG (N=3)	COHORT 3 10 MG/KG (N=3)	COHORT 4 20 MG/KG (N=19)	TOTAL (N=28)
AGE (YEARS) [1]	N	3	3	3	19	28
	MEAN (SD)	64.32 (1.024)	60.91 (11.020)	64.55 (1.804)	59.97 (10.685)	61.03 (9.423)
	MEDIAN	64.1	56.1	63.9	59.7	63.3
	(MIN, MAX)	(63.4, 65.4)	(53.1, 73.5)	(63.2, 66.6)	(41.2, 77.4)	(41.2, 77.4)
RACE	AMERICAN INDIAN OR ALASKA NATIVE	0	0	0	0	0
	ASIAN	0	0	0	0	0
	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0	0	0
	WHITE	3 (100.0%)	3 (100.0%)	2 (66.7 %)	16 (84.2 %)	24 (85.7 %)
	BLACK OF AFRICAN HERITAGE	0	0	1 (33.3 %)	3 (15.8 %)	4 (14.3 %)
ETHNICITY	HISPANIC	0	0	0	3 (15.8 %)	3 (10.7 %)
	NON HISPANIC	3 (100.0%)	2 (66.7 %)	0	16 (84.2 %)	21 (75.0 %)
	UNKNOWN	0	1 (33.3 %)	3 (100.0%)	0	4 (14.3 %)
SEX	MALE	2 (66.7 %)	2 (66.7 %)	2 (66.7 %)	12 (63.2 %)	18 (64.3 %)
	FEMALE	1 (33.3 %)	1 (33.3 %)	1 (33.3 %)	7 (36.8 %)	10 (35.7 %)
WEIGHT (KG)	N	3	3	3	19	28
	MEAN (SD)	84.4 (27.57)	85.8 (43.86)	86.1 (24.52)	88.2 (18.69)	87.3 (21.87)
	MEDIAN	99	73	83	82	82
	(MIN, MAX)	(53, 102)	(50, 135)	(63, 112)	(59, 129)	(50, 135)
HEIGHT (CM)	N	3	3	2	19	27
	MEAN (SD)	166.2 (16.51)	171.3 (14.28)	162.7 (12.39)	170.5 (9.04)	169.5 (10.25)
	MEDIAN	166	170	163	168	168
	(MIN, MAX)	(150, 183)	(157, 186)	(154, 171)	(159, 188)	(150, 188)

[1] AGE AT THE DATE OF INFORMED CONSENT.

PM: \\USADC NAS01A\SASDATA\SAS\PDL\ELOTUZUMAB\NJA39231\BIOSTATISTICS\PRODUCTION\TABLES\CSR\T 14 1 2 1.SAS (17JUL20[redacted] 16:48)

APPENDIX 38　いずれかの治験薬と関連のある有害事象（004 試験、治験薬投与例）

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
TOTAL SUBJECTS WITH AN EVENT	293 (92.1)	277 (87.4)	570 (89.8)
一般・全身障害および投与部位の状態	180 (56.6)	121 (38.2)	301 (47.4)
疲労	92 (28.9)	68 (21.5)	160 (25.2)
末梢性浮腫	46 (14.5)	29 (9.1)	75 (11.8)
発熱	40 (12.6)	18 (5.7)	58 (9.1)
無力症	37 (11.6)	19 (6.0)	56 (8.8)
倦怠感	11 (3.5)	5 (1.6)	16 (2.5)
悪寒	8 (2.5)	1 (0.3)	9 (1.4)
全身健康状態低下	2 (0.6)	3 (0.9)	5 (0.8)
浮腫	3 (0.9)	2 (0.6)	5 (0.8)
歩行障害	1 (0.3)	3 (0.9)	4 (0.6)
疼痛	3 (0.9)	1 (0.3)	4 (0.6)
顔面浮腫	2 (0.6)	1 (0.3)	3 (0.5)
インフルエンザ様疾患	2 (0.6)	1 (0.3)	3 (0.5)
胸部不快感	2 (0.6)	0	2 (0.3)
胸痛	2 (0.6)	0	2 (0.3)
全身性浮腫	1 (0.3)	1 (0.3)	2 (0.3)
局所腫脹	2 (0.6)	0	2 (0.3)
冷感	1 (0.3)	0	1 (0.2)
びくびく感	1 (0.3)	0	1 (0.2)
治癒不良	1 (0.3)	0	1 (0.2)
粘膜出血	1 (0.3)	0	1 (0.2)
異物感	1 (0.3)	0	1 (0.2)
漿膜炎	0	1 (0.3)	1 (0.2)
血液およびリンパ系障害	145 (45.6)	152 (47.9)	297 (46.8)
好中球減少症	86 (27.0)	115 (36.3)	201 (31.7)
血小板減少症	56 (17.6)	52 (16.4)	108 (17.0)
貧血	48 (15.1)	57 (18.0)	105 (16.5)
リンパ球減少症	30 (9.4)	9 (2.8)	39 (6.1)
白血球減少症	19 (6.0)	17 (5.4)	36 (5.7)
発熱性好中球減少症	6 (1.9)	3 (0.9)	9 (1.4)
好酸球増加症	2 (0.6)	1 (0.3)	3 (0.5)
内出血発生の増加傾向	0	2 (0.6)	2 (0.3)
汎血球減少症	2 (0.6)	0	2 (0.3)
大球性貧血	0	1 (0.3)	1 (0.2)
播種性血管内凝固	0	1 (0.3)	1 (0.2)
顆粒球減少症	1 (0.3)	0	1 (0.2)
血液毒性	1 (0.3)	0	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
単球減少症	0	1 (0.3)	1 (0.2)
単球増加症	1 (0.3)	0	1 (0.2)
脾臓梗塞	0	1 (0.3)	1 (0.2)
胃腸障害	140 (44.0)	110 (34.7)	250 (39.4)
下痢	59 (18.6)	44 (13.9)	103 (16.2)
便秘	46 (14.5)	43 (13.6)	89 (14.0)
悪心	39 (12.3)	29 (9.1)	68 (10.7)
消化不良	15 (4.7)	9 (2.8)	24 (3.8)
口内炎	15 (4.7)	5 (1.6)	20 (3.1)
嘔吐	14 (4.4)	6 (1.9)	20 (3.1)
腹痛	7 (2.2)	8 (2.5)	15 (2.4)
上腹部痛	9 (2.8)	6 (1.9)	15 (2.4)
口内乾燥	5 (1.6)	6 (1.9)	11 (1.7)
放屁	5 (1.6)	5 (1.6)	10 (1.6)
胃食道逆流性疾患	4 (1.3)	4 (1.3)	8 (1.3)
腹部膨満	2 (0.6)	4 (1.3)	6 (0.9)
腹部不快感	2 (0.6)	3 (0.9)	5 (0.8)
胃炎	2 (0.6)	3 (0.9)	5 (0.8)
嚥下障害	1 (0.3)	3 (0.9)	4 (0.6)
アフタ性口内炎	1 (0.3)	2 (0.6)	3 (0.5)
大腸炎	1 (0.3)	2 (0.6)	3 (0.5)
口腔内潰瘍形成	2 (0.6)	1 (0.3)	3 (0.5)
小腸炎	1 (0.3)	1 (0.3)	2 (0.3)
胃腸障害	1 (0.3)	1 (0.3)	2 (0.3)
消化器痛	1 (0.3)	1 (0.3)	2 (0.3)
歯肉腫脹	1 (0.3)	1 (0.3)	2 (0.3)
痔核	0	2 (0.6)	2 (0.3)
直腸出血	2 (0.6)	0	2 (0.3)
舌苔	2 (0.6)	0	2 (0.3)
下腹部痛	1 (0.3)	0	1 (0.2)
唾液欠乏	1 (0.3)	0	1 (0.2)
胆汁酸吸収不良	0	1 (0.3)	1 (0.2)
軟便	0	1 (0.3)	1 (0.2)
萎縮性胃炎	1 (0.3)	0	1 (0.2)
びらん性胃炎	1 (0.3)	0	1 (0.2)
消化管運動障害	1 (0.3)	0	1 (0.2)
歯肉の炎症	1 (0.3)	0	1 (0.2)
血便排泄	1 (0.3)	0	1 (0.2)
裂孔ヘルニア	1 (0.3)	0	1 (0.2)
大腸潰瘍	0	1 (0.3)	1 (0.2)
口唇腫脹	1 (0.3)	0	1 (0.2)
下部消化管出血	0	1 (0.3)	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
嚥下痛	0	1 (0.3)	1 (0.2)
食道痛	1 (0.3)	0	1 (0.2)
食道炎	0	1 (0.3)	1 (0.2)
口腔知覚不全	0	1 (0.3)	1 (0.2)
口腔内痛	1 (0.3)	0	1 (0.2)
膵炎	0	1 (0.3)	1 (0.2)
急性膵炎	1 (0.3)	0	1 (0.2)
逆流性胃炎	0	1 (0.3)	1 (0.2)
亜イレウス	0	1 (0.3)	1 (0.2)
舌変色	0	1 (0.3)	1 (0.2)
歯の脱落	1 (0.3)	0	1 (0.2)
歯痛	0	1 (0.3)	1 (0.2)
上部消化管出血	0	1 (0.3)	1 (0.2)
神経系障害	116 (36.5)	92 (29.0)	208 (32.8)
末梢性ニューロパチー	23 (7.2)	18 (5.7)	41 (6.5)
味覚異常	21 (6.6)	18 (5.7)	39 (6.1)
振戦	16 (5.0)	21 (6.6)	37 (5.8)
末梢性感覚ニューロパチー	13 (4.1)	21 (6.6)	34 (5.4)
浮動性めまい	15 (4.7)	12 (3.8)	27 (4.3)
錯感覚	13 (4.1)	13 (4.1)	26 (4.1)
頭痛	15 (4.7)	7 (2.2)	22 (3.5)
感覚鈍麻	8 (2.5)	5 (1.6)	13 (2.0)
記憶障害	5 (1.6)	4 (1.3)	9 (1.4)
多発ニューロパチー	3 (0.9)	5 (1.6)	8 (1.3)
嗜眠	3 (0.9)	3 (0.9)	6 (0.9)
末梢性運動ニューロパチー	4 (1.3)	0	4 (0.6)
傾眠	4 (1.3)	0	4 (0.6)
反射消失	2 (0.6)	1 (0.3)	3 (0.5)
注意力障害	0	3 (0.9)	3 (0.5)
味覚減退	0	3 (0.9)	3 (0.5)
健忘	1 (0.3)	1 (0.3)	2 (0.3)
平衡障害	0	2 (0.6)	2 (0.3)
脳血管発作	1 (0.3)	1 (0.3)	2 (0.3)
局在性痙攣	2 (0.6)	0	2 (0.3)
神経痛	1 (0.3)	1 (0.3)	2 (0.3)
神経毒性	0	2 (0.6)	2 (0.3)
一過性脳虚血発作	1 (0.3)	1 (0.3)	2 (0.3)
味覚消失	1 (0.3)	0	1 (0.2)
灼熱感	0	1 (0.3)	1 (0.2)
脳梗塞	1 (0.3)	0	1 (0.2)
認知障害	1 (0.3)	0	1 (0.2)
複合性局所疼痛症候群	0	1 (0.3)	1 (0.2)
痙攣	0	1 (0.3)	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
認知症	1 (0.3)	0	1 (0.2)
体位性めまい	1 (0.3)	0	1 (0.2)
異常感覚	1 (0.3)	0	1 (0.2)
ジスキネジア	1 (0.3)	0	1 (0.2)
蟻走感	0	1 (0.3)	1 (0.2)
不全片麻痺	0	1 (0.3)	1 (0.2)
反射減弱	1 (0.3)	0	1 (0.2)
筋緊張低下	1 (0.3)	0	1 (0.2)
片頭痛	1 (0.3)	0	1 (0.2)
視神経炎	1 (0.3)	0	1 (0.2)
嗅覚錯誤	0	1 (0.3)	1 (0.2)
ヘルペス後神経痛	0	1 (0.3)	1 (0.2)
精神運動亢進	0	1 (0.3)	1 (0.2)
感覚消失	1 (0.3)	0	1 (0.2)
てんかん重積状態	0	1 (0.3)	1 (0.2)
失神	1 (0.3)	0	1 (0.2)
感染症および寄生虫症	99 (31.1)	85 (26.8)	184 (29.0)
肺炎	22 (6.9)	10 (3.2)	32 (5.0)
気管支炎	12 (3.8)	13 (4.1)	25 (3.9)
鼻咽頭炎	11 (3.5)	9 (2.8)	20 (3.1)
気道感染	11 (3.5)	6 (1.9)	17 (2.7)
上気道感染	10 (3.1)	7 (2.2)	17 (2.7)
口腔ヘルペス	8 (2.5)	6 (1.9)	14 (2.2)
下気道感染	6 (1.9)	5 (1.6)	11 (1.7)
副鼻腔炎	7 (2.2)	3 (0.9)	10 (1.6)
肺感染	4 (1.3)	5 (1.6)	9 (1.4)
帯状疱疹	6 (1.9)	2 (0.6)	8 (1.3)
尿路感染	2 (0.6)	5 (1.6)	7 (1.1)
結膜炎	2 (0.6)	4 (1.3)	6 (0.9)
胃腸炎	1 (0.3)	5 (1.6)	6 (0.9)
感染	2 (0.6)	3 (0.9)	5 (0.8)
鼻炎	4 (1.3)	1 (0.3)	5 (0.8)
敗血症	2 (0.6)	3 (0.9)	5 (0.8)
蜂巣炎	3 (0.9)	1 (0.3)	4 (0.6)
インフルエンザ	2 (0.6)	2 (0.6)	4 (0.6)
大葉性肺炎	2 (0.6)	2 (0.6)	4 (0.6)
口腔カンジダ症	2 (0.6)	2 (0.6)	4 (0.6)
膀胱炎	2 (0.6)	1 (0.3)	3 (0.5)
ウイルス性胃腸炎	0	3 (0.9)	3 (0.5)
好中球減少性敗血症	1 (0.3)	2 (0.6)	3 (0.5)
口腔真菌感染	1 (0.3)	2 (0.6)	3 (0.5)
カンジダ感染	1 (0.3)	1 (0.3)	2 (0.3)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
毛包炎	1 (0.3)	1 (0.3)	2 (0.3)
せつ	1 (0.3)	1 (0.3)	2 (0.3)
消化管感染	0	2 (0.6)	2 (0.3)
陰部ヘルペス	1 (0.3)	1 (0.3)	2 (0.3)
単純ヘルペス	1 (0.3)	1 (0.3)	2 (0.3)
骨髄炎	1 (0.3)	1 (0.3)	2 (0.3)
咽頭炎	2 (0.6)	0	2 (0.3)
ニューモシスチス・イロベチイ肺炎	1 (0.3)	1 (0.3)	2 (0.3)
肺炎球菌性肺炎	2 (0.6)	0	2 (0.3)
敗血症性ショック	0	2 (0.6)	2 (0.3)
副鼻腔気管支炎	2 (0.6)	0	2 (0.3)
ウイルス感染	2 (0.6)	0	2 (0.3)
ウイルス性上気道感染	0	2 (0.6)	2 (0.3)
非定型マイコバクテリア感染	1 (0.3)	0	1 (0.2)
異型肺炎	1 (0.3)	0	1 (0.2)
気管支肺炎	1 (0.3)	0	1 (0.2)
気管支肺アスペルギルス症	1 (0.3)	0	1 (0.2)
カンピロバクター胃腸炎	0	1 (0.3)	1 (0.2)
脳アスペルギルス症	1 (0.3)	0	1 (0.2)
医療機器関連敗血症	0	1 (0.3)	1 (0.2)
糖尿病性足感染	0	1 (0.3)	1 (0.2)
真菌性耳感染	1 (0.3)	0	1 (0.2)
感染性腸炎	1 (0.3)	0	1 (0.2)
伝染性紅斑	0	1 (0.3)	1 (0.2)
大腸菌性尿路感染	1 (0.3)	0	1 (0.2)
真菌感染	0	1 (0.3)	1 (0.2)
消化器カンジダ症	0	1 (0.3)	1 (0.2)
性器感染	1 (0.3)	0	1 (0.2)
泌尿生殖器感染	0	1 (0.3)	1 (0.2)
H1N1 インフルエンザ	0	1 (0.3)	1 (0.2)
ヘルペスウイルス感染	1 (0.3)	0	1 (0.2)
喉頭炎	1 (0.3)	0	1 (0.2)
口唇感染	0	1 (0.3)	1 (0.2)
リステリア症	0	1 (0.3)	1 (0.2)
粘膜感染	1 (0.3)	0	1 (0.2)
口腔感染	1 (0.3)	0	1 (0.2)
口腔ウイルス感染	1 (0.3)	0	1 (0.2)
外耳炎	1 (0.3)	0	1 (0.2)
爪囲炎	0	1 (0.3)	1 (0.2)
腹膜炎	0	1 (0.3)	1 (0.2)
肺炎球菌性敗血症	1 (0.3)	0	1 (0.2)
腎盂腎炎	1 (0.3)	0	1 (0.2)
膿疱性皮疹	1 (0.3)	0	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
RS ウイルス感染	1 (0.3)	0	1 (0.2)
皮膚感染	0	1 (0.3)	1 (0.2)
ブドウ球菌性敗血症	0	1 (0.3)	1 (0.2)
レンサ球菌性菌血症	0	1 (0.3)	1 (0.2)
皮下組織膿瘍	0	1 (0.3)	1 (0.2)
手白癬	1 (0.3)	0	1 (0.2)
歯感染	0	1 (0.3)	1 (0.2)
気管炎	1 (0.3)	0	1 (0.2)
細菌性尿路感染	1 (0.3)	0	1 (0.2)
尿路性敗血症	1 (0.3)	0	1 (0.2)
水痘	1 (0.3)	0	1 (0.2)
ウイルス性下痢	1 (0.3)	0	1 (0.2)
代謝および栄養障害	97 (30.5)	71 (22.4)	168 (26.5)
高血糖	44 (13.8)	35 (11.0)	79 (12.4)
食欲減退	29 (9.1)	16 (5.0)	45 (7.1)
低カリウム血症	13 (4.1)	11 (3.5)	24 (3.8)
低リン酸血症	6 (1.9)	6 (1.9)	12 (1.9)
低カルシウム血症	4 (1.3)	4 (1.3)	8 (1.3)
低マグネシウム血症	7 (2.2)	1 (0.3)	8 (1.3)
糖尿病	5 (1.6)	2 (0.6)	7 (1.1)
脱水	5 (1.6)	1 (0.3)	6 (0.9)
低ナトリウム血症	2 (0.6)	4 (1.3)	6 (0.9)
低アルブミン血症	3 (0.9)	2 (0.6)	5 (0.8)
耐糖能障害	2 (0.6)	2 (0.6)	4 (0.6)
食欲亢進	1 (0.3)	2 (0.6)	3 (0.5)
体液貯留	2 (0.6)	0	2 (0.3)
食欲障害	1 (0.3)	0	1 (0.2)
高カリウム血症	1 (0.3)	0	1 (0.2)
高尿酸血症	1 (0.3)	0	1 (0.2)
栄養障害	1 (0.3)	0	1 (0.2)
肥満	0	1 (0.3)	1 (0.2)
テタニー	0	1 (0.3)	1 (0.2)
2 型糖尿病	0	1 (0.3)	1 (0.2)
ビタミン B12 欠乏	1 (0.3)	0	1 (0.2)
筋骨格系および結合組織障害	83 (26.1)	84 (26.5)	167 (26.3)
筋痙縮	52 (16.4)	53 (16.7)	105 (16.5)
筋力低下	16 (5.0)	17 (5.4)	33 (5.2)
筋肉痛	5 (1.6)	10 (3.2)	15 (2.4)
四肢痛	8 (2.5)	5 (1.6)	13 (2.0)
ミオパチー	7 (2.2)	3 (0.9)	10 (1.6)
背部痛	2 (0.6)	5 (1.6)	7 (1.1)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
筋骨格痛	4 (1.3)	1 (0.3)	5 (0.8)
関節痛	2 (0.6)	2 (0.6)	4 (0.6)
骨痛	4 (1.3)	0	4 (0.6)
関節腫脹	1 (0.3)	3 (0.9)	4 (0.6)
筋骨格硬直	2 (0.6)	2 (0.6)	4 (0.6)
四肢不快感	1 (0.3)	1 (0.3)	2 (0.3)
筋緊張	1 (0.3)	1 (0.3)	2 (0.3)
筋骨格不快感	0	2 (0.6)	2 (0.3)
骨壊死	2 (0.6)	0	2 (0.3)
筋萎縮症	1 (0.3)	0	1 (0.2)
関節炎	1 (0.3)	0	1 (0.2)
側腹部痛	0	1 (0.3)	1 (0.2)
関節硬直	0	1 (0.3)	1 (0.2)
筋攣縮	1 (0.3)	0	1 (0.2)
頚部痛	0	1 (0.3)	1 (0.2)
変形性関節症	0	1 (0.3)	1 (0.2)
重感	1 (0.3)	0	1 (0.2)
精神障害	81 (25.5)	81 (25.6)	162 (25.5)
不眠症	51 (16.0)	57 (18.0)	108 (17.0)
気分変化	15 (4.7)	5 (1.6)	20 (3.1)
錯乱状態	8 (2.5)	4 (1.3)	12 (1.9)
激越	4 (1.3)	7 (2.2)	11 (1.7)
不安	6 (1.9)	5 (1.6)	11 (1.7)
易刺激性	5 (1.6)	6 (1.9)	11 (1.7)
うつ病	6 (1.9)	4 (1.3)	10 (1.6)
睡眠障害	3 (0.9)	3 (0.9)	6 (0.9)
神経過敏	5 (1.6)	0	5 (0.8)
抑うつ気分	2 (0.6)	2 (0.6)	4 (0.6)
落ち着きのなさ	1 (0.3)	3 (0.9)	4 (0.6)
感情不安定	2 (0.6)	1 (0.3)	3 (0.5)
攻撃性	0	3 (0.9)	3 (0.5)
気分動揺	1 (0.3)	2 (0.6)	3 (0.5)
精神緩慢	0	2 (0.6)	2 (0.3)
異常行動	1 (0.3)	0	1 (0.2)
異常な夢	0	1 (0.3)	1 (0.2)
譫妄	1 (0.3)	0	1 (0.2)
感情的苦悩	0	1 (0.3)	1 (0.2)
リビド消失	0	1 (0.3)	1 (0.2)
妄想症	1 (0.3)	0	1 (0.2)
皮膚および皮下組織障害	83 (26.1)	78 (24.6)	161 (25.4)
発疹	24 (7.5)	31 (9.8)	55 (8.7)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
そう痒症	13 (4.1)	15 (4.7)	28 (4.4)
多汗症	13 (4.1)	12 (3.8)	25 (3.9)
紅斑	6 (1.9)	8 (2.5)	14 (2.2)
寝汗	10 (3.1)	3 (0.9)	13 (2.0)
蕁麻疹	7 (2.2)	3 (0.9)	10 (1.6)
脱毛症	2 (0.6)	3 (0.9)	5 (0.8)
皮膚乾燥	0	5 (1.6)	5 (0.8)
斑状丘疹状皮疹	3 (0.9)	2 (0.6)	5 (0.8)
薬疹	1 (0.3)	2 (0.6)	3 (0.5)
そう痒性皮疹	3 (0.9)	0	3 (0.5)
皮膚病変	2 (0.6)	1 (0.3)	3 (0.5)
斑状出血	1 (0.3)	1 (0.3)	2 (0.3)
毛髪成長異常	2 (0.6)	0	2 (0.3)
紅斑性皮疹	0	2 (0.6)	2 (0.3)
全身性皮疹	2 (0.6)	0	2 (0.3)
顔面腫脹	2 (0.6)	0	2 (0.3)
ざ瘡	0	1 (0.3)	1 (0.2)
血管浮腫	1 (0.3)	0	1 (0.2)
皮膚嚢腫	0	1 (0.3)	1 (0.2)
皮膚炎	1 (0.3)	0	1 (0.2)
ざ瘡様皮膚炎	0	1 (0.3)	1 (0.2)
アレルギー性皮膚炎	0	1 (0.3)	1 (0.2)
剥脱性皮膚炎	0	1 (0.3)	1 (0.2)
紅色症	0	1 (0.3)	1 (0.2)
毛髪変色	1 (0.3)	0	1 (0.2)
過角化	1 (0.3)	0	1 (0.2)
嵌入爪	0	1 (0.3)	1 (0.2)
白斑	1 (0.3)	0	1 (0.2)
丘疹	1 (0.3)	0	1 (0.2)
天疱瘡	1 (0.3)	0	1 (0.2)
点状出血	0	1 (0.3)	1 (0.2)
全身性そう痒症	0	1 (0.3)	1 (0.2)
紫斑	1 (0.3)	0	1 (0.2)
斑状皮疹	0	1 (0.3)	1 (0.2)
丘疹性皮疹	0	1 (0.3)	1 (0.2)
酒さ	0	1 (0.3)	1 (0.2)
皮膚灼熱感	1 (0.3)	0	1 (0.2)
皮膚びらん	0	1 (0.3)	1 (0.2)
皮膚亀裂	0	1 (0.3)	1 (0.2)
皮膚脆弱性	0	1 (0.3)	1 (0.2)
皮膚色素過剰	0	1 (0.3)	1 (0.2)
皮膚潰瘍	1 (0.3)	0	1 (0.2)
毛細血管拡張症	1 (0.3)	0	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
中毒性皮疹	0	1 (0.3)	1 (0.2)
乾皮症	1 (0.3)	0	1 (0.2)
黄色皮膚	0	1 (0.3)	1 (0.2)
呼吸器、胸郭および縦隔障害	64 (20.1)	57 (18.0)	121 (19.1)
発声障害	15 (4.7)	16 (5.0)	31 (4.9)
呼吸困難	13 (4.1)	17 (5.4)	30 (4.7)
咳嗽	10 (3.1)	6 (1.9)	16 (2.5)
しゃっくり	6 (1.9)	9 (2.8)	15 (2.4)
肺塞栓症	9 (2.8)	6 (1.9)	15 (2.4)
口腔咽頭痛	2 (0.6)	3 (0.9)	5 (0.8)
上気道の炎症	3 (0.9)	2 (0.6)	5 (0.8)
労作性呼吸困難	1 (0.3)	2 (0.6)	3 (0.5)
鼻出血	1 (0.3)	2 (0.6)	3 (0.5)
肺障害	2 (0.6)	1 (0.3)	3 (0.5)
肺臓炎	1 (0.3)	2 (0.6)	3 (0.5)
慢性閉塞性肺疾患	1 (0.3)	1 (0.3)	2 (0.3)
間質性肺疾患	1 (0.3)	1 (0.3)	2 (0.3)
胸水	2 (0.6)	0	2 (0.3)
鼻漏	2 (0.6)	0	2 (0.3)
喘息	1 (0.3)	0	1 (0.2)
咽喉乾燥	0	1 (0.3)	1 (0.2)
低酸素症	1 (0.3)	0	1 (0.2)
鼻閉	1 (0.3)	0	1 (0.2)
閉塞性細気管支炎	1 (0.3)	0	1 (0.2)
器質化肺炎	1 (0.3)	0	1 (0.2)
胸膜炎	0	1 (0.3)	1 (0.2)
胸膜痛	1 (0.3)	0	1 (0.2)
肺胞出血	1 (0.3)	0	1 (0.2)
肺出血	1 (0.3)	0	1 (0.2)
呼吸不全	1 (0.3)	0	1 (0.2)
窒息感	1 (0.3)	0	1 (0.2)
声帯障害	1 (0.3)	0	1 (0.2)
喘鳴	1 (0.3)	0	1 (0.2)
臨床検査	65 (20.4)	48 (15.1)	113 (17.8)
アラニンアミノトランスフェラーゼ増加	10 (3.1)	12 (3.8)	22 (3.5)
血中クレアチニン増加	10 (3.1)	9 (2.8)	19 (3.0)
アスパラギン酸アミノトランスフェラーゼ増加	6 (1.9)	11 (3.5)	17 (2.7)
血小板数減少	12 (3.8)	5 (1.6)	17 (2.7)
体重減少	7 (2.2)	3 (0.9)	10 (1.6)
好中球数減少	4 (1.3)	5 (1.6)	9 (1.4)
C一反応性蛋白増加	3 (0.9)	5 (1.6)	8 (1.3)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
腎クレアチニン・クリアランス減少	5 (1.6)	3 (0.9)	8 (1.3)
体重増加	3 (0.9)	5 (1.6)	8 (1.3)
白血球数減少	5 (1.6)	3 (0.9)	8 (1.3)
血中アルカリホスファターゼ増加	2 (0.6)	5 (1.6)	7 (1.1)
ヘモグロビン減少	5 (1.6)	2 (0.6)	7 (1.1)
血中ブドウ糖増加	5 (1.6)	0	5 (0.8)
フィブリン分解産物増加	3 (0.9)	1 (0.3)	4 (0.6)
グルタミン酸脱水素酵素増加	2 (0.6)	2 (0.6)	4 (0.6)
血中クレアチニン	1 (0.3)	2 (0.6)	3 (0.5)
血中クレアチニン減少	2 (0.6)	1 (0.3)	3 (0.5)
血中カリウム減少	0	3 (0.9)	3 (0.5)
フィブリンＤダイマー増加	2 (0.6)	1 (0.3)	3 (0.5)
糸球体濾過率減少	2 (0.6)	1 (0.3)	3 (0.5)
好中球数増加	1 (0.3)	2 (0.6)	3 (0.5)
アミラーゼ増加	1 (0.3)	1 (0.3)	2 (0.3)
血中乳酸脱水素酵素増加	2 (0.6)	0	2 (0.3)
血圧上昇	1 (0.3)	1 (0.3)	2 (0.3)
腎クレアチニン・クリアランス	2 (0.6)	0	2 (0.3)
好酸球数増加	1 (0.3)	1 (0.3)	2 (0.3)
γ－グルタミルトランスフェラーゼ増加	2 (0.6)	0	2 (0.3)
好中球数	1 (0.3)	1 (0.3)	2 (0.3)
抗体検査異常	0	1 (0.3)	1 (0.2)
血中カルシウム減少	1 (0.3)	0	1 (0.2)
血中クロール減少	0	1 (0.3)	1 (0.2)
血中コリンエステラーゼ減少	0	1 (0.3)	1 (0.2)
血中クレアチン増加	1 (0.3)	0	1 (0.2)
血中クレアチンホスホキナーゼ増加	1 (0.3)	0	1 (0.2)
血中フィブリノゲン増加	1 (0.3)	0	1 (0.2)
血中免疫グロブリンＧ減少	1 (0.3)	0	1 (0.2)
血中甲状腺刺激ホルモン減少	1 (0.3)	0	1 (0.2)
血中尿素増加	1 (0.3)	0	1 (0.2)
サイトメガロウイルス検査陽性	1 (0.3)	0	1 (0.2)
心電図異常	0	1 (0.3)	1 (0.2)
糸球体濾過率	1 (0.3)	0	1 (0.2)
グリコヘモグロビン増加	0	1 (0.3)	1 (0.2)
ヘモグロビン	1 (0.3)	0	1 (0.2)
肝酵素上昇	0	1 (0.3)	1 (0.2)
眼圧上昇	1 (0.3)	0	1 (0.2)
リンパ球数減少	1 (0.3)	0	1 (0.2)
リンパ球形態異常	1 (0.3)	0	1 (0.2)
単球数増加	0	1 (0.3)	1 (0.2)
プロカルシトニン増加	1 (0.3)	0	1 (0.2)
QOL 低下	0	1 (0.3)	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
血管障害	53 (16.7)	36 (11.4)	89 (14.0)
深部静脈血栓症	19 (6.0)	10 (3.2)	29 (4.6)
高血圧	12 (3.8)	6 (1.9)	18 (2.8)
潮紅	7 (2.2)	5 (1.6)	12 (1.9)
ほてり	4 (1.3)	4 (1.3)	8 (1.3)
血栓症	2 (0.6)	4 (1.3)	6 (0.9)
低血圧	4 (1.3)	0	4 (0.6)
静脈炎	2 (0.6)	1 (0.3)	3 (0.5)
表在性血栓性静脈炎	1 (0.3)	2 (0.6)	3 (0.5)
起立性低血圧	0	2 (0.6)	2 (0.3)
末梢冷感	1 (0.3)	1 (0.3)	2 (0.3)
血栓性静脈炎	1 (0.3)	1 (0.3)	2 (0.3)
静脈血栓症	0	2 (0.6)	2 (0.3)
四肢静脈血栓症	2 (0.6)	0	2 (0.3)
塞栓症	0	1 (0.3)	1 (0.2)
血腫	1 (0.3)	0	1 (0.2)
蒼白	1 (0.3)	0	1 (0.2)
骨盤静脈血栓症	1 (0.3)	0	1 (0.2)
末梢動脈血栓症	1 (0.3)	0	1 (0.2)
表在性静脈炎	1 (0.3)	0	1 (0.2)
鎖骨下静脈血栓症	1 (0.3)	0	1 (0.2)
血管拡張	1 (0.3)	0	1 (0.2)
眼障害	45 (14.2)	30 (9.5)	75 (11.8)
白内障	15 (4.7)	13 (4.1)	28 (4.4)
霧視	14 (4.4)	6 (1.9)	20 (3.1)
視力低下	4 (1.3)	3 (0.9)	7 (1.1)
眼乾燥	3 (0.9)	3 (0.9)	6 (0.9)
結膜出血	1 (0.3)	2 (0.6)	3 (0.5)
眼刺激	1 (0.3)	2 (0.6)	3 (0.5)
視力障害	3 (0.9)	0	3 (0.5)
眼瞼浮腫	1 (0.3)	1 (0.3)	2 (0.3)
緑内障	1 (0.3)	1 (0.3)	2 (0.3)
眼窩周囲浮腫	1 (0.3)	1 (0.3)	2 (0.3)
失明	1 (0.3)	0	1 (0.2)
核性白内障	1 (0.3)	0	1 (0.2)
結膜充血	1 (0.3)	0	1 (0.2)
複視	1 (0.3)	0	1 (0.2)
眼の障害	1 (0.3)	0	1 (0.2)
眼球浮腫	1 (0.3)	0	1 (0.2)
眼部腫脹	1 (0.3)	0	1 (0.2)
角膜炎	0	1 (0.3)	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
流涙増加	1 (0.3)	0	1 (0.2)
黄斑浮腫	1 (0.3)	0	1 (0.2)
近視	1 (0.3)	0	1 (0.2)
正常眼圧緑内障	0	1 (0.3)	1 (0.2)
眼充血	0	1 (0.3)	1 (0.2)
高眼圧症	0	1 (0.3)	1 (0.2)
光視症	1 (0.3)	0	1 (0.2)
心臓障害	19 (6.0)	12 (3.8)	31 (4.9)
動悸	8 (2.5)	3 (0.9)	11 (1.7)
頻脈	1 (0.3)	3 (0.9)	4 (0.6)
心房細動	0	2 (0.6)	2 (0.3)
心不全	1 (0.3)	1 (0.3)	2 (0.3)
うっ血性心不全	2 (0.6)	0	2 (0.3)
狭心症	0	1 (0.3)	1 (0.2)
不整脈	1 (0.3)	0	1 (0.2)
上室性不整脈	0	1 (0.3)	1 (0.2)
心房粗動	1 (0.3)	0	1 (0.2)
完全房室ブロック	1 (0.3)	0	1 (0.2)
徐脈	1 (0.3)	0	1 (0.2)
心停止	1 (0.3)	0	1 (0.2)
心拡大	1 (0.3)	0	1 (0.2)
期外収縮	1 (0.3)	0	1 (0.2)
左室不全	0	1 (0.3)	1 (0.2)
心筋虚血	0	1 (0.3)	1 (0.2)
結節性不整脈	0	1 (0.3)	1 (0.2)
心膜炎	0	1 (0.3)	1 (0.2)
洞性徐脈	1 (0.3)	0	1 (0.2)
上室性期外収縮	1 (0.3)	0	1 (0.2)
心室性不整脈	0	1 (0.3)	1 (0.2)
心室性期外収縮	1 (0.3)	0	1 (0.2)
内分泌障害	15 (4.7)	6 (1.9)	21 (3.3)
クッシング様症状	9 (2.8)	3 (0.9)	12 (1.9)
甲状腺機能低下症	2 (0.6)	1 (0.3)	3 (0.5)
クッシング症候群	1 (0.3)	1 (0.3)	2 (0.3)
甲状腺機能亢進症	1 (0.3)	1 (0.3)	2 (0.3)
副腎機能不全	1 (0.3)	0	1 (0.2)
自己免疫性甲状腺炎	0	1 (0.3)	1 (0.2)
ステロイド離脱症候群	1 (0.3)	0	1 (0.2)
傷害、中毒および処置合併症	14 (4.4)	6 (1.9)	20 (3.1)
挫傷	7 (2.2)	4 (1.3)	11 (1.7)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
注入に伴う反応	3 (0.9)	0	3 (0.5)
頭蓋脳損傷	0	1 (0.3)	1 (0.2)
上顆炎	1 (0.3)	0	1 (0.2)
肉離れ	0	1 (0.3)	1 (0.2)
肋骨骨折	1 (0.3)	0	1 (0.2)
腱断裂	1 (0.3)	0	1 (0.2)
外傷性血腫	1 (0.3)	0	1 (0.2)
腎および尿路障害	9 (2.8)	8 (2.5)	17 (2.7)
腎不全	4 (1.3)	1 (0.3)	5 (0.8)
急性腎不全	1 (0.3)	3 (0.9)	4 (0.6)
腎機能障害	2 (0.6)	2 (0.6)	4 (0.6)
排尿困難	1 (0.3)	1 (0.3)	2 (0.3)
尿意切迫	0	1 (0.3)	1 (0.2)
神経因性膀胱	1 (0.3)	0	1 (0.2)
頻尿	1 (0.3)	0	1 (0.2)
耳および迷路障害	8 (2.5)	5 (1.6)	13 (2.0)
回転性めまい	3 (0.9)	4 (1.3)	7 (1.1)
耳痛	2 (0.6)	0	2 (0.3)
聴力低下	2 (0.6)	0	2 (0.3)
耳そう痒症	0	1 (0.3)	1 (0.2)
聴覚障害	1 (0.3)	0	1 (0.2)
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）	8 (2.5)	5 (1.6)	13 (2.0)
骨髄異形成症候群	2 (0.6)	2 (0.6)	4 (0.6)
基底細胞癌	2 (0.6)	1 (0.3)	3 (0.5)
皮膚有棘細胞癌	2 (0.6)	0	2 (0.3)
赤白血病	1 (0.3)	0	1 (0.2)
消化器新生物	1 (0.3)	0	1 (0.2)
乳房脂肪腫	1 (0.3)	0	1 (0.2)
表皮内悪性黒色腫	0	1 (0.3)	1 (0.2)
扁平上皮癌	1 (0.3)	0	1 (0.2)
扁桃癌	0	1 (0.3)	1 (0.2)
生殖系および乳房障害	3 (0.9)	6 (1.9)	9 (1.4)
腟の炎症	1 (0.3)	2 (0.6)	3 (0.5)
女性化乳房	1 (0.3)	1 (0.3)	2 (0.3)
良性前立腺肥大症	0	1 (0.3)	1 (0.2)
乳房痛	0	1 (0.3)	1 (0.2)
勃起不全	0	1 (0.3)	1 (0.2)
前立腺炎	1 (0.3)	0	1 (0.2)

System Organ Class (%) Preferred Term (%)	E-Ld N = 318	Ld N = 317	Total N = 635
肝胆道系障害	6 (1.9)	1 (0.3)	7 (1.1)
肝機能異常	1 (0.3)	1 (0.3)	2 (0.3)
高ビリルビン血症	2 (0.6)	0	2 (0.3)
薬物性肝障害	1 (0.3)	0	1 (0.2)
肝炎	1 (0.3)	0	1 (0.2)
肝毒性	1 (0.3)	0	1 (0.2)
免疫系障害	3 (0.9)	2 (0.6)	5 (0.8)
過敏症	3 (0.9)	1 (0.3)	4 (0.6)
低γグロブリン血症	0	1 (0.3)	1 (0.2)
社会環境	0	1 (0.3)	1 (0.2)
日常生活動作障害者	0	1 (0.3)	1 (0.2)

AE or SAE with related or missing relationship to any study drug.

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.

MedDRA 17.0

CTC Version 3.0

Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ae-ca204004.sas 14APR2015:16:18:43

APPENDIX 39　　いずれかの治験薬と関連のある有害事象（004 試験、日本人部分集団、治験薬投与例）

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31			Ld N = 29		
	ANY GRADE	Grade 3-4	Grade 5	ANY GRADE	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	30 (96.8)	23 (74.2)	0	28 (96.6)	21 (72.4)	0
一般・全身障害および投与部位の状態	20 (64.5)	1 (3.2)	0	16 (55.2)	2 (6.9)	0
発熱	10 (32.3)	0	0	4 (13.8)	1 (3.4)	0
末梢性浮腫	7 (22.6)	0	0	5 (17.2)	1 (3.4)	0
倦怠感	5 (16.1)	0	0	4 (13.8)	0	0
悪寒	2 (6.5)	0	0	0	0	0
無力症	1 (3.2)	0	0	0	0	0
疲労	1 (3.2)	0	0	3 (10.3)	0	0
全身性浮腫	1 (3.2)	1 (3.2)	0	1 (3.4)	0	0
顔面浮腫	0	0	0	1 (3.4)	0	0
感染症および寄生虫症	18 (58.1)	11 (35.5)	0	16 (55.2)	4 (13.8)	0
肺炎	9 (29.0)	6 (19.4)	0	2 (6.9)	1 (3.4)	0
鼻咽頭炎	4 (12.9)	0	0	7 (24.1)	0	0
気管支炎	3 (9.7)	0	0	4 (13.8)	1 (3.4)	0
膀胱炎	2 (6.5)	0	0	0	0	0
口腔カンジダ症	2 (6.5)	0	0	1 (3.4)	0	0
非定型マイコバクテリア感染	1 (3.2)	0	0	0	0	0
気管支肺炎	1 (3.2)	1 (3.2)	0	0	0	0
蜂巣炎	1 (3.2)	0	0	0	0	0
感染性腸炎	1 (3.2)	1 (3.2)	0	0	0	0
単純ヘルペス	1 (3.2)	0	0	0	0	0
帯状疱疹	1 (3.2)	0	0	1 (3.4)	1 (3.4)	0
インフルエンザ	1 (3.2)	0	0	0	0	0
大葉性肺炎	1 (3.2)	1 (3.2)	0	0	0	0
咽頭炎	1 (3.2)	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31 ANY GRADE	 Grade 3-4	 Grade 5	Ld N = 29 ANY GRADE	 Grade 3-4	 Grade 5
肺炎球菌性肺炎	1 (3.2)	1 (3.2)	0	0	0	0
腎盂腎炎	1 (3.2)	1 (3.2)	0	0	0	0
敗血症	1 (3.2)	1 (3.2)	0	0	0	0
手白癬	1 (3.2)	0	0	0	0	0
胃腸炎	0	0	0	3 (10.3)	0	0
ウイルス性胃腸炎	0	0	0	2 (6.9)	1 (3.4)	0
口腔ヘルペス	0	0	0	1 (3.4)	0	0
皮下組織膿瘍	0	0	0	1 (3.4)	0	0
歯感染	0	0	0	1 (3.4)	0	0
上気道感染	0	0	0	2 (6.9)	0	0
尿路感染	0	0	0	1 (3.4)	0	0
神経系障害	18 (58.1)	3 (9.7)	0	14 (48.3)	1 (3.4)	0
味覚異常	6 (19.4)	0	0	5 (17.2)	0	0
感覚鈍麻	4 (12.9)	0	0	1 (3.4)	0	0
頭痛	3 (9.7)	0	0	0	0	0
末梢性ニューロパチー	3 (9.7)	0	0	6 (20.7)	1 (3.4)	0
末梢性感覚ニューロパチー	3 (9.7)	1 (3.2)	0	3 (10.3)	0	0
傾眠	2 (6.5)	1 (3.2)	0	0	0	0
脳梗塞	1 (3.2)	1 (3.2)	0	0	0	0
認知症	1 (3.2)	0	0	0	0	0
末梢性運動ニューロパチー	1 (3.2)	0	0	0	0	0
一過性脳虚血発作	1 (3.2)	1 (3.2)	0	0	0	0
味覚減退	0	0	0	3 (10.3)	0	0
記憶障害	0	0	0	1 (3.4)	0	0
ヘルペス後神経痛	0	0	0	1 (3.4)	0	0
振戦	0	0	0	2 (6.9)	0	0
血液およびリンパ系障害	16 (51.6)	12 (38.7)	0	11 (37.9)	11 (37.9)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31 ANY GRADE	 Grade 3-4	 Grade 5	Ld N = 29 ANY GRADE	 Grade 3-4	 Grade 5
好中球減少症	9 (29.0)	7 (22.6)	0	9 (31.0)	9 (31.0)	0
貧血	6 (19.4)	2 (6.5)	0	3 (10.3)	2 (6.9)	0
リンパ球減少症	5 (16.1)	5 (16.1)	0	1 (3.4)	1 (3.4)	0
血小板減少症	3 (9.7)	1 (3.2)	0	2 (6.9)	2 (6.9)	0
白血球減少症	2 (6.5)	2 (6.5)	0	1 (3.4)	1 (3.4)	0
好酸球増加症	1 (3.2)	0	0	0	0	0
発熱性好中球減少症	0	0	0	1 (3.4)	1 (3.4)	0
皮膚および皮下組織障害	14 (45.2)	0	0	10 (34.5)	0	0
発疹	8 (25.8)	0	0	4 (13.8)	0	0
蕁麻疹	3 (9.7)	0	0	1 (3.4)	0	0
紅斑	1 (3.2)	0	0	1 (3.4)	0	0
白斑	1 (3.2)	0	0	0	0	0
そう痒症	1 (3.2)	0	0	3 (10.3)	0	0
斑状丘疹状皮疹	1 (3.2)	0	0	1 (3.4)	0	0
皮膚嚢腫	0	0	0	1 (3.4)	0	0
ざ瘡様皮膚炎	0	0	0	1 (3.4)	0	0
嵌入爪	0	0	0	1 (3.4)	0	0
丘疹性皮疹	0	0	0	1 (3.4)	0	0
胃腸障害	13 (41.9)	1 (3.2)	0	15 (51.7)	0	0
便秘	8 (25.8)	0	0	10 (34.5)	0	0
下痢	2 (6.5)	0	0	4 (13.8)	0	0
口内炎	2 (6.5)	0	0	0	0	0
嘔吐	2 (6.5)	0	0	1 (3.4)	0	0
アフタ性口内炎	1 (3.2)	0	0	0	0	0
大腸炎	1 (3.2)	1 (3.2)	0	0	0	0
胃炎	1 (3.2)	0	0	0	0	0
萎縮性胃炎	1 (3.2)	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31 ANY GRADE	 Grade 3-4	 Grade 5	Ld N = 29 ANY GRADE	 Grade 3-4	 Grade 5
歯肉腫脹	1 (3.2)	0	0	1 (3.4)	0	0
悪心	1 (3.2)	0	0	1 (3.4)	0	0
腹部不快感	0	0	0	2 (6.9)	0	0
上腹部痛	0	0	0	2 (6.9)	0	0
嚥下障害	0	0	0	1 (3.4)	0	0
胃食道逆流性疾患	0	0	0	1 (3.4)	0	0
臨床検査	12 (38.7)	3 (9.7)	0	9 (31.0)	2 (6.9)	0
血小板数減少	3 (9.7)	0	0	1 (3.4)	1 (3.4)	0
白血球数減少	3 (9.7)	2 (6.5)	0	0	0	0
腎クレアチニン・クリアランス減少	2 (6.5)	0	0	2 (6.9)	0	0
フィブリン分解産物増加	2 (6.5)	0	0	0	0	0
好中球数減少	2 (6.5)	2 (6.5)	0	1 (3.4)	1 (3.4)	0
体重減少	2 (6.5)	0	0	1 (3.4)	0	0
血中アルカリホスファターゼ増加	1 (3.2)	0	0	2 (6.9)	0	0
血中クレアチニン増加	1 (3.2)	0	0	0	0	0
血中免疫グロブリンＧ減少	1 (3.2)	0	0	0	0	0
血圧上昇	1 (3.2)	0	0	0	0	0
Ｃ－反応性蛋白増加	1 (3.2)	0	0	1 (3.4)	0	0
アラニンアミノトランスフェラーゼ増加	0	0	0	1 (3.4)	0	0
アスパラギン酸アミノトランスフェラーゼ増加	0	0	0	1 (3.4)	0	0
好中球数	0	0	0	1 (3.4)	0	0
体重増加	0	0	0	1 (3.4)	1 (3.4)	0
代謝および栄養障害	11 (35.5)	6 (19.4)	0	7 (24.1)	6 (20.7)	0
食欲減退	3 (9.7)	1 (3.2)	0	4 (13.8)	3 (10.3)	0
糖尿病	3 (9.7)	2 (6.5)	0	1 (3.4)	0	0
高血糖	3 (9.7)	2 (6.5)	0	3 (10.3)	3 (10.3)	0
低ナトリウム血症	2 (6.5)	1 (3.2)	0	1 (3.4)	1 (3.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31			Ld N = 29		
	ANY GRADE	Grade 3-4	Grade 5	ANY GRADE	Grade 3-4	Grade 5
脱水	1 (3.2)	0	0	0	0	0
高カリウム血症	1 (3.2)	0	0	0	0	0
低アルブミン血症	1 (3.2)	0	0	0	0	0
低カルシウム血症	1 (3.2)	0	0	0	0	0
低カリウム血症	1 (3.2)	1 (3.2)	0	0	0	0
低リン酸血症	0	0	0	1 (3.4)	1 (3.4)	0
呼吸器、胸郭および縦隔障害	9 (29.0)	1 (3.2)	0	10 (34.5)	1 (3.4)	0
しゃっくり	3 (9.7)	0	0	5 (17.2)	0	0
上気道の炎症	3 (9.7)	0	0	2 (6.9)	0	0
発声障害	2 (6.5)	0	0	3 (10.3)	0	0
喘息	1 (3.2)	0	0	0	0	0
低酸素症	1 (3.2)	1 (3.2)	0	0	0	0
間質性肺疾患	1 (3.2)	0	0	1 (3.4)	1 (3.4)	0
閉塞性細気管支炎	1 (3.2)	1 (3.2)	0	0	0	0
肺臓炎	1 (3.2)	0	0	0	0	0
口腔咽頭痛	0	0	0	1 (3.4)	0	0
筋骨格系および結合組織障害	7 (22.6)	1 (3.2)	0	4 (13.8)	1 (3.4)	0
筋痙縮	5 (16.1)	0	0	2 (6.9)	0	0
筋力低下	2 (6.5)	1 (3.2)	0	1 (3.4)	1 (3.4)	0
関節痛	1 (3.2)	0	0	1 (3.4)	0	0
骨壊死	1 (3.2)	0	0	0	0	0
ミオパチー	0	0	0	1 (3.4)	0	0
精神障害	7 (22.6)	1 (3.2)	0	8 (27.6)	0	0
不眠症	4 (12.9)	0	0	8 (27.6)	0	0
気分変化	2 (6.5)	0	0	0	0	0
譫妄	1 (3.2)	1 (3.2)	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31 ANY GRADE	 Grade 3-4	 Grade 5	Ld N = 29 ANY GRADE	 Grade 3-4	 Grade 5
うつ病	1 (3.2)	0	0	0	0	0
眼障害	6 (19.4)	3 (9.7)	0	8 (27.6)	3 (10.3)	0
白内障	2 (6.5)	2 (6.5)	0	5 (17.2)	3 (10.3)	0
核性白内障	1 (3.2)	1 (3.2)	0	0	0	0
結膜出血	1 (3.2)	0	0	0	0	0
眼乾燥	1 (3.2)	0	0	0	0	0
緑内障	1 (3.2)	0	0	0	0	0
近視	1 (3.2)	0	0	0	0	0
光視症	1 (3.2)	0	0	0	0	0
霧視	1 (3.2)	0	0	0	0	0
眼瞼浮腫	0	0	0	1 (3.4)	0	0
角膜炎	0	0	0	1 (3.4)	0	0
正常眼圧緑内障	0	0	0	1 (3.4)	0	0
血管障害	5 (16.1)	1 (3.2)	0	5 (17.2)	3 (10.3)	0
ほてり	3 (9.7)	0	0	1 (3.4)	0	0
深部静脈血栓症	2 (6.5)	1 (3.2)	0	2 (6.9)	2 (6.9)	0
高血圧	0	0	0	1 (3.4)	1 (3.4)	0
起立性低血圧	0	0	0	1 (3.4)	0	0
血栓症	0	0	0	1 (3.4)	0	0
内分泌障害	3 (9.7)	0	0	0	0	0
クッシング様症状	2 (6.5)	0	0	0	0	0
ステロイド離脱症候群	1 (3.2)	0	0	0	0	0
心臓障害	2 (6.5)	0	0	2 (6.9)	1 (3.4)	0
心拡大	1 (3.2)	0	0	0	0	0
動悸	1 (3.2)	0	0	1 (3.4)	0	0
心房細動	0	0	0	1 (3.4)	1 (3.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	E-Ld N = 31 ANY GRADE	 Grade 3-4	 Grade 5	Ld N = 29 ANY GRADE	 Grade 3-4	 Grade 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）	2 (6.5)	2 (6.5)	0	0	0	0
基底細胞癌	1 (3.2)	1 (3.2)	0	0	0	0
骨髄異形成症候群	1 (3.2)	1 (3.2)	0	0	0	0
腎および尿路障害	2 (6.5)	1 (3.2)	0	1 (3.4)	0	0
神経因性膀胱	1 (3.2)	1 (3.2)	0	0	0	0
頻尿	1 (3.2)	0	0	0	0	0
腎機能障害	0	0	0	1 (3.4)	0	0
肝胆道系障害	1 (3.2)	0	0	1 (3.4)	0	0
肝機能異常	1 (3.2)	0	0	1 (3.4)	0	0
生殖系および乳房障害	0	0	0	1 (3.4)	0	0
良性前立腺肥大症	0	0	0	1 (3.4)	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
AE or SAE with related or missing relationship to any study drug.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ae-sum-comb.sas 20JAN2015:04:51:58

APPENDIX 40　10%以上に認められた有害事象（1702 試験、治験薬投与例）

System Organ Class (%) Preferred Term (%)	2.5 mg/kg N = 3			5 mg/kg N = 3			10 mg/kg N = 3			20 mg/kg N = 19		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	3 (100.0)	3 (100.0)	0	3 (100.0)	3 (100.0)	0	3 (100.0)	3 (100.0)	0	19 (100.0)	14 (73.7)	0
血液およびリンパ系障害	3 (100.0)	2 (66.7)	0	2 (66.7)	2 (66.7)	0	3 (100.0)	3 (100.0)	0	15 (78.9)	4 (21.1)	0
貧血	3 (100.0)	1 (33.3)	0	2 (66.7)	1 (33.3)	0	2 (66.7)	0	0	12 (63.2)	0	0
血小板減少症	3 (100.0)	1 (33.3)	0	2 (66.7)	1 (33.3)	0	2 (66.7)	1 (33.3)	0	11 (57.9)	1 (5.3)	0
白血球減少症	1 (33.3)	0	0	1 (33.3)	0	0	3 (100.0)	1 (33.3)	0	8 (42.1)	1 (5.3)	0
リンパ球減少症	1 (33.3)	1 (33.3)	0	1 (33.3)	1 (33.3)	0	3 (100.0)	3 (100.0)	0	10 (52.6)	2 (10.5)	0
好中球減少症	1 (33.3)	0	0	1 (33.3)	0	0	2 (66.7)	1 (33.3)	0	9 (47.4)	2 (10.5)	0
胃腸障害	3 (100.0)	0	0	3 (100.0)	1 (33.3)	0	3 (100.0)	0	0	17 (89.5)	0	0
下痢	3 (100.0)	0	0	3 (100.0)	0	0	3 (100.0)	0	0	12 (63.2)	0	0
悪心	3 (100.0)	0	0	2 (66.7)	0	0	2 (66.7)	0	0	11 (57.9)	0	0
便秘	2 (66.7)	0	0	1 (33.3)	0	0	3 (100.0)	0	0	7 (36.8)	0	0
腹部ヘルニア	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
腹痛	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	3 (15.8)	0	0
上腹部痛	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
潰瘍性大腸炎	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
嘔吐	1 (33.3)	0	0	1 (33.3)	1 (33.3)	0	1 (33.3)	0	0	7 (36.8)	0	0
胃食道逆流性疾患	0	0	0	1 (33.3)	0	0	1 (33.3)	0	0	2 (10.5)	0	0
歯痛	0	0	0	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0
一般・全身障害および投与部位の状態	3 (100.0)	1 (33.3)	0	3 (100.0)	0	0	3 (100.0)	0	0	18 (94.7)	6 (31.6)	0
疲労	3 (100.0)	1 (33.3)	0	3 (100.0)	0	0	3 (100.0)	0	0	15 (78.9)	3 (15.8)	0
悪寒	2 (66.7)	0	0	0	0	0	1 (33.3)	0	0	6 (31.6)	0	0
歩行障害	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
局所腫脹	1 (33.3)	0	0	0	0	0	0	0	0	1 (5.3)	0	0
腫瘤	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
浮腫	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
発熱	1 (33.3)	0	0	0	0	0	0	0	0	9 (47.4)	0	0
顔面浮腫	0	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
注入部位紅斑	0	0	0	1 (33.3)	0	0	0	0	0	0	0	0
疼痛	0	0	0	1 (33.3)	0	0	0	0	0	4 (21.1)	0	0
代謝および栄養障害	3 (100.0)	0	0	2 (66.7)	0	0	3 (100.0)	1 (33.3)	0	16 (84.2)	5 (26.3)	0

System Organ Class (%) Preferred Term (%)	2.5 mg/kg N = 3			5 mg/kg N = 3			10 mg/kg N = 3			20 mg/kg N = 19		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
食欲減退	2 (66.7)	0	0	0	0	0	2 (66.7)	0	0	2 (10.5)	0	0
脱水	1 (33.3)	0	0	1 (33.3)	0	0	2 (66.7)	0	0	2 (10.5)	0	0
水分摂取量減少	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
高血糖	1 (33.3)	0	0	1 (33.3)	0	0	3 (100.0)	1 (33.3)	0	11 (57.9)	2 (10.5)	0
低ナトリウム血症	1 (33.3)	0	0	1 (33.3)	0	0	2 (66.7)	0	0	2 (10.5)	0	0
痛風	0	0	0	1 (33.3)	0	0	0	0	0	0	0	0
筋骨格系および結合組織障害	3 (100.0)	0	0	2 (66.7)	0	0	2 (66.7)	0	0	9 (47.4)	2 (10.5)	0
筋痙縮	1 (33.3)	0	0	0	0	0	0	0	0	1 (5.3)	0	0
筋力低下	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
筋肉痛	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
四肢痛	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	3 (15.8)	1 (5.3)	0
関節痛	0	0	0	1 (33.3)	0	0	1 (33.3)	0	0	2 (10.5)	0	0
骨痛	0	0	0	1 (33.3)	0	0	0	0	0	2 (10.5)	1 (5.3)	0
筋骨格系胸痛	0	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
筋骨格痛	0	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
神経系障害	3 (100.0)	0	0	3 (100.0)	1 (33.3)	0	3 (100.0)	0	0	15 (78.9)	3 (15.8)	0
感覚鈍麻	2 (66.7)	0	0	0	0	0	0	0	0	0	0	0
末梢性ニューロパチー	2 (66.7)	0	0	2 (66.7)	1 (33.3)	0	2 (66.7)	0	0	7 (36.8)	2 (10.5)	0
浮動性めまい	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	3 (15.8)	0	0
味覚異常	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
錯感覚	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	1 (5.3)	0	0
頭痛	0	0	0	2 (66.7)	0	0	1 (33.3)	0	0	8 (42.1)	0	0
末梢性感覚ニューロパチー	0	0	0	1 (33.3)	0	0	2 (66.7)	0	0	4 (21.1)	0	0
呼吸器、胸郭および縦隔障害	3 (100.0)	0	0	1 (33.3)	0	0	2 (66.7)	0	0	11 (57.9)	1 (5.3)	0
咳嗽	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	6 (31.6)	0	0
呼吸困難	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	6 (31.6)	0	0
労作性呼吸困難	1 (33.3)	0	0	0	0	0	0	0	0	3 (15.8)	1 (5.3)	0
湿性咳嗽	1 (33.3)	0	0	0	0	0	0	0	0	1 (5.3)	0	0
副鼻腔うっ血	1 (33.3)	0	0	0	0	0	0	0	0	2 (10.5)	0	0
鼻漏	0	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
感染症および寄生虫症	2 (66.7)	1 (33.3)	0	3 (100.0)	1 (33.3)	0	3 (100.0)	0	0	16 (84.2)	4 (21.1)	0
鼻咽頭炎	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	1 (5.3)	0	0
肺炎	1 (33.3)	1 (33.3)	0	1 (33.3)	0	0	0	0	0	5 (26.3)	1 (5.3)	0

System Organ Class (%) Preferred Term (%)	2.5 mg/kg N = 3			5 mg/kg N = 3			10 mg/kg N = 3			20 mg/kg N = 19		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
上気道感染	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	7 (36.8)	1 (5.3)	0
ウイルス性胃腸炎	0	0	0	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0
敗血症	0	0	0	1 (33.3)	1 (33.3)	0	0	0	0	0	0	0
精神障害	2 (66.7)	0	0	2 (66.7)	0	0	3 (100.0)	0	0	5 (26.3)	1 (5.3)	0
不安	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	0	0	0
うつ病	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
不眠症	1 (33.3)	0	0	1 (33.3)	0	0	1 (33.3)	0	0	3 (15.8)	0	0
落ち着きのなさ	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
心臓障害	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	2 (10.5)	1 (5.3)	0
頻脈	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	1 (5.3)	0	0
臨床検査	1 (33.3)	0	0	1 (33.3)	0	0	3 (100.0)	1 (33.3)	0	13 (68.4)	4 (21.1)	0
血中アルカリホスファターゼ増加	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	2 (10.5)	0	0
血中重炭酸塩減少	1 (33.3)	0	0	0	0	0	2 (66.7)	0	0	3 (15.8)	0	0
血中クレアチンホスホキナーゼ増加	1 (33.3)	0	0	0	0	0	1 (33.3)	0	0	1 (5.3)	0	0
血中リン増加	1 (33.3)	0	0	0	0	0	0	0	0	1 (5.3)	0	0
血中クレアチニン増加	0	0	0	1 (33.3)	0	0	0	0	0	3 (15.8)	1 (5.3)	0
血中マグネシウム減少	0	0	0	1 (33.3)	0	0	0	0	0	1 (5.3)	0	0
良性、悪性および詳細不明の新生物 (嚢胞およびポリープを含む)	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
消化器の良性新生物	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
腎および尿路障害	1 (33.3)	0	0	0	0	0	0	0	0	3 (15.8)	0	0
排尿困難	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
生殖系および乳房障害	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
陰嚢痛	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
皮膚および皮下組織障害	1 (33.3)	0	0	1 (33.3)	0	0	1 (33.3)	0	0	7 (36.8)	0	0
小水疱性皮疹	1 (33.3)	0	0	0	0	0	0	0	0	0	0	0
毛孔性皮疹	0	0	0	1 (33.3)	0	0	0	0	0	0	0	0
血管障害	1 (33.3)	0	0	2 (66.7)	0	0	1 (33.3)	0	0	5 (26.3)	0	0
低血圧	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0	2 (10.5)	0	0
起立性低血圧	0	0	0	1 (33.3)	0	0	1 (33.3)	0	0	0	0	0

System Organ Class (%) Preferred Term (%)	2.5 mg/kg N = 3			5 mg/kg N = 3			10 mg/kg N = 3			20 mg/kg N = 19		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
静脈炎	0	0	0	1 (33.3)	0	0	0	0	0	0	0	0
免疫系障害	0	0	0	1 (33.3)	0	0	1 (33.3)	1 (33.3)	0	1 (5.3)	0	0
過敏症	0	0	0	1 (33.3)	0	0	1 (33.3)	1 (33.3)	0	0	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms220688/stats/primary/prog/tables/rt-ae-ca204002.sas 12MAY20[redacted]:10:21:01

APPENDIX 41　　死亡例の一覧（004 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	1451-00225	WHITE	10 mg/kg	FEMALE	7[redacted]	アスパラギン酸アミノトランスフェラーゼ増加	2	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	5	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						薬物性肝障害	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						毛包炎	22	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アフタ性口内炎	55		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性膵炎	75	5D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						疾患進行	106	15D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						高ビリルビン血症	106	14D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						多臓器不全	112	8D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
E-LD	2400-00035	WHITE	10 mg/kg	FEMALE	6[redacted]	消化不良	1	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻部不快感	2	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	2	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	22	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	33	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	33	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	63	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	210	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	253	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頚部痛	270	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	299		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	299	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	299		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	335		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	355	53D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
E-LD	2400-00101	WHITE	10 mg/kg	MALE	5[redacted]	副鼻腔うっ血	1	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	8	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	24	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	30	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	80		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	84	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	87		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	157	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	183	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	188	125D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	196		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	201		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	272		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢不快感	356		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	395	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	456		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	457		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	467	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	467		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	467		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高カルシウム血症	467	12D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高尿酸血症	467	5D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	467	13D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						錯乱状態	477	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						傾眠	478	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疾患進行	479	31D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						低換気	479		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	2407-00198	WHITE	10 mg/kg	MALE	[redacted]	背部痛	5		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	7	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血便排泄	12	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	14	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	14	8D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	42	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	42	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	53	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	56	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外見に対する無関心	56		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	56		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蒼白	56		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ感染	57	47D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	57	121D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						局所腫脹	61	17D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						深部静脈血栓症	63	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	67	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						舌障害	85	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	109	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	112	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	139	13.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿失禁	139	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	140	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	141		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						労作性呼吸困難	148	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	150	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜痛	163	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房粗動	164		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	164	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	164	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	164	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便失禁	164	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大葉性肺炎	164	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胸水	164	76D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	164	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	164	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	165	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中カリウム減少	165	6.8H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	165	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失見当識	165	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低酸素症	165	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						四肢痛	165	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	166	19D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嚥下障害	166	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	166	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	171	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	173	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道うっ血	239	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						変色痰	239	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	308		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	368	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	392		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	411	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	448	61D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚢胞	448		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射減弱	448		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	448		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	466		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	476		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪性新生物進行	476	45D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋力低下	476		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	509		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	509		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						便秘	509		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	509		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高血圧	510		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	512		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	513		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						譫妄	513		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ビタミンB1減少	515		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	519	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4102-00327	WHITE	10 mg/kg	MALE	6[redacted]	便秘	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	2	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	8	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	15	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						関節炎	43	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	85	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	85	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	99	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	127	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	134	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	134	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	134	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	155	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	162	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	211	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	211	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	225	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上顎炎	225	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	225	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	234	12.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	273	10D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4109-00080	WHITE	10 mg/kg	MALE	7[redacted]	血中重炭酸塩減少	2	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	4	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	4	47D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発疹	8	4D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高ビリルビン血症	16	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	23	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	23	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	30	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	37	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	44	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	51	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	51	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	51	133D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	58	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	72	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過角化	83	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	86	98D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	86	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	115	97D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	115	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	115	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	115	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	128	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	128	42D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	128	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	142	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	156	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	156	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	170	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	170	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞増加症	170	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	184	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	184	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	184	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	196	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	198	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	198	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞増加症	198	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	198	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	205		NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	212	34D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	212	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	212		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	212	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉内出血	212	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	212	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						形質細胞増加症	212		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	218	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	218	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	218	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	235	30.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						口腔内出血	235	30.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						好中球減少症	236	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	246	45.6H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						無力症	246		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						血中クレアチニン増加	246	45.6H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						尿路出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						肝不全	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						悪性新生物進行	246	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						疼痛	246		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						腎不全	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						皮膚出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						精神状態変化	247		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						好中球減少症	247	23.7H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	248		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	248		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	4201-00324	WHITE	10 mg/kg	MALE	[redacted]	悪心	8	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喉頭炎	9	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	14	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	21	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	24	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	28	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上腹部痛	44	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	79		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	146		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						自殺既遂	158	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4201-00736	WHITE	10 mg/kg	FEMALE	[redacted]	下痢	3	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	9	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼出血	10	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	37D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	19	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	23	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	28	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	29	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	38	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節腫脹	51	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	66	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	92	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	103	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	107		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	175	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	227	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	229	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	252	155D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻炎	262	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						治癒不良	292	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	345	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	350	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	465	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性皮膚炎	500	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	505	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ブドウ球菌性髄膜炎	524	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4301-00622	WHITE	10 mg/kg	FEMALE	7[redacted]	悪心	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	11		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	22	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	29	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔内痛	36	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	37	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						感染	43	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	43	9D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						振戦	46	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	48	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	48	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	48	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						動悸	48	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	57	73D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	70	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	84	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	98	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	112	29D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						眼乾燥	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	140		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位腫脹	154	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	158	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	168		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						死亡	186	17.6H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4404-00433	WHITE	10 mg/kg	FEMALE	7[redacted]	食欲減退	1	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	15	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	38	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	42	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						動悸	71		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸水	71	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	74	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	78	48.0H	RELATED	GRADE 4	AE	DOSE REDUCED	
						挫傷	85	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	91		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	100		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						全身健康状態低下	104		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						敗血症	108	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4409-00640	OTHER	10 mg/kg	MALE	[redacted]	貧血	1	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球数減少	1	57D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	29	55D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						表在性血栓性静脈炎	29	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異常感覚	43	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	50	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	57	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						硬結	59	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔気管支炎	62	38D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	99	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	103	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭部損傷	103	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	103	25D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節痛	113	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						異常感覚	113	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						平衡障害	141		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						難聴	141	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	184	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	184	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						認知障害	213		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	213	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異常感覚	213		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	256	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疾患進行	262	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4414-00462	WHITE	10 mg/kg	FEMALE	8[redacted]	末梢性浮腫	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	13	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上腕骨骨折	14	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						低カリウム血症	36	3D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						下痢	227		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	265		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						肺障害	267	13D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4600-00082	WHITE	10 mg/kg	MALE	8[redacted]	貧血	1	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	1	30M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性感覚ニューロパチー	1	54D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	6	16.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	15	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	21	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	22	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	29	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	29	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	29	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	29	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	36	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	36	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	43	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	50	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	50	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	50	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	50	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	5D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	50	5D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						大動脈瘤破裂	54	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4600-00274	WHITE	10 mg/kg	MALE	8[redacted]	貧血	1	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	1	709D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	1	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1	66D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	9	91D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23	687D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	44	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	51	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	67	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	72	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	72	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	100	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性感覚ニューロパチー	100	266D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	135	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	142	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	142	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	142	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	156	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	170	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	184	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	198	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	198	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	213	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	213	497D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	213	41D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	213	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	226	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	228	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	240	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	240	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	269	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	269	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	269	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	269	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	296	126D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	310	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	323	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	323	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	323	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	338	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	349	10D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高カリウム血症	352	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	380	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	380	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	380	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	394	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高窒素血症	408	302D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	408	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	408	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	422	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	422	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	436	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	436	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	436	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	450	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高カリウム血症	499	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	499	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	506	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	520	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	520	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	534	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	548	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	548	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	548	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	562	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	562	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	562	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	576	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	576	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	590	120D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	604	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						γ－グルタミルトランスフェラーゼ増加	604	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	604	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	618	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	618	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	618	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	639	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	639	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	639	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	639	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	646	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	646	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	646	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	674	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	674	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	674	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	688	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	688	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	688	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯乱状態	696		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						肺炎	696	14D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4600-00363	WHITE	10 mg/kg	FEMALE	[redacted]	アラニンアミノトランスフェラーゼ増加	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	1	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	1	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	1	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高リン酸塩血症	8	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	15	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	15	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	16	98D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	18	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	22	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	29	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	36	64D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	36	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カルシウム血症	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	36	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	43	72D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	43	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	50	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	71	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カルシウム血症	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	86		NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						貧血	100	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	100	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	100	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症性ショック	114	10M	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4602-00426	WHITE	10 mg/kg	MALE	4[redacted]	貧血	2	99D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	2	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	9	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	24	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	37	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	37	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	44	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	58	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	80	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	212	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	239		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	239		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	239		NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	240	26D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4602-00458	WHITE	10 mg/kg	MALE	8[redacted]	貧血	5	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心房細動	5	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						心房細動	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	9	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	20	18D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	25	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	27	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	30	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	30	168D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	37	34D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	37	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性運動ニューロパチー	43	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	43	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	49	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	50	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性運動ニューロパチー	50	21D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						尿路感染	62	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						痛風	63	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	64	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	64	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋力低下	70	9D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性運動ニューロパチー	70	9D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	78	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	78	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	192	41.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						回転性めまい	195	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	197	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						憩室炎	270	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腹痛	301	14D	NOT RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						悪性新生物進行	353	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4702-00440	WHITE	10 mg/kg	MALE	5[redacted]	関節炎	2	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	178	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	293	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	303		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症	618	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4901-00531	WHITE	10 mg/kg	FEMALE	7[redacted]	血中尿酸増加	11	15D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						疲労	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	18	8D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						血中アルブミン減少	30	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	30	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	142	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	142	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						血中アルブミン減少	170	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ブドウ糖増加	226	290D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便失禁	257		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	318		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	350	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低アルブミン血症	366	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	393	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低換気	410	124D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺の悪性新生物	412	122D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						無力症	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						処置による疼痛	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	464	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	471		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						ラ音	478		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	493	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低アルブミン血症	506		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	532	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						全身健康状態低下	532	48.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4902-00173	WHITE	10 mg/kg	MALE	6[redacted]	咳嗽	1	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	1	83D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	6	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	31	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	45	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	45	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	45	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	52		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						食欲減退	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						感覚鈍麻	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	52	32D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						口内炎	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						振戦	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疾患進行	73	85D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						体液貯留	81	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						汎血球減少症	90	19D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	5006-00343	WHITE	10 mg/kg	FEMALE	7[redacted]	好中球減少症	43	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	43	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	57	32D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						尿路感染	101	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	127	126D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	141	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						無力症	217	36D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						肺炎	240	13D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5200-00309	WHITE	10 mg/kg	MALE	8[redacted]	高血糖	54	4D	RELATED	GRADE 3	AE	DOSE REDUCED	
						血小板数減少	324	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	336	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支肺炎	351	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	380		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	492		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	492		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中乳酸脱水素酵素増加	492		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						C－反応性蛋白増加	496	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						粘膜出血	496	17D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						下痢	511	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	526	12D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						髄膜腫	526		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
E-LD	5202-00232	WHITE	10 mg/kg	MALE	7[redacted]	鼻咽頭炎	10	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	10	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	16	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	16	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	29	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	57	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球減少症	113	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	113	30D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球減少症	141	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	175	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリン分解産物増加	182	422D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	198	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	225	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	248	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	280	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	281	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	323	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	351	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	407	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	449	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	477	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	490	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	491	13.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	497	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	535	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	561	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						皮膚潰瘍	561	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	571		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	589	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心雑音	589		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	589	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	617	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	645	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	645	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	648	68D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	659	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	671	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中甲状腺刺激ホルモン減少	673	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	701		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心内膜炎	703	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	715	1.5H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	715	9D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	729	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	729	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	729	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低アルブミン血症	743	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	743	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口の錯感覚	783	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	785	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	792	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	797	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	799	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	799	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	799		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	806	24.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	827	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	828	48.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	841		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	869		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	870	39D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5202-00619	WHITE	10 mg/kg	FEMALE	6[redacted]	上気道感染	4	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	9	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	9	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	96	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	112	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	127	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支炎	135	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						敗血症性ショック	157	15D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	176	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	197	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支肺アスペルギルス症	197	42D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	197		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						慢性閉塞性肺疾患	198		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺アスペルギルス症	239	94D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	253	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血糖症	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	253	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	267	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	267	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	267	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	281	71D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	281	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	295	111D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	295	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	309	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	309	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	323	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	323	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						挫傷	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	337	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	337		RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	351	39D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支肺アスペルギルス症	351		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						低アルブミン血症	351	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	351	134D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	351		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳アスペルギルス症	389		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						尿路感染	405	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	502		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						疾患進行	511	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5204-00441	WHITE	10 mg/kg	FEMALE	[redacted]	背部痛	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	377	10D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						糸球体濾過率減少	603	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						疾患進行	652	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5204-00744	WHITE	10 mg/kg	FEMALE	[redacted]	体重増加	15	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顆粒球減少症	29	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顆粒球減少症	36	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気圧性中耳炎	45	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	80	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	155	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267	38.2H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	339	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	341	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	388	41.9H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	425	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	473	18D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	501	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5208-00568	WHITE	10 mg/kg	MALE	[redacted]	胆管炎	5	23D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	11	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	15	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	17	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	19	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	33	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	35	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝損傷	35	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	84		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耐糖能障害	84		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	109	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	112		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	112	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	130	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	190	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5208-00569	WHITE	10 mg/kg	MALE	5[redacted]	貧血	7	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						好中球減少症	7	17D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						血小板減少症	7		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						咽頭炎	8	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	11	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	46	16.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	58	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ節症	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						咳嗽	79	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	79	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	79		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	91	35D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						好中球減少症	91		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	99		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						大腿骨頚部骨折	107		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
E-LD	5208-00618	WHITE	10 mg/kg	MALE	7[redacted]	貧血	7	64D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	28	72D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	29	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	68		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	71		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高カリウム血症	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	194	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5303-00516	WHITE	10 mg/kg	FEMALE	6[redacted]	下痢	73	14D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						下痢	96	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	101		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	UNKNOWN
						敗血症	117	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						細菌性尿路感染	117	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	5501-00241	WHITE	10 mg/kg	FEMALE	8[redacted]	鼻漏	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	24	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	29	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	50	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	141	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	197	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	207	47D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支痙攣	323	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	323	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	323	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	379	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	387	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	393	43D	RELATED	GRADE 2	AE	DOSE REDUCED	
						斑状出血	407	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	421	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	435	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	435	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	449	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	477	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	491	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	505	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疼痛	505	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	533		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	547	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	575	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内不快感	624		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	637	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心肺停止	672	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5501-00339	WHITE	10 mg/kg	MALE	[redacted]	貧血	-24	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-24	5D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-3	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肝機能検査異常	7	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	7	8D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	7	14.7H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	8	13.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔カンジダ症	9	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	13	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血腫	19	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	26	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	33	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	40		NOT RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						霧視	40	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	47	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低血圧	47	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	47	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	54	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	54		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	68	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	68		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	82		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	96		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						両耳難聴	138		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	138		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						四肢痛	138		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	152		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	152	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	166		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	187		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						腎前性腎不全	187	12D	NOT RELATED	GRADE 5	SAE	DRUG INTERRUPTED	FATAL
						膿瘍	195		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5505-00076	WHITE	10 mg/kg	MALE	6[redacted]	関節痛	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	1	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	1	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	2	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	15	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	23	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	30		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	30		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						振戦	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痙攣	99	9D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	105	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	134	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	169	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						夜間頻尿	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	184		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	194	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血便排泄	194	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	197	48.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						無力症	197		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	197		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	197		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	199	25.6H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	201	3D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						背部痛	202		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	204		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						骨痛	204		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						微小血管症性溶血性貧血	206	6D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						消化器新生物	209	3D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5801-00635	WHITE	10 mg/kg	MALE	7[redacted]	振戦	1	15M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						膀胱移行上皮癌	15	12.2H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED /RESOLVED
						蒼白	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	49	84D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						真菌性肺炎	50	45D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						呼吸窮迫	150	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5801-00682	WHITE	10 mg/kg	FEMALE	6[redacted]	疲労	1	321D	RELATED	GRADE 1	AE	DOSE REDUCED	
						蒼白	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						インフルエンザ	39	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼡径部痛	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	91		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	106		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	106		RELATED	GRADE 1	AE	DOSE REDUCED	
						尿路感染	134	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						大腸穿孔	145	289D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	321		RELATED	GRADE 2	AE	DOSE REDUCED	
						肺塞栓症	458	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺塞栓症	463	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5900-00151	WHITE	10 mg/kg	FEMALE	[redacted]	腎機能障害	1	2D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						疲労	3	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	3	739D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	5	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	5	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	8	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	8	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	8	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	11	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	12	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	22	720D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	720D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔咽頭痛	33	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	39	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咽頭炎	39	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ミオパチー	50	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						ミオパチー	71	181D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						直腸出血	75	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	602D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	155	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	155	587D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	199	543D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						後天性涙道狭窄	209		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	246		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ミオパチー	252	490D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	271		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	292		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	292		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	292	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	310	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	320	15D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	320	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						大腸菌検査陽性	320	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	320	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	322	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						運動性低下	420	322D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紫斑	448		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	454		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	454	288D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	459	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	463	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						菌血症	472		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	472	270D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	472		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	502	240D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化管運動障害	533		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	547	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	564		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	594	148D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	640	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	648		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	659	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	700	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	700		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	732	9D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						腎不全	732	10D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
E-LD	5903-00584	WHITE	10 mg/kg	MALE	[redacted]	振動覚低下	1	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	2	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						重感	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	4	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	4	21.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	5	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	5	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	9	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	17	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	42		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肉離れ	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	68	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	93	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	98	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						RS ウイルス感染	99	26D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性浮腫	113	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	124	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	134		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						形質細胞性骨髄腫	169	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5905-00730	WHITE	10 mg/kg	FEMALE	7[redacted]	皮膚反応	1	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	15	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	15	99D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	15	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	22	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	22	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	29	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	36	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	58	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	58		RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						背部痛	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	106	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	113	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	6014-00036	ASIAN	10 mg/kg	MALE	7[redacted]	ほてり	1	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝機能異常	4	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						しゃっくり	9	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	14	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	35	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	183	99D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	189		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						心拡大	239	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	252	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	253	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	271	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨髄異形成症候群	281	605D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						齲歯	348	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	397	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	398		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	400	24D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支炎	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肋骨骨折	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	428		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	429		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	458		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	462	116D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	1442-00667	WHITE	0	FEMALE	5[redacted]	脊椎圧迫骨折	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心房細動	27	18D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						背部痛	27	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸困難	27	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	27	28D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カルシウム血症	28	102D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	28	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多尿	28	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	31		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	36	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						菌血症	48	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	48	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	48	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	48	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	67	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	83	13D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						敗血症性ショック	83	13D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カルシウム血症	85	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	85	8.8H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低血圧	85	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	86	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	87	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						嘔吐	87	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	92	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	126	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	126	37.4H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎	126		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						敗血症	126	5D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						不整脈	127	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	127	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	129	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	1480-00630	WHITE	0	FEMALE	8[redacted]	悪心	5	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	8	14.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	15	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	15		RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	20	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	24	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	36		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	43	2D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						転倒	45	22.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	56		RELATED	GRADE 2	AE	DOSE REDUCED	
						ヘモグロビン減少	56	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	71	28.0H	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						胃腸出血	86	2D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	106	1M	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2400-00113	WHITE	0	MALE	6[redacted]	記憶障害	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						陰嚢血瘤	4	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	4	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	5	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	5	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	5	28.4H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	6	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	8	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	10	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	12	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高ビリルビン血症	13	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	18	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	29	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						耳感染	46	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	49	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	90D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	64	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	68	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	70	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症	113	28D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カルシウム血症	139		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	140		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疾患進行	140	56D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						傾眠	140		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	140	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	2403-00030	WHITE	0	MALE	8[redacted]	貧血	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格硬直	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	2	26D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						側腹部痛	6	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	6	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻閉	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	16	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	16	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	19		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	19	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	20		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	21		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	21		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	24	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	26		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	26		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	28	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	36	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	40		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	40		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						食欲減退	43		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	43		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	49	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2405-00326	WHITE	0	MALE	6[redacted]	悪寒	6	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	6		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						寝汗	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	21		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	26	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	28	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	43	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	43	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	49		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	60	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心筋虚血	60	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性心筋梗塞	99	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						心筋梗塞	122		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						急性腎不全	122	13D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2405-00448	BLACK OR AFRICAN AMERICAN	0	FEMALE	7[redacted]	便秘	2	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	2	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	2	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	16	20D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嚥下障害	17	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	17	17D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節腫脹	17	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	17	17D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	17	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	17	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	17	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	22	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	12D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						急性腎不全	22	12D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						嘔吐	22	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	23	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	36	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	37	27D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						嘔吐	37	27D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						貧血	51	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	51	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	64		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	64		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	124		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						急性腎不全	124	53D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	2407-00016	WHITE	0	MALE	7[redacted]	尿閉	18	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	18	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	19		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻尿	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	49	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹部膨満	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						間代	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	130	10D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	147	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	150	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	150	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	154		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						陰茎浮腫	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						陰嚢浮腫	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	159	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	159		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						貧血	160	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胸水	162		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム検査陽性	164		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						不安	166		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	166		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	168		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪性新生物進行	171	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2407-00219	WHITE	0	MALE	6[redacted]	嚢胞	71	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	238		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	365	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	369		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						譫妄	370	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						髄膜転移	370	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2407-00590	WHITE	0	MALE	6[redacted]	貧血	6	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	13	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						無力症	14		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪床出血	14	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	20	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	27	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	27	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	35	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						蜂巣炎	35	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						表在性血栓性静脈炎	35	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	40		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	48	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	66		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	66	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	66		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸時疼痛	66	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	67	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						レンサ球菌性菌血症	67	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿閉	67		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	68	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	69		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	70	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道うっ血	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						構語障害	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血便排泄	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚変色	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	74		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	74		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	75	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	76		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	77		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	77		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	78		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						落ち着きのなさ	79		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	80		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便失禁	80	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	80	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	81	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						十二指腸胃逆流	81	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肛門周囲痛	81		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	82		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	83	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結腸腺癌	84	251D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						貧血	84	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						水分過負荷	87	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	87		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	88		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	89	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	90	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カルシウム増加	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	91	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊髄圧迫	91		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						低マグネシウム血症	94	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	95	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	124	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	3400-00161	WHITE	0	MALE	6[redacted]	黄色板腫	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	105	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	112		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心筋虚血	123	8D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						気管支肺炎	130	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	3400-00179	WHITE	0	MALE	6[redacted]	関節痛	5		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						そう痒症	5	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	26	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	101	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	114	433D	RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	125	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失語症	181	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高コレステロール血症	193		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						緑内障	277		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	301		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性冠動脈症候群	318	4D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						滑液包炎	360		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	450		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						扁桃潰瘍	464	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						扁桃癌	493	335D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
LD	4100-00683	WHITE	0	MALE	8[redacted]	発熱	7	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	45	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	62	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	62	24D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	85	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	99		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	124	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	127	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	155	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	169	8D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						浮腫	253	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大赤血球症	281	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	365	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害者	463		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	477		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	533	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	574	32D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4200-00641	WHITE	0	FEMALE	[redacted]	関節痛	-9	35D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						カテーテル留置部位感染	1	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	8	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路感染	15	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	20	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外傷性骨折	42		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						骨髄炎	64	56D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						疾患進行	112	9D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4201-00589	WHITE	0	FEMALE	7[redacted]	ウイルス感染	35	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	36	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	41	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	41	22D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	44	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	65	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	99	162D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	29D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	134	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	176	34D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	210	16D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	212	33D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	255	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺塞栓症	280	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血栓性静脈炎	348	11D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						静脈血栓症	348	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支炎	369		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						塞栓症	369		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						左室不全	369		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						尿路感染	370	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	398	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4414-00457	WHITE	0	MALE	7[redacted]	貧血	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カルシウム血症	1	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚びらん	9		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	8D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	58	41D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						肝機能異常	58		NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						腎不全	58		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
LD	4511-00252	OTHER	0	FEMALE	4[redacted]	口腔ヘルペス	6	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	50	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	283	11D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4512-00059	WHITE	0	MALE	6[redacted]	貧血	-2	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	-2	37D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	-2	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	-2	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	-2	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	1	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	15	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	22	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	29	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	43	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	71		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	71	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	71	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ニューモシスチス・イロベチイ肺炎	71	9D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						発熱	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	71	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	73	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	74	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	74	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	75	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	76	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	77	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	78	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	78	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79	15.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79	32.9H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	79	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	80	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	80	24.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	4600-00078	WHITE	0	MALE	7[redacted]	貧血	2	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	2	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	2	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	2	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	8	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	75	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	85	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	85	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	85	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						イレウス	98		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						閉塞性臍径ヘルニア	98		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
						血中クレアチニン増加	99	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高カリウム血症	99	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	99	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						敗血症性ショック	104	12.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4601-00680	WHITE	0	FEMALE	6[redacted]	気管支炎	-18	10D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/RESOLVED
						血中カルシウム減少	9		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	10	12.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						左室機能不全	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						一過性脳虚血発作	15	5D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/RESOLVED
						貧血	26		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	26		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	40		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	40		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下部消化管出血	47	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上部消化管出血	47	4D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	51	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	51	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						漿膜炎	52	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						頭蓋脳損傷	155	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						交通事故	155	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						軟部組織損傷	155		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/NOT RESOLVED
LD	4601-00689	WHITE	0	MALE	[redacted]	貧血	-2	28.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	8		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	10	40.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	11	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	11	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	14	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						食欲減退	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						嘔吐	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	30	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	47	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	69	9.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						軟部組織損傷	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	104		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯感覚	104		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	109	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	192	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺塞栓症	203	46.0H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						脳出血	213	31D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4601-00691	WHITE	0	FEMALE	8[redacted]	糸球体濾過率	1	7D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器細菌感染	6	10D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	13	44D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器感染	41	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						膀胱炎	58	10D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中クレアチニン	77	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	79	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	79	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	93	41D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	105	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	119		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	148	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	148	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	148	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	162		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カリウム血症	177	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	204	69D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器感染	218	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						尿路感染	218	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン	219	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	246	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	288	83D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	316	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失禁	344		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	344		NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						尿路感染	344	20D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						血中クレアチニン	366	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	374	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	400		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	400	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	466	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	470	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	475	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心停止	589	11.5H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4700-00322	WHITE	0	MALE	5[redacted]	貧血	8		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						急性腎不全	8	15D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	8		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腫瘍崩壊症候群	8	14D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	11	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						敗血症	34	34D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4700-00520	WHITE	0	FEMALE	5[redacted]	敗血症	7	16D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4702-00460	WHITE	0	MALE	7[redacted]	副腎機能不全	1	84D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	7	15.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	12	372D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	107		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副腎機能不全	167	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						気管支炎	169	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						丹毒	236	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						丹毒	266	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢動脈狭窄	266		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	333	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	364	24.5H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	511	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部ヘルニア	513		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	532	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						錯乱状態	542		RELATED	GRADE 1	AE	DOSE REDUCED	
						白内障	570		RELATED	GRADE 3	AE	DOSE REDUCED	
						結膜炎	570	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						橈骨骨折	581	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	606		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	616	10.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚損傷	647	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	658		RELATED	GRADE 2	AE	DOSE REDUCED	
						死亡	691	17.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4901-00191	WHITE	0	MALE	7[redacted]	高血糖	2	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	4	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	9	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	16	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	16	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耳痛	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	35	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	36	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	50	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	56	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	63	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	69		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						発熱	73	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	75		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪性新生物進行	75	17D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺炎	75		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						尿路感染	82	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心房細動	85	24.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4901-00404	WHITE	0	FEMALE	8[redacted]	下痢	2	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	20	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	43	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	53	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	78	10D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	92	102D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	92	12D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	103	46D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	154	39D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	154	20D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						咽頭炎	154	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃潰瘍	168	12D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	182	12D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4901-00656	WHITE	0	MALE	6[redacted]	鼻咽頭炎	8	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	16		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	21	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム増加	38	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	39		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	39		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	44	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	51	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	61	3D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	67	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	67	76D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	69	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	72	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発疹	72		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	72	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	74	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	77	5D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	77	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	81	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	81	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	86	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	93	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	93	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	100		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	102		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						意識消失	125	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白内障	131	94D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	149	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	153	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	156	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	156	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	161	39D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	161	5D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	161	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	185	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	191	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	191	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	199	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	213	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼充血	224		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	227	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	241	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	255	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	269	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	297	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	326	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	326	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	338	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	352	17D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	369	19D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	369		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						疾患進行	387	4D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4903-00192	WHITE	0	MALE	7[redacted]	貧血	1	24.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	25.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	51	4D	RELATED	GRADE 4	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						好中球減少症	57	42D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	82		RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	85	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	96	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	99	8D	RELATED	GRADE 1	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						好中球減少症	102	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	106	7D	RELATED	GRADE 4	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱性好中球減少症	113	29.2H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	127	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	141	5.1H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	155	5D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						貧血	166	5.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	183		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						ヘモグロビン減少	183	12D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						呼吸困難	185	9D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症	185	10D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						痛風	188	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	195	1.5H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5003-00469	WHITE	0	MALE	8[redacted]	下痢	1	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	8	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨盤痛	18	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	19	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	21	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	22	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	64	23D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	66	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	66	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	101	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						C－反応性蛋白増加	107	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	129	613D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	129	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	131	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	134	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	157	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	163	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	164	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	170	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	182	20D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高血圧	182	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	185	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血尿	193		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	196	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	196	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	210	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	210	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	254	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	424	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	465	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	470	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	479	9D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						平衡障害	505		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	522		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	550	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	568	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺塞栓症	569	9D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿閉	570	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	599	98D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	620		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭炎	648	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	662	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						複視	678	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	680	39D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	690	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	718		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	742	47D	RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5005-00230	WHITE	0	MALE	6[redacted]	起立性低血圧	39	12.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	127	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						毛細血管脆弱	169	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	170	30D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						悪性新生物進行	182	18D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	5007-00369	WHITE	0	MALE	6[redacted]	貧血	1	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	147D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	43	33.6H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	44	3D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	85	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	85	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	113	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	127	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	197	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	211	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	240	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	281	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	281	42D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	294	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	309	112D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	323	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						静脈炎	330	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	351	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	365	57D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						無力症	393		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						貧血	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	504	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	536		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	547		RELATED	GRADE 1	AE	DOSE REDUCED	
						鼻出血	692		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	692		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腸出血	700	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5010-00398	WHITE	0	MALE	7[redacted]	発熱	4	29D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	8	26D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						軸索型ニューロパチー	26		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	30		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	43	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	47	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	78	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	169	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疾患進行	246	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5014-00519	WHITE	0	MALE	6[redacted]	心房細動	6		NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						悪寒	6	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	6	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						呼吸困難	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						乏尿	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						肺臓炎	6		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						肺塞栓症	6	29.8H	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	6	48.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸性アルカローシス	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						敗血症性ショック	6		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						頻脈	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球数減少	7	24.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						白血球数減少	7	24.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
LD	5200-00126	WHITE	0	FEMALE	7[redacted]	気管支炎	-17	11D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	113	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	183	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	197	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						高尿酸血症	197	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支肺炎	204	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	239	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	253		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支肺炎	332	4D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5204-00349	WHITE	0	FEMALE	7[redacted]	糸球体濾過率減少	15	182D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						糸球体濾過率減少	197	56D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	200	53D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	252	4.5H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5204-00371	WHITE	0	MALE	7[redacted]	肺炎	215	25D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						形質細胞性骨髄腫	510	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5208-00645	WHITE	0	MALE	5[redacted]	医療機器関連感染	-15	7D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	8	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	21	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	50	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						耐糖能障害	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	50	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	8D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	50	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	57	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	57	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	71		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中カルシウム減少	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	71		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	71		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						不全対麻痺	73		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						脊椎圧迫骨折	73		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						疾患進行	117	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5302-00223	WHITE	0	FEMALE	7[redacted]	咽頭炎	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						尿路感染	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						間質性肺疾患	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	85	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	92	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	104	122D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	127	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	155	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞腫	183	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞腫	197	35D	NOT RELATED	GRADE 5	SAE	DRUG INTERRUPTED	FATAL
						血栓性静脈炎	197	35D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞腫	205	27D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	215	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						対麻痺	226	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞腫	230	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	5303-00141	WHITE	0	MALE	6[redacted]	尿路感染	1	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	23	100D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	49	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	57	154D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	85	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	148	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	211	28D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肥満	211		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	225		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	239	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	253		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨血管腫	367	33D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腹痛	413	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腹膜炎	417	22D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5303-00528	WHITE	0	MALE	5[redacted]	錯感覚	37	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						原発巣不明の悪性新生物	43	32D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5501-00342	WHITE	0	MALE	7[redacted]	浮動性めまい	21	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	29	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	34	8D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	113		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	131		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	153	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	153	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	155	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不整脈	202	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨盤痛	225		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						激越	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	253	5D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ラ音	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						縮瞳	274	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳症	283	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5501-00557	WHITE	0	MALE	7[redacted]	発疹	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	22	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	50	177D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚潰瘍	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	71	9D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	71	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						臨床検査異常	71	9D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	71	10D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	99	63D	RELATED	GRADE 1	AE	DOSE REDUCED	
						呼吸困難	106		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カルシウム血症	106	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						蜂巣炎	117		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	117	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱水	127	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心不全	162	8D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						腎不全	162	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気道感染	172	19D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						心不全	190	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血腫	190		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	190	134D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸不全	190	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	191	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気道感染	201	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	218	106D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不安	223	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	223	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	227	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心不全	227	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低血圧	227	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎不全	227	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口腔カンジダ症	239	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	260		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						喀血	260	8D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						出血性素因	260	8D	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						貧血	267		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						痔出血	267	15D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						皮膚剥脱	267		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	269	3D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						全身健康状態低下	288		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						発熱	295	18D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心不全	355	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5501-00671	WHITE	0	MALE	5[redacted]	貧血	8		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	29	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/RESOLVED
						血中クレアチニン増加	45	27D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5503-00423	WHITE	0	MALE	7[redacted]	不安	7		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	20	22.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						失神寸前の状態	21	3.3H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						好中球減少症	42	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						関節痛	70	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	98	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	98		RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						気道感染	103	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						敗血症性ショック	124	8D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血尿	132	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	140	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	140	10D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症性ショック	146	14D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						形質細胞性骨髄腫	161	18D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						敗血症性ショック	161		RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
LD	5504-00300	WHITE	0	FEMALE	7[redacted]	無力症	8	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	8	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	8	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻出血	13	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高血糖	13	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	13	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						点状出血	13	24.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	14	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	16	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	16	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	16	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	16	5D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	21	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	21	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高血糖	36	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	36	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	36	19D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	48	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						不整脈	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	48	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	48	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	48	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋虚血	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	48	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	55	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	55	4D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	57	54D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	59	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	59	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	59	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気道感染	61	24D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	64	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	64	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	64	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	64	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	71	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	78	69D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	78	69D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	85	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	85	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	85	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	85	36D	NOT RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						心拍数増加	98	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	106	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	106	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	118	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	121	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	121	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	129	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	129	18D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	134	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	134	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	142	5D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						白血球減少症	142	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	142	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	146	11.8H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5801-00562	WHITE	0	FEMALE	5[redacted]	貧血	8	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼部腫脹	27	45D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	29	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	35	7.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	43	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	43	14D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	48	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疾患進行	72		NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5900-00290	WHITE	0	MALE	5[redacted]	高血糖	1	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	23		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	23	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	29	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎仙痛	50	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	85	51D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	113		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	136	33D	RELATED	GRADE 2	AE	DOSE REDUCED	
						くしゃみ	156		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	169		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	193	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	193		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						硬膜下血腫	253	15D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5907-00148	WHITE	0	MALE	6[redacted]	徐脈	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	8	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	8	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	10	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	10	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎臓痛	11	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	12	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	15	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	15	4D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						徐脈	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性腎不全	15	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	15	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	16	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	17	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚感染	19	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アスパラギン酸アミノトランスフェラーゼ増加	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	22	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	23	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	23	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚感染	24	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	43	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	43	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性腎不全	43	44D	NOT RELATED	GRADE 2	AE	DOSE INCREASED	
						血小板減少症	43	44D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	68	53D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ミオパチー	68	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	99	57D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	113	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	113	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						慢性腎不全	113	43D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	141	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						結膜出血	149	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	155	24D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						慢性腎不全	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	178	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	180	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	182	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	183	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	183	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	183	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	183	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	183	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	187	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	189	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	191	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	207	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	225	36D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	248	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	248	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	253	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	253	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	254	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中リン減少	260	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	260	8D	RELATED	GRADE 1	AE	DOSE REDUCED	
						血小板減少症	260	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267	183D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	281	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	309	126D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	351	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	351	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	351	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	393	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	413	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	413	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	422	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血圧	435	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	435	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	446		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	478	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	488	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯感染	520		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯牙破折	530		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	536	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	561		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						下痢	561	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	571	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	603	48.0H	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						血小板減少症	605	12D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血小板減少症	617		RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						骨髄異形成症候群	632	207D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						気管支肺炎	820	19D	RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5910-00588	WHITE	0	MALE	6[redacted]	悪寒	3	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	39	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	50	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	50	108D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	51	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	85		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	85	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	87	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	87		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	141		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						体重増加	143		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	154	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	164	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	167	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	190	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	192	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						小脳症候群	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼振	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモジデリン沈着症	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	302	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	323	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	325	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	443	35D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						神経皮膚炎	449		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋梗塞	523	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	6008-00042	ASIAN	0	MALE	6[redacted]	下痢	33	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	33	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	65		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						高尿酸血症	65		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						発熱	70	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	82	0S	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
NOT TREATED	2401-00264	WHITE		MALE	8[redacted]	脱水			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						硬膜下血腫		13.4H	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
NOT TREATED	5011-00374	WHITE		MALE	6[redacted]	形質細胞性骨髄腫		11D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺臓炎		11D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

APPENDIX 42　　死亡例の一覧（1703 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
10 mg/kg	2404	WHITE	10 mg/kg	Female	[redacted]	貧血	1	8 D	E,L	GRADE 2	AE	NONE
						悪寒	8	1 D	E	GRADE 1	AE	NONE
						靱帯捻挫	15	1 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	29	8 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	71	CONT.	NOT RELATED	GRADE 1	AE	NONE
						口腔カンジダ症	95	5 D	E,L	GRADE 1	AE	NONE
						背部痛	113	113 D	NOT RELATED	GRADE 1	AE	NONE
						季節性アレルギー	123	5 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	141	85 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	226	56 D	NOT RELATED	GRADE 2	AE	NONE
						背部痛	226	56 D	NOT RELATED	GRADE 2	AE	NONE
						四肢痛	261	3 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	264	CONT.	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	267	23 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	281	43 D	NOT RELATED	GRADE 2	AE	NONE
						疲労	290	3 D	NOT RELATED	GRADE 2	AE	NONE
						疲労	292	CONT.	NOT RELATED	GRADE 1	AE	NONE
						口内炎	295	15 D	E,L	GRADE 2	AE	NONE
						下痢	309	27 D	NOT RELATED	GRADE 1	AE	DELAYED
						ウイルス感染	330	22 D	NOT RELATED	GRADE 1	AE	DELAYED
						下痢	335	3 D	NOT RELATED	GRADE 3	AE	DELAYED
						好中球減少症	339	6 D	E,L	GRADE 3	AE	NONE
						湿性咳嗽	347	5 D	NOT RELATED	GRADE 1	AE	NONE
						ほてり	348	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	358	1 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	359	CONT.	NOT RELATED	GRADE 1	AE	NONE
						痔核	359	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	365	CONT.	NOT RELATED	GRADE 3	AE	NONE
						胃腸出血	374	21 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						代謝性アシドーシス	374	4 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						心房細動	376	19 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						急性腎不全	376	19 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						消化管穿孔	416	6 D	NOT RELATED	GRADE 5	SAE	NONE
						代謝性アシドーシス	419	3 D	NOT RELATED	GRADE 5	SAE	NONE
10 mg/kg	2412	WHITE	10 mg/kg	Female	[redacted]	寝汗	2	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	6	1 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	13	CONT.	NOT RELATED	GRADE 1	AE	NONE
						便秘	18	7 D	L,D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						悪心	24	2 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	39	4 D	D	GRADE 2	AE	NONE
						副鼻腔炎に伴う頭痛	41	10 D	NOT RELATED	GRADE 1	AE	NONE
						寝汗	42	2 D	D	GRADE 1	AE	NONE
						発声障害	45	41 D	D	GRADE 1	AE	NONE
						疲労	45	5 D	D	GRADE 2	AE	NONE
						霧視	45	41 D	D	GRADE 1	AE	NONE
						貧血	50	22 D	L	GRADE 2	AE	NONE
						悪心	54	2 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	66	5 D	D	GRADE 2	AE	NONE
						寝汗	68	2 D	D	GRADE 1	AE	NONE
						発疹	69	31 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	71	1 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	73	27 D	L,D	GRADE 2	AE	NONE
						低カリウム血症	85	15 D	NOT RELATED	GRADE 3	AE	NONE
						低カリウム血症	99	15 D	NOT RELATED	GRADE 1	AE	NONE
						血小板減少症	99	36 D	L	GRADE 1	AE	NONE
						味覚異常	106	CONT.	D	GRADE 1	AE	NONE
						貧血	113	8 D	E,L	GRADE 2	AE	DELAYED
						低カリウム血症	113	8 D	NOT RELATED	GRADE 3	AE	NONE
						好中球減少症	113	8 D	E,L	GRADE 3	AE	DELAYED
						下痢	120	141 D	L	GRADE 1	AE	NONE
						好中球減少症	120	29 D	L	GRADE 1	AE	NONE
						末梢性浮腫	127	36 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	176	15 D	L	GRADE 2	AE	NONE
						好中球減少症	176	15 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	190	15 D	L	GRADE 3	AE	NONE
						血小板減少症	190	15 D	L	GRADE 3	AE	NONE
						貧血	204	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	204	15 D	L	GRADE 2	AE	NONE
						血小板減少症	204	42 D	L	GRADE 1	AE	NONE
						貧血	218	CONT.	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	218	15 D	NOT RELATED	GRADE 3	AE	NONE
						霧視	226	CONT.	D	GRADE 1	AE	NONE
						低カリウム血症	246	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	246	36 D	L	GRADE 2	AE	NONE
						血小板減少症	246	22 D	L	GRADE 2	AE	NONE
						疲労	253	15 D	L,D	GRADE 2	AE	NONE
						食欲減退	260	CONT.	L,D	GRADE 1	AE	NONE
						下痢	260	464 D	L,D	GRADE 1	AE	NONE
						低カリウム血症	260	8 D	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						白血球数減少	260	8 D	L	GRADE 3	AE	DELAYED
						疲労	267	276 D	L,D	GRADE 1	AE	NONE
						血小板減少症	267	15 D	L	GRADE 3	AE	NONE
						好中球減少症	281	15 D	L	GRADE 3	AE	NONE
						好中球減少症	295	57 D	L	GRADE 2	AE	NONE
						好中球減少症	351	43 D	L	GRADE 3	AE	NONE
						血小板減少症	365	15 D	L	GRADE 3	AE	NONE
						鼻出血	372	8 D	L	GRADE 1	AE	NONE
						歯肉出血	372	8 D	L	GRADE 1	AE	NONE
						嘔吐	382	1 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	393	43 D	L	GRADE 2	AE	NONE
						血小板減少症	393	71 D	L	GRADE 2	AE	NONE
						上気道感染	403	18 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	435	71 D	L	GRADE 3	AE	NONE
						血小板減少症	463	14 D	L	GRADE 1	AE	NONE
						血小板減少症	477	99 D	L	GRADE 2	AE	NONE
						貧血	491	29 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	505	127 D	L	GRADE 2	AE	NONE
						疲労	513	49 D	L,D	GRADE 3	AE	DELAYED
						血小板減少症	575	15 D	L	GRADE 3	AE	NONE
						血小板減少症	589	CONT.	L	GRADE 1	AE	NONE
						好中球減少症	645	99 D	L	GRADE 2	AE	NONE
						低カリウム血症	701	29 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	724	2 D	D	GRADE 3	AE	NONE
						咳嗽	765	7 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	841	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	925	29 D	L	GRADE 2	AE	NONE
						疲労	925	29 D	E,L,D	GRADE 3	AE	DELAYED
						疲労	953	CONT.	E,L,D	GRADE 1	AE	NONE
						関節痛	1142	CONT.	NOT RELATED	GRADE 1	AE	NONE
						転倒	1182	1 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1185	21 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	1281	CONT.	E,L,D	GRADE 2	AE	DELAYED
						敗血症	1297	16 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
20 mg/kg	4002	WHITE	20 mg/kg	Male	7[redacted]	下痢	1	1 D	NOT RELATED	GRADE 1	AE	NONE
						しゃっくり	8	26 D	D	GRADE 1	AE	NONE
						四肢痛	8	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	35	1 D	NOT RELATED	GRADE 1	AE	NONE
						記憶障害	36	15 D	NOT RELATED	GRADE 1	AE	NONE
						発疹	49	2 D	NOT RELATED	GRADE 1	AE	NONE
						悪寒	77	2 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	77	18 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	77	2 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	94	49 D	NOT RELATED	GRADE 1	AE	NONE
						発疹	114	7 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	142	6 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	165	22 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	167	6 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	170	17 D	NOT RELATED	GRADE 2	AE	NONE
						紅斑	170	17 D	E	GRADE 2	AE	NONE
						疲労	170	17 D	E,L,D	GRADE 2	AE	NONE
						色素沈着障害	170	17 D	E	GRADE 2	AE	NONE
						皮膚亀裂	226	14 D	E,L,D	GRADE 1	AE	NONE
						霧視	226	14 D	L,D	GRADE 1	AE	NONE
						下痢	253	CONT.	L	GRADE 1	AE	NONE
						皮膚乾燥	253	16 D	L,D	GRADE 2	AE	NONE
						末梢性浮腫	253	16 D	L,D	GRADE 1	AE	NONE
						皮膚乾燥	268	57 D	L,D	GRADE 1	AE	NONE
						健忘	350	CONT.	D	GRADE 1	AE	NONE
						斑状出血	422	81 D	D	GRADE 1	AE	NONE
						筋骨格硬直	422	CONT.	L,D	GRADE 1	AE	NONE
						創傷	422	85 D	NOT RELATED	GRADE 1	AE	NONE
						引っかき傷	436	14 D	NOT RELATED	GRADE 1	AE	NONE
						非心臓性胸痛	492	29 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	604	50 D	NOT RELATED	GRADE 1	AE	NONE
						創合併症	611	36 D	D	GRADE 2	AE	INTERRUPTED
						悪寒	624	19 D	NOT RELATED	GRADE 1	AE	NONE
						錯乱状態	624	37 D	NOT RELATED	GRADE 2	AE	NONE
						食欲減退	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						倦怠感	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	627	20 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						貧血	632	43 D	NOT RELATED	GRADE 1	AE	NONE
						瞳孔不同	632	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腎不全	632	15 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	639	CONT.	NOT RELATED	GRADE 1	AE	NONE
						擦過傷	639	4 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	639	8 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚剥脱	639	CONT.	NOT RELATED	GRADE 2	AE	NONE
						筋骨格痛	646	CONT.	NOT RELATED	GRADE 1	AE	NONE
						錯乱状態	660	40 D	NOT RELATED	GRADE 3	SAE	NONE
						腎不全	699	1 D	NOT RELATED	GRADE 5	SAE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
20 mg/kg	4007	WHITE	20 mg/kg	Female	[redacted]	頭痛	1	3 D	D	GRADE 1	AE	NONE
						悪心	2	21 D	E	GRADE 1	AE	NONE
						落ち着きのなさ	2	2 D	D	GRADE 1	AE	NONE
						食欲減退	8	22 D	L	GRADE 1	AE	NONE
						疲労	8	2 D	E,L	GRADE 2	AE	NONE
						記憶障害	8	8 D	D	GRADE 1	AE	NONE
						不安	15	15 D	D	GRADE 1	AE	NONE
						無力症	15	2 D	E,L,D	GRADE 1	AE	NONE
						うつ病	15	15 D	D	GRADE 1	AE	NONE
						便秘	16	8 D	D	GRADE 1	AE	NONE
						上腹部痛	18	3 D	NOT RELATED	GRADE 1	AE	NONE
						浮動性めまい	18	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	19	5 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	22	8 D	NOT RELATED	GRADE 2	AE	NONE
						上腹部痛	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	37	2 D	NOT RELATED	GRADE 2	AE	NONE
						悪心	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	40	18 D	NOT RELATED	GRADE 2	AE	NONE
						体重増加	50	8 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	57	85 D	E,L,D	GRADE 3	AE	NONE
						咳嗽	60	CONT.	NOT RELATED	GRADE 1	AE	NONE
						水疱	71	71 D	NOT RELATED	GRADE 2	AE	NONE
						痂皮	71	CONT.	NOT RELATED	GRADE 2	AE	NONE
						四肢痛	85	15 D	NOT RELATED	GRADE 1	AE	NONE
						灼熱感	99	1 D	E,L	GRADE 1	AE	NONE
						筋痙縮	99	43 D	E,L	GRADE 1	AE	NONE
						血中ブドウ糖増加	111	CONT.	L,D	GRADE 3	AE	NONE
						多汗症	127	28 D	L,D	GRADE 1	AE	NONE
						発疹	127	8 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	133	30 D	D	GRADE 1	AE	NONE
						麦粒腫	139	3 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	141	29 D	E,L,D	GRADE 1	AE	NONE
						末梢性ニューロパチー	155	197 D	L	GRADE 1	AE	NONE
						皮膚変色	168	2 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	169	CONT.	L,D	GRADE 2	AE	NONE
						霧視	218	8 D	D	GRADE 1	AE	NONE
						頭痛	251	3 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	253	8 D	D	GRADE 2	AE	NONE
						上気道感染	253	8 D	NOT RELATED	GRADE 2	AE	NONE
						うつ病	393	CONT.	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	393	CONT.	E,L,D	GRADE 1	AE	NONE
						四肢痛	393	CONT.	NOT RELATED	GRADE 1	AE	NONE
						背部痛	418	6 D	NOT RELATED	GRADE 3	AE	DELAYED
						感覚鈍麻	435	CONT.	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	469	8 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
						肺炎	469	8 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						多臓器不全	471	6 D	NOT RELATED	GRADE 4	SAE	INTERRUPTED
						敗血症	471	6 D	NOT RELATED	GRADE 4	SAE	INTERRUPTED
						多臓器不全	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
						肺炎	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
						敗血症	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED

APPENDIX 43　　投与終了後 60 日以内の死亡理由の内訳（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31	Ld N = 29	Total N = 60
NUMBER OF SUBJECTS WHO DIED WITHIN 60 DAYS OF LAST DOSE	0	1 (3.4)	1 (1.7)
PRIMARY CAUSE OF DEATH:			
DISEASE	0	1 (3.4)	1 (1.7)
STUDY DRUG TOXICITY	0	0	0
INFECTION	0	0	0
OTHER MALIGNANCY/NEOPLASM	0	0	0
CARDIOVASCULAR DISEASE	0	0	0
FATAL BLEEDING	0	0	0
OTHER	0	0	0
UNKNOWN	0	0	0

Includes death within 60 days of last dose.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-dt-60.sas　　21JAN2015:10:52:34

APPENDIX 44　　死亡例の一覧（009 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-BD	4901-00059	WHITE	10 mg/kg	FEMALE	[redacted]	貧血	1	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	4	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	12.6H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	12	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	19	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔内出血	19	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						直腸出血	19	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	19	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	22	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻出血	25	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	25	3D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	28	4D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	32	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	32	39D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						血小板減少症	32		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						貧血	37	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	45		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	46	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎感染	46		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	47	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	58		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	4930-00018	WHITE	10 mg/kg	FEMALE	[redacted]	血小板減少症	32	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	36	28D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	36	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						咳嗽	41	2D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	41	2D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	49	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						急性腎不全	130	9D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-BD	4943-00106	WHITE	10 mg/kg	MALE	[redacted]	発熱	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	29	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	33	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	33	71D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						貧血	46	58D	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						疲労	46	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	50	54D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						間質性肺疾患	64	39D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						悪性新生物進行	103	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-BD	4946-00101	WHITE	10 mg/kg	FEMALE	[redacted]	高尿酸血症	-8	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	1	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	4	154D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	8	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	21	137D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	21	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	32	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	39	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	39	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クッシング様症状	66	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						眼窩周囲浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						骨痛	71	87D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	96	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	96	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高クレアチニン血症	96	62D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	99	59D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						真菌性肺炎	102	56D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-BD	4962-00086	WHITE	10 mg/kg	FEMALE	[redacted]	下気道感染	7	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	22	260D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	32	18D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	34	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹痛	35	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	68	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						坐骨神経痛	105	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	116	33D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	130		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	365	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	456	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腎不全	565	22D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						貧血	566	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
BD	1927-00125	BLACK OR AFRICAN AMERICAN	0	FEMALE	5[redacted]	振戦	7	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	11	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋肉痛	11	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	11	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	15	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	22	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	22	48.0H	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板数減少	22	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎不全	23	90D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	23	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	24	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	24	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	25	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	26	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	29	3D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						頭痛	32	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	32	46D	RELATED	GRADE 3	AE	DOSE REDUCED	
						肺炎	38	35D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						呼吸音異常	72	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口唇乾燥	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	72	41D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	112		NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	1927-00168	BLACK OR AFRICAN AMERICAN	0	MALE	7[redacted]	筋骨格系胸痛	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	11	13D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						顎痛	11		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴力低下	19		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						第７脳神経麻痺	19		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	23	44D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4905-00149	WHITE	0	FEMALE	[redacted]	関節痛	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単ニューロパチー	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	1	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	4	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						インフルエンザ	20	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	22	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脂肪腫	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	29	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	29	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	32	4D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	36		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	50	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	55		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	59	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	64	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	68		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						変形性関節症	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歩行障害	125	9D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	167	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4905-00179	WHITE	0	FEMALE	[redacted]	貧血	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						細菌性腎盂腎炎	20	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						硬膜下血腫	36	19D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						肺炎	43		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
BD	4915-00082	OTHER	0	MALE	[redacted]	無力症	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	29	10D	RELATED	GRADE 1	AE	DOSE REDUCED	
						心肺停止	38	54M	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4934-00103	WHITE	0	MALE	[redacted]	高血圧	1	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性肺水腫	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						関節炎	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						悪心	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	51	14D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性腎不全	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						敗血症	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頻脈	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪性新生物進行	73	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4934-00112	WHITE	0	FEMALE	[redacted]	貧血	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	1	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	1	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	8	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	11	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	11	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	11	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						麻痺性イレウス	14	43D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板数減少	14	43D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						敗血症	56	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4942-00075	WHITE	0	MALE	[redacted]	白血球減少症	1	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	1	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						そう痒症	2	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	2	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	8	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	26	46.5H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	29	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	32	10D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	43	2D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	46	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	53	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	53	10D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	64	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						発熱	78	36D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						肺炎	88	9D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						形質細胞性骨髄腫	109	6D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4947-00068	WHITE	0	FEMALE	5[redacted]	筋骨格痛	1	267D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身性皮疹	23	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	32	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	43	173D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	64	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	64	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	85	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	132	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	138	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	145	10D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼痛	154	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	171	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	172	96D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	201	14D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高カルシウム血症	215	27D	NOT RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						腎不全	215	23D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						敗血症性ショック	267	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4962-00042	WHITE	0	FEMALE	[redacted]	悪心	4	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	4	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	14	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	14	31.3H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心肺停止	19	24.0H	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						胃腸出血	19	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
NOT TREATED	1984-00147	WHITE		FEMALE	[redacted]	貧血			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						脳損傷		4D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺炎			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NOT TREATED	4945-00155	WHITE		MALE	[redacted]	心停止		22M	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						心不全			NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						肺炎		9D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱		5D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

APPENDIX 45　　重篤な有害事象を発現した被験者の一覧（004 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	1403-00224	WHITE	10 mg/kg	FEMALE	[redacted]	疲労	3	698D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	7	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	19	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	19	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎痛	56	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	57	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	57	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	69	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						薬剤離脱症候群	75		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	85	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	113		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	113	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	121	49D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						呼吸困難	121	20D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						喘鳴	121	20D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	124	17D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						倦怠感	124	17D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						口腔咽頭痛	124	17D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	124	17D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						不安	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	144	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	195	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	196	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						びまん性脱毛症	224		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	229	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	252		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	252		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	257	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	273	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	344	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	356		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	363	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	400	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	415	466D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	418	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	428		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	428	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	431		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	431	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胸痛	433		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼の異常感	437		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	442	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	484		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						耳痛	501	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	501	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						両耳難聴	581		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	584	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						認知障害	586	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	597	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便失禁	610	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	636	40D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	638	24.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼充血	638		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	672	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	676	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	680	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	682	177D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性呼吸不全	683	8D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						頭痛	683	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヒトライノウイルス検査陽性	683	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カリウム血症	683	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						A 型インフルエンザウイルス検査陽性	683	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔咽頭痛	683	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	683	47D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						喀痰培養陽性	683	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						点状出血	684	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	686	24.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低リン酸血症	687	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	699	175D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	701	139D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	701	180D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	732	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						耳垢栓塞	742	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クッシング様症状	754		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						妄想症	754		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	761		RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	767	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	820		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食中毒	826	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	831	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	840		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						記憶障害	845		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	859	30M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紫斑	859	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	873		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嵌入爪	873		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	881	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	881	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	881	21D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	887	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	887	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	901		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1403-00271	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	7[redacted]	不安	-1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	10	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	12	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						バニオン	29	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	29	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	33	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	39	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格硬直	141	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						汎血球減少症	141		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	169	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	182		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃腸障害	182		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化管浮腫	182		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	212	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性胸水	235	4D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						形質細胞腫	247	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
E-LD	1405-00037	WHITE	10 mg/kg	MALE	6[redacted]	口内炎	50	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	68	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	68	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	75	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	112		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	226	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	292	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						斑状出血	820	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	820	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	995	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	997		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ヘモグロビン減少	1008	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	1406-00757	WHITE	10 mg/kg	FEMALE	[redacted]	貧血	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	1	11.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	1	1.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	1	9.0H	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						眼部腫脹	4	18D	RELATED	GRADE 1	AE	DOSE REDUCED	
						発疹	4	18D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	8	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	8	1.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	9	15.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	9	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	10	19.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	12	3.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	22	7D	RELATED	GRADE 1	AE	DOSE REDUCED	
						低カリウム血症	22	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	22	630D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	22		RELATED	GRADE 1	AE	DOSE REDUCED	
						排尿困難	28	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	36	1.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クロストリジウム検査陽性	46	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	57	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						斑状出血	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	57	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低カリウム血症	57	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	83	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	85	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	85	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	85	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	92	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	95	3.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	96	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	99	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	258	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	291	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	291	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						気管支拡張症	295	57D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発疹	353	3D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性浮腫	374	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	421	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	449	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	495	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	506		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性鼻炎	514	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	519		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	645	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	650	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	652	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	652	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	673	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	673	4.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	688	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	688	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道咳症候群	688	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1414-00033	WHITE	10 mg/kg	MALE	6[redacted]	胸痛	1	30.3H	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-LD	1414-00108	WHITE	10 mg/kg	FEMALE	6[redacted]	味覚異常	31		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	58		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	58		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	58		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	68	269D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	85	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						陰部ヘルペス	131		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	141	29D	RELATED	GRADE 3	AE	DOSE REDUCED	
						貧血	169		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	169		RELATED	GRADE 2	AE	DOSE REDUCED	
						陰部ヘルペス	184	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	197	170D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	248	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頭痛	277	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	336	60D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	336	44D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						失神	359	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						体重減少	366	532D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	395	167D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感情不安定	505	29D	RELATED	GRADE 3	AE	DOSE REDUCED	
						注入部位血管外漏出	519	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						上腹部痛	561	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	561		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						挫傷	575	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	673		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	673		RELATED	GRADE 2	AE	DOSE REDUCED	
						アレルギー性鼻炎	673		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚢胞	730	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ビタミンB12欠乏	730		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	785		RELATED	GRADE 1	AE	DOSE REDUCED	
						血中クレアチニン増加	841		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	846	24D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻閉	846	24D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						体重減少	897		RELATED	GRADE 3	AE	DOSE REDUCED	
						尾骨痛	948	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	967	17D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	1414-00319	WHITE	10 mg/kg	FEMALE	[redacted]	不眠症	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	25	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	43	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	43		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	51	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	58	148D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒性皮疹	85	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	113	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	190	36D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性浮腫	206		RELATED	GRADE 2	AE	DOSE REDUCED	
						異型肺炎	262	50D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						深部静脈血栓症	280	32D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋力低下	280	86D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	311	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感情不安定	383	11D	RELATED	GRADE 2	AE	DOSE REDUCED	
						蜂巣炎	393	57D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	393	225D	RELATED	GRADE 3	AE	DOSE REDUCED	
						創傷	408	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	415	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	421	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	428	22D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	588	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多尿	591	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	591	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						乳癌	633		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
E-LD	1416-00377	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	5[redacted]	悪心	5	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	7	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス異常	7	42D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						ヘモグロビン減少	7	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	7	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	7	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	7		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	10	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	10		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	10		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	10	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	12	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	14	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	14	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	21	8D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						低アルブミン血症	21	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	21	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	23	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	23	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻漏	23	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	26	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ヘモグロビン尿	26	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	26	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蛋白尿	26		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	26	3D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						頻脈	26	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血糖症	27	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	27	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	27	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中クレアチニン増加	28	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘルペスウイルス感染	28	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	28	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	31	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	34	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	34	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	50	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	55	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						悪心	55	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嘔吐	55	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	56	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱水	56	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						ヘモグロビン減少	56	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	56	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	56	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球数減少	56	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	57	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	63		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	63		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	63	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	63	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	71	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	71	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	71	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	74	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	74	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	77		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1418-00597	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	悪寒	1	14M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						呼吸困難	1	14M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	2	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	11	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	11		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体部白癬	16	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	20	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	20	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス性消化管感染	25	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	28	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						複視	31	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	37	9D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	38	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸困難	41	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	45	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋力低下	46	31D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						ウイルス感染	46	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	48	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	48	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	48	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	48	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胸痛	52	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	53	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	55	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	55	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	56	93D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚髄神経根障害	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	70	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	70	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	83	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	97	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	97	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	113	55D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	114	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	126		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	127	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	141	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	168	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	168	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	195	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	195		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食中毒	208	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	223	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	223	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	240		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	251	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面損傷	260	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面損傷	265	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	279	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	296	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	307	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	307	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	335	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	350		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	364	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	377	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	391	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	391	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	413	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	420	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	420	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上気道感染	421	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	428	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	434	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	434	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	461	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	478	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	478	54D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	491	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	504	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	522	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	530	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	532	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	559	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	574	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	574	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無気肺	602		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	612	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	630	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	631	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	640	26D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	643	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	657	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支反応性亢進	658	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支反応性亢進	660	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支反応性亢進	670		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	671	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						性器びらん	680		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	685	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	685	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格痛	689	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	689	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	690	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	699		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	699		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大腿骨骨折	701		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	1427-00553	WHITE	10 mg/kg	MALE	[redacted]	低アルブミン血症	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	8	235D	RELATED	GRADE 2	AE	DOSE REDUCED	
						リンパ球減少症	15	182D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						そう痒性皮疹	19	93D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	22	90D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	49	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						基底細胞癌	78	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						挫傷	111		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	134	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	166	59D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	171	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	173	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						脱水	174	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	174	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低酸素症	174	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						トロポニン増加	174	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	175	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	189		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	196		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低リン酸血症	217	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	224	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	231	37D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	243	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発声障害	252		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注射部位血腫	252		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	257	48.0H	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	259		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						点状出血	267	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心室不全	267	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	268	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	270	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1438-00009	WHITE	10 mg/kg	MALE	6[redacted]	口内乾燥	1	1042D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口渇	1	951D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	8	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	27		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	69	974D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	81	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	111	686D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下気道感染	144	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	334		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						健忘	365		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アフタ性口内炎	434	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	434	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	434	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	467	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔障害	479	166D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						歯肉潰瘍	533	506D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下気道感染	555	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カルシウム血症	589	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	603	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	623	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	631	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	701	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	715	124D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肋骨骨折	729		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻の炎症	754	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	780		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胆嚢炎	788	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カルシウム血症	788	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	788	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肝機能検査異常	788	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	788	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	788	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	791	238D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	792		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						活動性低下	792	237D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	805	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	811		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	840	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低血圧	855	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	869	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	871	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	883		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	889		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	889	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	896	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球減少症	911	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	938	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	939		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	1438-00051	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	7[redacted]	貧血	-4	3D	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						脱水	-4	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高カルシウム血症	-4	5D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	5	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路感染	7	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	10	20D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	10	454D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	10		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	14	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	16	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	41	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	44	420D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	271	12.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	450	4D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						胃腸出血	450	4D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-LD	1442-00485	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	6[redacted]	筋骨格系胸痛	1	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	4	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸障害	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分動揺	57	29D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	64	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カテーテル留置部位発疹	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	162		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	162		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	169		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	175		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	193		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	225		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	225	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	239	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						流涙増加	281		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ビタミンＤ欠乏	281		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	309	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	309		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疼痛	365		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クッシング様症状	393		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	393	309D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	405		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	405		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	505	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	536		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	561		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	617		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						成長障害	648	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	648	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	659	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	785		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1443-00008	WHITE	10 mg/kg	FEMALE	4[redacted]	筋力低下	1	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	1	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	12	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	12	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	38		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	38	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	48	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	58		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	80	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	84	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	85	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	106	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	143		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	170	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	170	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	187	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						処置による疼痛	211	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	218	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	218	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	218	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	359	119D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	409	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	421		RELATED	GRADE 3	AE	DOSE REDUCED	
						肺炎	512	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	1443-00017	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	疲労	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	4		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内乾燥	7		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	31	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	50		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	132	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	132	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	198	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神寸前の状態	219	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	335	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						咳嗽	366	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	366	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	670	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	681	170D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	851		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白内障	852		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	852		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	869	21D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						顎痛	883		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	883		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	897	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	1448-00620	WHITE	10 mg/kg	MALE	5[redacted]	振戦	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	4	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	4	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	4	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	4	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	5	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						医療機器関連感染	8	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	10	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	10	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	11	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚静脈血栓症	15	485D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血尿	28	211D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	36	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	49	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔感染	57	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	64	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	67	577D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	78	58D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						筋骨格系胸痛	107		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						アレルギー性鼻炎	148		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	177	62D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低γグロブリン血症	210		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	295		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	324	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						インフルエンザ様疾患	324	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頻脈	326	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	383	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	383	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	407		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	447	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肝腫大	468		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯周病	477	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	487		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	490	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	492	98D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	493	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鎖骨骨折	504		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	521	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	521	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	554		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上肢骨折	563	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						接触性皮膚炎	575	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	588	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	589		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	600	11D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	641	10D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						関節痛	643		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	643		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルブミン減少	643	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ	643	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	643	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	643	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	643	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						洞性頻脈	643	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	643	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルブミン減少	644	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心雑音	644	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ヘモグロビン減少	644	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	644		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						国際標準比	644		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						国際標準比増加	644	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球数減少	644		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	644	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						蛋白尿	644		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	645	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	645		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	645	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						国際標準比増加	645	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	645	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ	646		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	646	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	647	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	647	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	648	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	649	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	649	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	649	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	649	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板数減少	650	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	659	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	659	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	659	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	664	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	664		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	671		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	671	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	671		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	678		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	1451-00225	WHITE	10 mg/kg	FEMALE	7[redacted]	アスパラギン酸アミノトランスフェラーゼ増加	2	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	5	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						薬物性肝障害	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						毛包炎	22	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アフタ性口内炎	55		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性膵炎	75	5D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						疾患進行	106	15D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						高ビリルビン血症	106	14D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						多臓器不全	112	8D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	1466-00654	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	4[redacted]	非心臓性胸痛	17	112D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	20		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	20	109D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	20	94D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格硬直	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	20	66D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	20	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻尿	20	94D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	20	94D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	22	44.2H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋骨格痛	22	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋骨格痛	25		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	36	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	36	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	36	78D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	36	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	37	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	38	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	100	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	100		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性胃腸炎	124	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	155	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	156		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	198		RELATED	GRADE 1	AE	DOSE REDUCED	
						霧視	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入部位血管外漏出	338	11.6H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						局所腫脹	338	11.6H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						悪心	366	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	450	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口唇損傷	514	21D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	1477-00378	WHITE	10 mg/kg	FEMALE	5[redacted]	高血糖	2		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						回転性めまい	3	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	9	142D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳不快感	9	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	9	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	9		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	11	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	11	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内痛	11	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	11	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	12	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	14	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	16	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	16	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	19	48.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						慢性閉塞性肺疾患	19	48.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	20	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						難聴	23	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	23		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頭痛	23	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	23	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	30	323D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	44	54D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	51	100D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	79	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ラ音	86	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	94	18D	RELATED	GRADE 3	AE	DOSE REDUCED	
						頭痛	100	15.4H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	111	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	207	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	207	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	210	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	210	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	237	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	249	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口唇炎	254	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	254	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣びらん	254	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						側腹部痛	284	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						片耳難聴	324		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	338	85D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	343		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	367	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身性皮疹	367	21D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発疹	402	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	422		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						帯状疱疹	430	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身性皮疹	430	21D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						発疹	452	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	482		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	491	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	491	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	501	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	501	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	520	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	543		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	544	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	578	132D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	578	125D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	586	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	587	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						裂孔ヘルニア	611		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						狭心症	618		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	618		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上室性頻脈	618	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						2型糖尿病	618		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	639	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						眼圧検査異常	642		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	644	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	671	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	703	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						動悸	703	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	1477-00406	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	[redacted]	体重減少	2	117D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	3		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	3	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	3	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	9	120D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	12		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	15	188D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	16		RELATED	GRADE 4	AE	DOSE REDUCED	
						末梢性ニューロパチー	18		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	18		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	23	149D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈不全	23		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頭痛	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	37	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼡径部痛	44	128D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	50	79D	RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						食欲減退	51	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	51		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						咳嗽	64	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	68	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	68	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						温度変化不耐症	68	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	72		RELATED	GRADE 2	AE	DOSE REDUCED	
						口腔咽頭痛	79	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	79	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼刺激	142	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	172	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	180	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						記憶障害	202		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	220		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ジストニア	233	385D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ジストニア	233	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠時無呼吸症候群	233		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頭痛	260	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	278	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	294		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	317	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						回転性めまい	323	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	331	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中免疫グロブリンG減少	372	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	372	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	372	25M	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	394	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	444	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中免疫グロブリンG減少	527	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						治癒不良	528	90D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						縫合	528	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中免疫グロブリンG減少	597	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	597	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	597	1.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚潰瘍	611	61D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	618	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						血中免疫グロブリンG減少	625	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血尿	632	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中免疫グロブリンG減少	667	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	674	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	769	32D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中免疫グロブリンG減少	786	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	786	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
E-LD	1481-00334	WHITE	10 mg/kg	MALE	8[redacted]	疲労	2	189D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注入に伴う反応	2	11.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	3	580D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	10	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	10	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	10	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	10	105D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	10	4.6H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	10	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	16	71D	RELATED	GRADE 2	AE	DOSE REDUCED	
						四肢痛	16	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	19	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	23	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	33	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						無力症	37	154D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						振戦	37	8D	RELATED	GRADE 2	AE	DOSE REDUCED	
						体重減少	37	64D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	39	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	44	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低血圧	44	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	44	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	63	23D	RELATED	GRADE 2	AE	DOSE REDUCED	
						血中クレアチニン	64	380D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	72	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	86	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	86	603D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	86	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	114	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	128	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	128	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	128	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	156	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	156	78D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	156	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	184		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	184	314D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	184	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	184	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	184	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	184	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	191	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	191	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	205	267D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	205	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脂漏性角化症	219	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	233	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	233	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	261	428D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	289	140D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	295	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	317	155D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	317		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	331	47D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						頚部痛	332	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	345	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	345	127D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	345	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚嚢腫	350	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	350	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	400	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	406	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						副鼻腔炎	427	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	429	140D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	441	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	452		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	461	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	468	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	470	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	471	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	471	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	471	29D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	471	29D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						粘膜の炎症	471	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	499		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	499		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	499	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	541	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔カンジダ症	541	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	545	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	568	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						落ち着きのなさ	568		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	583	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯乱状態	583		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	583	28D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						関節痛	598		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	611	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	611	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	611	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	625	64D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	630	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上気道感染	661	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	675	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	688		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	2400-00035	WHITE	10 mg/kg	FEMALE	6[redacted]	消化不良	1	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻部不快感	2	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	2	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	22	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	33	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	33	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	63	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	210	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	253	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頚部痛	270	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	299		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	299	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	299		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	335		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	355	53D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
E-LD	2400-00101	WHITE	10 mg/kg	MALE	5[redacted]	副鼻腔うっ血	1	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	8	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	24	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	30	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	80		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	84	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	87		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	157	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	183	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	188	125D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	196		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						深部静脈血栓症	201		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	272		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢不快感	356		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	395	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	456		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	457		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	467	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	467		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	467		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高カルシウム血症	467	12D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高尿酸血症	467	5D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	467	13D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						錯乱状態	477	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						傾眠	478	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疾患進行	479	31D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						低換気	479		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	2400-00484	WHITE	10 mg/kg	MALE	5[redacted]	痔瘻	-15	4D	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						浮動性めまい	3	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	5	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	5	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	5	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	5	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	9	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	15	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	16	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	24		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						直腸出血	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	32	169D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	32	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	33	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	35	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	36	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	39	195D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	44	12M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	50	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	52	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸周囲膿瘍	54	204D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	130	63D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						国際標準比増加	141	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						直腸出血	141	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	146	187D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	164	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						頭痛	174	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	176	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	182	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	193	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	193	194D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	208	95D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	225	51D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	230	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	240	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	247	73D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	247	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸周囲膿瘍	257	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	289	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	289	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	303	27D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						食欲減退	310	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	313	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	330	67D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	330		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	333	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	346	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	346	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	355	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	359	55D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	375	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	375	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	383		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	383		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	390	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	397	54D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	414		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	416	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	419	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	438	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脊髄圧迫	438		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						背部痛	440	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	2400-00655	WHITE	10 mg/kg	MALE	[redacted]	動悸	2	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	4	114D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	9	46D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	9	185D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	10	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	11		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						片頭痛	21	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	72	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	76	112D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	76	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	101		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	109	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	109	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分動揺	161	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気分動揺	175		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	183	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	183	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	188	48D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	188		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	218	24.0H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						頭痛	225	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	236		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	241		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	271		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	276		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	277	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						健忘	311		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	312	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						胸痛	338		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	368	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不整脈	389		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						労作性呼吸困難	389		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	2403-00021	WHITE	10 mg/kg	FEMALE	3[redacted]	発熱	1	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	2	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	9	119D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	9		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口の錯感覚	15	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	19	109D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	21	30D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	44	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	46	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	50	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	50	302D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	66	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	71	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						乳房痛	71	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	87		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	87		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	87	467D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	87	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	87	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	93	230D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	99	78D	RELATED	GRADE 1	AE	DOSE REDUCED	
						背部痛	102	221D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	124	53D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	204	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	280	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						片頭痛	281		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	288	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						夜間呼吸困難	308	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	322	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	322	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	337	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						反射消失	344		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	367		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	389		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	460	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	519	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						骨痛	540		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	540		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	540		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口の感覚鈍麻	544		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	552	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	2403-00022	WHITE	10 mg/kg	MALE	6[redacted]	鼻咽頭炎	2	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	11	157D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	12	212D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	14		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	21		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	28	140D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋攣縮	48		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	79	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	80	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	80	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	104	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	104	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	105	63D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	105	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	109	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	109		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不整脈	112	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						四肢痛	113	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	120	104D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	122	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	122	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	122	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	133	91D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	140	183D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	168	266D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	180	100D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	195	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	196	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	217	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	252	182D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	252		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	252	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	259	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						点状出血	260	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	271		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						裂傷	329	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	334	100D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	336	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						点状出血	336		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	349	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	361	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	362	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	363		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	364	42D	RELATED	GRADE 2	AE	DOSE REDUCED	
E-LD	2405-00130	WHITE	10 mg/kg	MALE	6[redacted]	高血糖	8		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	15	24.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	23	230D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	44	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脂肪腫	45		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	50	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						霧視	115	193D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	126		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	224	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	236	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	251	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						四肢痛	255	53D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	260	328D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						せつ	262	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	281	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	308	168D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	308	329D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	428	9D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						関節痛	476	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	504	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	504	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	504		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	553	35D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	616		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	637		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	649		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						うっ滞性皮膚炎	658		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	2405-00668	WHITE	10 mg/kg	MALE	5[redacted]	高カルシウム血症	1	22D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	2	8.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	3	20D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	3	20D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	7	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性腎不全	7	5D	NOT RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						腎機能障害	7	8D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						便秘	9	328D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	9	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	22	315D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	22	62D	RELATED	GRADE 1	AE	DOSE REDUCED	
						疲労	23	78D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疼痛	27	240D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	27	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	28	309D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	29	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	36	351D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	41	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	50	287D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔咽頭痛	55		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	60		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	60	341D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	84	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	91	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	101	12D	RELATED	GRADE 3	AE	DOSE REDUCED	
						筋力低下	101	12D	RELATED	GRADE 3	AE	DOSE REDUCED	
						疲労	113	218D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	113	154D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						悪心	113	322D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	113	161D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	144	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	267	70D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疼痛	267	91D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性感覚ニューロパチー	274	57D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						霧視	323	35D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	330	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	331		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	337	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	337	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						排尿躊躇	337	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿閉	337	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	358	64D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	358		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	358	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	385		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	2406-00046	WHITE	10 mg/kg	FEMALE	7[redacted]	背部痛	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	3	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	3	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	10		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	10	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	10		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口渇	10		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	10	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	17	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	31		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	31	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	44		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	44		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	71	77D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						背部痛	75		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	76	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鉄欠乏	79		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	86		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注射部位出血	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	141		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	147	16D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						皮膚腫瘤	162		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	186	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	194	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	241		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	241	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	267		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カテーテル留置部位蕁麻疹	268	12.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	359	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	365	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	372	23D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						紅斑	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎に伴う頭痛	421	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	477		RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	506		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	533		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	638	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	673	11D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						クロストリジウム検査陽性	735	51D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	807	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						クロストリジウム検査陽性	814		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	855		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						そう痒症	871		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	968		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	1009		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性上気道感染	1023		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
E-LD	2406-00340	WHITE	10 mg/kg	MALE	7[redacted]	背部痛	-7		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	5	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						運動失調	6	18D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	6		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						汎血球減少症	6	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	6	18D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脊椎圧迫骨折	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						精神状態変化	9		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路感染	21		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	30		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿閉	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						閉塞性尿路疾患	41	25D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	2407-00006	WHITE	10 mg/kg	FEMALE	[redacted]	末梢性浮腫	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	13		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	15	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	15	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	17	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	27		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	30	34D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						貧血	35	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	35	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	42	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						関節痛	43	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	56	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	57	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	64		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋力低下	64		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						関節痛	106		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						神経痛	106		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	127	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	138	49D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						悪心	138		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	145	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						熱傷	155	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	156	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	160	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						切開部位感染	170	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	174	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	2407-00015	WHITE	10 mg/kg	FEMALE	5[redacted]	口内乾燥	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	8	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						緊張性頭痛	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	15	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	22	475D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	29	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻部不快感	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	50	1005D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	50	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	56	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	57	114D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	57	114D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	57	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血便排泄	58	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	59	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻脈	64	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	65	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	95	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	95	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異型肺炎	99	14D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低酸素症	99	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道うっ血	99	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口唇炎	114	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	142	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	206	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腱炎	210	37D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						感覚鈍麻	212	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	212	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腱炎	247	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						内出血発生の増加傾向	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	300	86D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	307	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						睡眠の質低下	307	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	307	31D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						挫傷	312	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	317	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	324	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	324	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	324	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喉頭炎	337	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						百日咳	337	54D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	338	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	338	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	351	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	361	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	381	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	393	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯膿瘍	406	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	443	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	445	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	446	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	446	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎	446	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						ライノウイルス感染	446	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	447	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性気管支炎	449	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	450	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						側腹部痛	457	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸水	457	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						慢性気管支炎	462	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						カンジダ感染	469	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						粘膜変色	478	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	478	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	492	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	492	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節可動域低下	505		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	531	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	532		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						副鼻腔炎	532	114D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	606	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	606	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	637	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状皮疹	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	651	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	708	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位反応	730	13.4H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外陰腟不快感	759	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	778	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						カンジダ感染	788	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耳感染	847	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下気道感染	892	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						カンジダ感染	895	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	959	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	969		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	1055		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	1055		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	2407-00198	WHITE	10 mg/kg	MALE	6[redacted]	背部痛	5		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	7	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血便排泄	12	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	14	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	14	8D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	42	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	42	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	53	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	56	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外見に対する無関心	56		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	56		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蒼白	56		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ感染	57	47D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	57	121D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						局所腫脹	61	17D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						深部静脈血栓症	63	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	67	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						舌障害	85	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	109	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	112	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	139	13.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	139	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	140	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	141		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						労作性呼吸困難	148	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	150	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜痛	163	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房粗動	164		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	164	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	164	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	164	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便失禁	164	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大葉性肺炎	164	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胸水	164	76D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	164	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	164	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	165	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中カリウム減少	165	6.8H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	165	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失見当識	165	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低酸素症	165	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						四肢痛	165	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	166	19D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嚥下障害	166	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低マグネシウム血症	166	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	171	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	173	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道うっ血	239	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						変色痰	239	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	308		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	368	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	392		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	411	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	448	61D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚢胞	448		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射減弱	448		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	448		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	466		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	476		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪性新生物進行	476	45D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						筋力低下	476		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	509		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	509		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	509		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	509		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高血圧	510		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	512		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	513		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						譫妄	513		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ビタミンB1減少	515		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	519	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	2407-00361	WHITE	10 mg/kg	MALE	8[redacted]	発疹	3	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	23	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	36	104D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						医療機器不具合	43	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	84		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	98	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	99	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	99	12D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						舌障害	120	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚢胞	140		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	140	34D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						擦過傷	155	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	156	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	168		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼窩周囲浮腫	168	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	173		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	175	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔障害	225	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	237	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	239	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乳頭腫	266	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	267	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	267		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失禁	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性運動ニューロパチー	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						股部白癬	295	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	308		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	334		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						足部白癬	334		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蜂巣炎	355	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	356	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						足部白癬	356	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	361	156D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						局所腫脹	365		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	365		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	394		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	2407-00465	WHITE	10 mg/kg	MALE	6[redacted]	無力症	5	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	5	188D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体位性めまい	5	52D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	5	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	5	188D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副腎機能不全	8	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	8	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						四肢痛	8	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺水腫	8	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	8	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性腎不全	8	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						脊椎圧迫骨折	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	9	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸水	9	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低リン酸血症	11	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	13	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	13	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	13	8D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						洞性徐脈	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	16	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	17	3D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						発熱	19	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	20	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	20	23.8H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						悪心	23		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼感染	26	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	35	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	35	11D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						錯乱状態	49	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						好中球減少症	56	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹部不快感	83	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	84	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						毛包炎	84		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	84	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						振戦	84	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	86	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	87	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口腔咽頭痛	109	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	112		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	116	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	116	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	119	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	120	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						譫妄	122	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	124	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	145	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	145	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						平衡障害	169	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	201	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	201	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	201	24.0H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						鼻咽頭炎	243	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						局所腫脹	247	90D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	257	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気道感染	297	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	322	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	323	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	323	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	323	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	323	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	351	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	363	30D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	365	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	373	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血腫	383	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	392	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	429	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						側腹部痛	432	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肋骨骨折	432	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	435	16D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎	460	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	543		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻咽頭炎	547	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	754	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
E-LD	2407-00507	WHITE	10 mg/kg	MALE	4[redacted]	消化不良	15	40M	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						潮紅	15	40M	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面腫脹	15	40M	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	22	25M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	29	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	36	2.3H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼球浮腫	36	2.3H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面浮腫	36	2.3H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						潮紅	36	2.3H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	36	2.3H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	43	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼球浮腫	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	70	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口唇水疱	171	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	179	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	183	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	183	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	197	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						潮紅	225	40.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	270	151D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						反射消失	280	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚乳頭腫	336	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						サンバーン	336	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	416	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	469		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	473		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	495		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						心雑音	502		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	2407-00554	WHITE	10 mg/kg	MALE	6[redacted]	疲労	2	54D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	8	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	8	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	14	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	15	154D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	15	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	22	1.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	26	1.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低血圧	29	1.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						引っかき傷	29	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	36	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	43	1.6H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	56	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蒼白	71	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	99		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						粘膜変色	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	160		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	182	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎球菌性肺炎	225	26D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	2409-00100	WHITE	10 mg/kg	MALE	6[redacted]	呼吸困難	-1	393D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	6		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	20	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腿骨骨折	24	0S	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血腫	24	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	31	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	57	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	57	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	66	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	66	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						起立性低血圧	84		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜出血	103	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						強膜充血	109	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	137	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	150	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	196	197D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	272	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ブドウ糖増加	280	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	374		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						光線性皮膚症	391	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	415	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	429	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	439	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	448	4D	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						末梢性感覚ニューロパチー	448		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	456	10D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性腎不全	456	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						失神	456	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	457	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						第一度房室ブロック	457		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	457	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	463	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	507	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						強膜充血	526	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	595	65D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	604	97D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	604	97D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	654	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	654	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	700	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎嚢胞	744		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	779	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	779	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	847	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	863		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節痛	865	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	896	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	896	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔咽頭痛	896	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						舌潰瘍	896	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	902		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胆石症	902		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	910		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	926		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	926		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	930	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						便秘	931		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨壊死	937		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	939		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	952		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
E-LD	2409-00482	WHITE	10 mg/kg	FEMALE	7[redacted]	低アルブミン血症	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	2		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	2	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	9	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	16	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	16	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	17	39D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	19	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						食欲減退	19	38D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉痛	19	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						舌痛	19	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	19	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	19	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	19	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	23	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	29	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	29	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						斑状皮疹	29	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷	37	161D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	38	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	51	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	56	142D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉の炎症	96		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	96		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	96		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚潰瘍	96	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血栓症	156		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	169	386D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	174		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	224		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	281	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	281	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	309	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						皮膚変色	315		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	365	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						挫傷	389	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	426	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	426	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	441	52D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	441	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	441	52D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	466	47D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頚部痛	466	47D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	468		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	468	30D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						過小食	468	59D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低酸素症	468	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						国際標準比増加	468	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	468	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎球菌性敗血症	468	52D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						体重減少	468	38D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	469		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カルシウム減少	470	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	470	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中リン減少	471	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中カリウム減少	471	8D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血尿	471	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿量減少	471	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						洞性頻脈	473	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	485	105D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腸球菌感染	499	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢拘縮	506	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	506	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	527		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	553	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	555	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ヘモグロビン減少	555	35D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						国際標準比増加	555	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	555	35D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板数減少	555	35D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎	555	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	3400-00417	WHITE	10 mg/kg	MALE	6[redacted]	便秘	1	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胆石症	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	32	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						肺炎	32	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	36	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼感染	46	354D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭炎	75	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						包茎	102		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下肢骨折	235	47D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	333		RELATED	GRADE 2	AE	DOSE REDUCED	
						悪心	333		RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	364	36D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
E-LD	3401-00265	WHITE	10 mg/kg	MALE	5[redacted]	構語障害	1	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						片頭痛	1	417D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口の錯感覚	1	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	2	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	25	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	30	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	31	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	31	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	50	422D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	66	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	97	10D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腱断裂	97	326D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯感染	125	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	136		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	154	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	186	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	186	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋攣縮	194	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	280		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	297	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	299	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	308		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	361	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	379	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚有棘細胞癌	409	34D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						腱手術	422	84D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	490	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	517	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	3402-00066	WHITE	10 mg/kg	MALE	7[redacted]	発熱	2	35.0H	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						不眠症	7		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	42	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	53	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	53	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	70		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	84		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						中皮腫	85		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
E-LD	3402-00103	WHITE	10 mg/kg	MALE	6[redacted]	便秘	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多幸気分	7	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	15	1.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						注入に伴う反応	36	25M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						期外収縮	50		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	68		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	93	111D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	126	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	150		RELATED	GRADE 2	AE	DOSE REDUCED	
						高血圧	175		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	196	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	217	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	245	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	270	9D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	273	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎機能障害	276	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋痙縮	371		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	371		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	3404-00575	WHITE	10 mg/kg	MALE	6[redacted]	筋痙縮	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	145	233D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						労作性呼吸困難	145	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						臍径ヘルニア	229		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	229	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神寸前の状態	242	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	369	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	372		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	399	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	399	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	399	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	399	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						運動失調	420		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	420		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	420		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	3404-00628	WHITE	10 mg/kg	MALE	7[redacted]	筋痙縮	7	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	29	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	197	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	197	196D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						創傷感染	197	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	282	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚癌	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	316	22D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ニューモシスチス・イロベチイ肺炎	393	22D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸困難	455		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	505	63D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔ヘルペス	505	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						扁平上皮癌	567	24.0H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	589	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎機能障害	604		RELATED	GRADE 1	AE	DOSE REDUCED	
						インフルエンザ様疾患	643	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	657	85D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						皮膚有棘細胞癌	657	85D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ウイルス感染	701		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	729		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	3406-00115	WHITE	10 mg/kg	MALE	5[redacted]	悪寒	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	47	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						圧痛	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	157		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	157	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	235		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	254	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	259	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	319	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	327		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	386	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						細菌性敗血症	476	21D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	3408-00211	WHITE	10 mg/kg	MALE	5[redacted]	疲労	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性鼻炎	19	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔障害	67	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	95	4.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	108	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	155	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	171	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	176	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アレルギー性鼻炎	194	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	324	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	324	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	326	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	330	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	416	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						化学的損傷	526	18D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						蜂巣炎	530	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	610	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	822	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	822	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	822	31D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アレルギー性鼻炎	822	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	854	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	854	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	863	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	3409-00158	WHITE	10 mg/kg	FEMALE	[redacted]	顔面神経障害	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	2	66D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	30	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	34	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	66	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	68		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	96	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	99	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	110	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口内炎	110	33D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	137		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	170	71D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	188	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	193	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	196		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
E-LD	3409-00267	WHITE	10 mg/kg	MALE	7[redacted]	上気道感染	2	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	17	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	32	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	34	40D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	59	197D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	85	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痔核	87		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	89	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						失神寸前の状態	89	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						失神	89	121D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	90	48.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪心	101	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	101		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	127	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	182		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	210	24.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						失神	249	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						視力低下	278		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	311		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	331	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	353		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	395	42D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	409		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	437	320D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	533	272D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳感染	548	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	548	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	561		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	561	176D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚新生物切除	563	41D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						疲労	757		RELATED	GRADE 3	AE	DOSE REDUCED	
						心房細動	805	7D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	805	25D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嗜眠	805		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	805	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肋骨骨折	813	17D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						白内障	883	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	3409-00268	WHITE	10 mg/kg	MALE	5[redacted]	背部痛	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	1	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	8	109D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	10	600D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	13	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	29		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	58	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	58	259D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	58	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	64		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	71		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	71	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						薬物過敏症	117	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	117	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	122	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	128	91D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	246	35D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	281	35D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	284	32D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発声障害	285		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	285	59D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嗜眠	316		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	327	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	339	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	339	481D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	339	55D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	339	20D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	344	141D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	358	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気分変化	358	126D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	379	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	381		RELATED	GRADE 2	AE	DOSE REDUCED	
						下気道感染	466	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭紅斑	470	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	484		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	484		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	610	39D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						足底筋膜炎	649	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	680		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食中毒	752	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	820		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	856		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支肺炎	871	17D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胸痛	871	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4003-00364	WHITE	10 mg/kg	FEMALE	8[redacted]	心房細動	3	2.7H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	3	3D	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	15	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	15	50D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	64	49D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	71	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	71	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	71	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						水腎症	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎嚢胞	99		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	106		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	125		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	125		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	125		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	125		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	125		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	155	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	168		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	202		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	213	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4102-00327	WHITE	10 mg/kg	MALE	6[redacted]	便秘	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	2	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	8	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	15	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						関節炎	43	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	85	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	85	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	99	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	127	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	134	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	134	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	134	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	155	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	162	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	211	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	211	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	225	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上顆炎	225	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	225	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	234	12.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	273	10D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4102-00459	WHITE	10 mg/kg	FEMALE	6[redacted]	神経過敏	2	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	3	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	3	3D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	4	12D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	5	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	6	4D	RELATED	GRADE 4	AE	DOSE REDUCED	
						筋痙縮	14	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	16		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	16	168D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	23		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	30	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	30	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	30		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	44	0S	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯根端切除	114	56D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	128	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢冷感	128	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	128	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	156	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	169	16D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	184	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗅覚錯誤	184	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	198	154D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	282	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	310	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	325	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	338	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	352	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	366	140D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	422	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白内障	432	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	444	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	444	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	444	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼圧上昇	480	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	481	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	490	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	506		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	562		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4103-00306	WHITE	10 mg/kg	MALE	7[redacted]	呼吸困難	2	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	8	14.9H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	8	14.9H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	9	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	9	22.4H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カルシウム血症	9	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	9	6D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						心房拡張	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	15	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						僧帽弁閉鎖不全症	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	22	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	22	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	26	6D	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						消化不良	26	13D	RELATED	GRADE 2	AE	DOSE REDUCED	
						全身健康状態低下	26	6D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						白血球減少症	26	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	27	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						びらん性胃炎	30		RELATED	GRADE 2	AE	DOSE REDUCED	
						低カルシウム血症	30	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クレブシエラ感染	30	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頭痛	31	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	32	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	33	6D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						リンパ球減少症	39	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	39	106D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	46	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	47	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	49	10D	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	49	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	49	47D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心室性期外収縮	49		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						創傷	49	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	50	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	53	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肋骨骨折	57	8D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	58	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	60	16.4H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	61	23.4H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	61	23.4H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	64	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	64	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	74	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	74	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	74	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	75	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心不全	78		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	78	4D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	79	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	79	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	79	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	80	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	88	64D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	96	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	102	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						寝汗	102	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胃腸炎	143	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下腹部痛	193	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	199	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺塞栓症	212	16D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						呼吸困難	214	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						僧帽弁閉鎖不全症	214		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	215	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺感染	217	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	218	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	218	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	219	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	219	15.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						国際標準比増加	220	16.4H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	243	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	256	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸困難	256	8D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						頭痛	256	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	256	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	256	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						期外収縮	260		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	262	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	270	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	298	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	312	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	312	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	312	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	337	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	340		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	368	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	393	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心不全	396		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	396	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	410	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	424	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	424	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	424	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	452	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	466	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	480	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	487	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	487	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	494	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺感染	494	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸時疼痛	494	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	494	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	535	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	535	2D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						呼吸困難	550		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	550	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	550	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	564	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						細菌性尿路感染	597	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						シュードモナス性尿路感染	597	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	620	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	649		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クッシング様症状	676	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	676	21D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						ラ音	676	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	684	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	684	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						炎症	684	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						インフルエンザ	684	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	684	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						敗血症	684	13D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						スフィンゴモナス・パウシモビリス感染	687	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カリウム血症	688	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ブドウ球菌感染	688	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						カテーテル留置部位疼痛	690	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内痛	693	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	774	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						排尿困難	786	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	816		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鉄欠乏性貧血	816		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	901	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	901	3D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4104-00653	WHITE	10 mg/kg	MALE	5[redacted]	発熱	3	46.3H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高血糖	8	175D	RELATED	GRADE 2	AE	DOSE REDUCED	
						悪心	8	722D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	83	30D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						神経痛	83	279D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	113	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管炎	188	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	202	21D	RELATED	GRADE 3	AE	DOSE REDUCED	
						白内障	249		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	323	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	351	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺感染	371	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	382	38D	RELATED	GRADE 3	AE	DOSE REDUCED	
						ウイルス感染	383	3D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						脊椎圧迫骨折	457		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃腸炎	467	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	503		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	583	148D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体温上昇	640	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	699		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4109-00080	WHITE	10 mg/kg	MALE	7[redacted]	血中重炭酸塩減少	2	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	4	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	4	47D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発疹	8	4D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高ビリルビン血症	16	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	23	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	23	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	30	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	37	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	44	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中重炭酸塩減少	51	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	51	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	51	133D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	58	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	72	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過角化	83	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	86	98D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	86	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	115	97D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	115	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	115	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	115	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	128	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	128	42D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	128	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	142	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	156	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	156	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	170	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	170	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞増加症	170	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	184	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	184	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	184	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	196	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	198	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	198	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	198	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞増加症	198	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	198	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	205		NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	212	34D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	212	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	212		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	212	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉内出血	212	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	212	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞増加症	212		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中重炭酸塩減少	218	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中クレアチニン増加	218	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	218	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	235	30.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						口腔内出血	235	30.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						好中球減少症	236	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	246	45.6H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						無力症	246		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						血中クレアチニン増加	246	45.6H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						尿路出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						肝不全	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						悪性新生物進行	246	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						疼痛	246		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						腎不全	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						皮膚出血	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						精神状態変化	247		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						好中球減少症	247	23.7H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	248		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	248		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4201-00324	WHITE	10 mg/kg	MALE	7[redacted]	悪心	8	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喉頭炎	9	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	14	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	21	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	24	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	28	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上腹部痛	44	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	79		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	146		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						自殺既遂	158	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4201-00499	WHITE	10 mg/kg	MALE	6[redacted]	下痢	7	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	7	69D	RELATED	GRADE 3	AE	DOSE REDUCED	
						帯状疱疹	10	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	28	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	38	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	40	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ニューモシスチス・イロベチイ肺炎	53	18D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/RESOLVED
						貧血	59	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						幻覚	59	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	77		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	82	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	83	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	84	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						疲労	86	88D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	98	43D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	124	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	125	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	127	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	147	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	174	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						H1N1 インフルエンザ	175	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						インフルエンザ性肺炎	176	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	177	23D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	180	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						細菌性肺炎	181	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	189	15D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						ウイルス感染	196	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	200		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	203	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	203	29D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	231	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸困難	266		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯感覚	275		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	286	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	301	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						汎血球減少症	348		RELATED	GRADE 4	AE	DOSE NOT CHANGED	
E-LD	4201-00535	WHITE	10 mg/kg	MALE	6[redacted]	高血糖	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	17	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	48	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	55	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	150	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯周病	259		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	331	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸困難	338	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	580	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	582	9D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						クッシング様症状	635	67D	RELATED	GRADE 2	AE	DOSE REDUCED	
						クッシング様症状	702		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4201-00637	WHITE	10 mg/kg	MALE	8[redacted]	高血圧	1	3.8H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						多発ニューロパチー	9	196D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	10	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	23	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	23	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	37	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリンＤダイマー増加	50	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	60	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経過敏	88	46D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	90	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	102	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	103	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸困難	108	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	108	11D	RELATED	GRADE 3	AE	DOSE REDUCED	
						多汗症	117	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	119	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	149	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						ミオパチー	149	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	164	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	205		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	209	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支肺炎	248	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						頭痛	268	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	299	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	385	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	445	59D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	454	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	519	14D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						ウイルス感染	584	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	585	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	597	83D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						胸痛	608		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	620	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	633	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	666	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	671	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	680	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸困難	683		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	693	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	706		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4201-00736	WHITE	10 mg/kg	FEMALE	[redacted]	下痢	3	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	9	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼出血	10	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	37D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	19	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	23	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	28	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	29	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	38	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	51	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	66	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	92	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	103	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	107		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	175	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	227	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	229	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	252	155D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻炎	262	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						治癒不良	292	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	345	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	350	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	465	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性皮膚炎	500	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	505	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ブドウ球菌性髄膜炎	524	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4202-00402	WHITE	10 mg/kg	MALE	5[redacted]	鼻出血	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	17	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	19	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	22	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	78	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	99	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球数減少	99	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	113	43D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	127	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	155	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	155	71D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						多汗症	168	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	168	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	169	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	169	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疾患進行	176	85D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						鼻出血	176	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	178	9D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						蜂巣炎	199	13D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血圧上昇	227	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4202-00698	WHITE	10 mg/kg	FEMALE	6[redacted]	咳嗽	46	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	62	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	62	66D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	62	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	66	48D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	70	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃炎	130	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						尿路感染	133	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	166	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	168	100D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						中耳の炎症	168	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳不快感	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4203-00476	WHITE	10 mg/kg	FEMALE	6[redacted]	背部痛	169	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	183	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	195	600D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	197	501D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						中耳炎	278	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻炎	278	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						閉塞性気道障害	301	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	351		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管炎	506	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	540	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	611	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	698	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						背部痛	700		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	795	9D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						下痢	804		RELATED	GRADE 1	AE	DRUG WITHDRAWN	
E-LD	4300-00674	WHITE	10 mg/kg	FEMALE	[redacted]	動悸	1	5.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	2	28.3H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	2	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	2	16.7H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	3	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	6	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	6	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	6	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						舌苔	10	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	17	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	24		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	54	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	122	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						悪寒	170	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	170	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	170	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	210	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						瘢痕ヘルニア	254		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	268	42D	RELATED	GRADE 2	AE	DOSE REDUCED	
						振戦	268	42D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	324	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	352	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	352	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	369	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	408	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	422	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状出血	422	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	452	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	454	8D	NOT RELATED	GRADE 1	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						口唇感染	458	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重減少	458	238D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4301-00622	WHITE	10 mg/kg	FEMALE	[redacted]	悪心	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	11		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	22	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	29	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内痛	36	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	37	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						感染	43	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	43	9D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						振戦	46	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	48	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	48	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	48	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						動悸	48	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	57	73D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	70	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	84	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	98	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	112	29D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						眼乾燥	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	140		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位腫脹	154	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	158	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	168		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						死亡	186	17.6H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4301-00749	WHITE	10 mg/kg	FEMALE	5[redacted]	便秘	1	143D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	6	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	13	384D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	21	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	33	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣の炎症	33	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	47	171D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	51		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	61	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	61		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	61		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	61	225D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	113	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	145	11D	RELATED	GRADE 3	AE	DOSE REDUCED	
						便秘	156		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	156	542D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	203	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中カリウム減少	211	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	211	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						浮動性めまい	217	40D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	257		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	359	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	369		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	397	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	410		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	412		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	428	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	448		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非心臓性胸痛	482		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	517		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	537	62D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						水痘ウイルス検査陽性	595	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	597	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						水痘ウイルス検査陽性	601	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						水痘ウイルス検査陽性	611	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	612	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						副鼻腔炎	612	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	628		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	698		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	4302-00307	WHITE	10 mg/kg	MALE	[redacted]	消化不良	1	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	14	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	22	38D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	67	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	85	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	176		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	206	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	232	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	274	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上気道感染	279	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						過敏症	286	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	295	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						インフルエンザ	296	12D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎球菌性肺炎	344	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	492	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	562	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	565	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	568	4D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	570	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	602	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉膿瘍	614	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	630	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						嘔吐	649	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						十二指腸潰瘍	687	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	687		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食道カンジダ症	687	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺臓炎	719	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	728	3D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺臓炎	731	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						関節痛	776		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	787	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4302-00332	WHITE	10 mg/kg	FEMALE	5[redacted]	膀胱炎	2	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	22	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	68	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔カンジダ症	71	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	72	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	74	7D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ヘモグロビン減少	75	17.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球数減少	75	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						過敏症	76	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	87	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	158	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	184	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	185	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	185	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	185	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	191	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚢胞	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	216	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	224	27.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4401-00048	WHITE	10 mg/kg	MALE	7[redacted]	気管支炎	1	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性リンパ性白血病	43		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						便秘	51	342D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ浮腫	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	71	256D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚びらん	127	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心不全	166	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腹痛	247	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	276	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	327		RELATED	GRADE 3	AE	DOSE REDUCED	
						高血圧	337		RELATED	GRADE 2	AE	DOSE REDUCED	
						悪心	359	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	359	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	365	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	380		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	393	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	406	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						歯痛	533		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	547	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	575	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	785	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	814	59D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						低リン酸血症	869	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	883		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						骨髄異形成症候群	911		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
E-LD	4401-00167	WHITE	10 mg/kg	MALE	[redacted]	リンパ球減少症	2	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	23	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						リンパ球減少症	30	56D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						労作性呼吸困難	44	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	73	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	98	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						リンパ球減少症	100	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						発疹	102	27D	RELATED	GRADE 1	AE	DOSE REDUCED	
						背部痛	142	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	142	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	172	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						睡眠障害	172	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	184	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	185		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格硬直	198	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	212	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	213	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	255	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	270	152D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						痛風	297	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	352		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	352	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						転倒	399		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	408		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副甲状腺機能亢進症	423		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	436	136D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	464	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨壊死	472	98D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						リンパ球減少症	506	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨壊死	570	15D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不安	582		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腸閉塞	585	6D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃腸炎	705		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	825		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	825		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4401-00456	WHITE	10 mg/kg	MALE	7[redacted]	リンパ球減少症	8	28D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						浮動性めまい	23	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	23	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	36	49D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	51	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	85	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						リンパ球減少症	99	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	124	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	127	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	141	43D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						気管支炎	171	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	184	13D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	184	55D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼠径ヘルニア	185		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	197	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						認知障害	198		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	207	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	211	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	212	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	212	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	225	65D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						無力症	239		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	239	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	239	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺障害	239	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	239	10D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	239	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	239	50D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						下痢	242	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯乱状態	243		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						失語症	245		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脳血管発作	246		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						皮膚真菌感染	254		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	289		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	4401-00513	WHITE	10 mg/kg	MALE	5[redacted]	無力症	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	1	48.0H	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						胸部不快感	9	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	22	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	23		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	57	43D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						副鼻腔炎	62	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性扁桃炎	63	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						副鼻腔炎	67	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	71	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	72	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	85		RELATED	GRADE 2	AE	DOSE REDUCED	
						不眠症	86		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						記憶障害	114		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃腸炎	152	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						毛髪変色	170	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	174	9D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						毛髪変色	199		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝炎	211	70D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						腹痛	216	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	216	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4402-00537	WHITE	10 mg/kg	FEMALE	6[redacted]	貧血	9	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	9	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	49	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺塞栓症	57	8D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						静脈血栓症	57	159D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺塞栓症	64	183D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4404-00159	WHITE	10 mg/kg	MALE	8[redacted]	無力症	1	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	12		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うっ血性心不全	15	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						うっ血性心不全	22	2D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						発熱	31	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	35	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈性不整脈	38	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低血圧	45	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4404-00392	WHITE	10 mg/kg	FEMALE	6[redacted]	四肢痛	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	16	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	23	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	23	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	52	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	52	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						唾液欠乏	57	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痔核	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	127		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	132	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心房細動	134		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	141	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	155	17D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						体重減少	155		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺障害	164	8D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4404-00433	WHITE	10 mg/kg	FEMALE	7[redacted]	食欲減退	1	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						蒼白	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	15	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	38	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	42	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						動悸	71		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸水	71	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	74	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	78	48.0H	RELATED	GRADE 4	AE	DOSE REDUCED	
						挫傷	85	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	91		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	100		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						全身健康状態低下	104		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						敗血症	108	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4405-00439	WHITE	10 mg/kg	FEMALE	[redacted]	リンパ球減少症	1	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢動脈血栓症	15	69D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						四肢痛	19	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	29	13D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						リンパ球減少症	43	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	85	3D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						骨盤静脈血栓症	85	281D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						リンパ球減少症	99	97D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺感染	116	19D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿路感染	116	19D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨盤骨折	117	18D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						低血圧	155	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						気管支炎	177	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	183	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	191	382D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白内障	191	374D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	197	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						下痢	200	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	209	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	211	56D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	226	476D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	283	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	302	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	309	360D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻炎	344	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼠径ヘルニア	464		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						後天性リポジストロフィー	464	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	489	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	507		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	533	136D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						気管支炎	612	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	631	71D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						リンパ漏	646	92D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	646	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	669	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	702		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	702		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4405-00759	WHITE	10 mg/kg	FEMALE	[redacted]	肺感染	-9	10D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肝細胞損傷	1	50D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	2	131D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	2		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経過敏	2		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	13	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						リンパ球減少症	13		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	15	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						背部痛	18	250D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	18	11D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	19	53D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃潰瘍	40		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	43	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯感覚	63		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	126	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	132	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	165	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	165	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	169	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	183		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	190	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	258		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胆嚢炎	336	120D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	337	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						気管支炎	363	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	381	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						リンパ球減少症	393	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						嘔吐	398	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	422	14D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						胆石症	454	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						知覚過敏	487		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺障害	500	5D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	548		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	574	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胃腸炎	609		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	623	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						汎血球減少症	638	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不眠症	640		RELATED	GRADE 2	AE	DOSE REDUCED	
						神経過敏	640		RELATED	GRADE 2	AE	DOSE REDUCED	
E-LD	4406-00229	OTHER	10 mg/kg	MALE	7[redacted]	深部静脈血栓症	99	3D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						肺塞栓症	99	3D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-LD	4406-00283	OTHER	10 mg/kg	MALE	6[redacted]	筋痙縮	2	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	9	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	13	32D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	30	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	30	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	34	232D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						肺塞栓症	34	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
E-LD	4409-00492	OTHER	10 mg/kg	FEMALE	[redacted]	便秘	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	107	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喉頭炎	149	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	169	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						重感	169	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紫斑	183	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢静脈血栓症	184	48.0H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						喉頭炎	276	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	332	19D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	418	17D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嵌入爪	420	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	472	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	472	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	490		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	502	17D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支炎	536	11D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	564	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	678	53D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	735	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	745	54D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4409-00583	OTHER	10 mg/kg	MALE	[redacted]	C一反応性蛋白増加	1	14.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	2	85D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺感染	2	9D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						栄養障害	2	128D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	14	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	23	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	23	3D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						上腹部痛	30	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	34	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	37	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	44	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	55	18D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						扁桃肥大	59	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	72	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	72	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重減少	72	102D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	103	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	115		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	115	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性運動ニューロパチー	115		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	115	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎関節症候群	129	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	140	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						水痘	140	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嚥下障害	141	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	149		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	158	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	158	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	158	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	174	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯肉膿瘍	174	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射減弱	174	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	174		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	174		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	174		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺の悪性新生物	191		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4409-00640	OTHER	10 mg/kg	MALE	7[redacted]	貧血	1	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球数減少	1	57D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	29	55D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						表在性血栓性静脈炎	29	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異常感覚	43	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	50	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	57	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						硬結	59	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔気管支炎	62	38D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	99	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	103	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭部損傷	103	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	103	25D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節痛	113	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						異常感覚	113	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						平衡障害	141		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						難聴	141	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	184	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	184	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						認知障害	213		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	213	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異常感覚	213		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	256	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疾患進行	262	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4411-00413	WHITE	10 mg/kg	MALE	6[redacted]	無力症	15	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎盂腎杯拡張症	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔感染	85	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	99		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	99	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	99	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	141	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	155	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化管運動障害	155		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咽頭炎	155	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不整脈	191		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	211	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	211	155D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						複視	273	92D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動脈瘤	295		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血栓症	295		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	365		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺胞出血	365	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ	383		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4414-00462	WHITE	10 mg/kg	FEMALE	8[redacted]	末梢性浮腫	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	13	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上腕骨骨折	14	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						低カリウム血症	36	3D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						下痢	227		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	265		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						肺障害	267	13D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4505-00089	WHITE	10 mg/kg	FEMALE	7[redacted]	浮動性めまい	2	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						熱感	2	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	16	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘルペスウイルス感染	23	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	44	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	44	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	44	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪心	51	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	57	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						体重減少	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	91	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	91	20.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	91	3.8H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	93	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低カリウム血症	94		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4505-00182	WHITE	10 mg/kg	MALE	6[redacted]	呼吸困難	2	98D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	15	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	15	463D	RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	22	268D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	22	268D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						丹毒	29	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	37	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	43	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	43	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	50	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	86	294D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈炎	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	99	379D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚腫瘤	99	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	103	187D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	113	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	113	177D	RELATED	GRADE 1	AE	DOSE REDUCED	
						関節痛	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	127	134D	RELATED	GRADE 1	AE	DOSE REDUCED	
						鼻咽頭炎	127	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						浮動性めまい	150		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	170	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						紅斑	183	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						良性前立腺肥大症	219		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	219	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	219	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	233	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	261	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	261	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	261	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	268	22D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	275	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	289	91D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	317	63D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	325	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	325	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	331	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	337	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	403	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	403	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	405	255D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	407		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						骨盤痛	407	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺塞栓症	407	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	407	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	422	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	424	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	463	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	463	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	463	225D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	463	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						胃炎	484	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	489	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	491	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹痛	519	40D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	519	16D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	519	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	535	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	557	23.9H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	557	117D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	557	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	575	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						錯感覚	575	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	583	77D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	596	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						恥骨痛	603	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						網膜剥離	612	48D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頭痛	631	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼出血	645	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳鳴	687		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	715		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	715		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	729		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	729		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						高尿酸血症	729		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性腎不全	729	4D	NOT RELATED	GRADE 1	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						全身健康状態低下	741	27D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4505-00207	WHITE	10 mg/kg	FEMALE	3[redacted]	心血管障害	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	2	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	3	144D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	14	38D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	16		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚異常	19	215D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	24	301D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	29	134D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	41	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	43	13D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	47	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	51	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	51	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	55	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	62	228D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	62	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	72	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	83	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	91		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	91	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	105		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	105	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	119	472D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	119	199D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	119	342D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	119	86D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	147	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	147		RELATED	GRADE 2	AE	DOSE REDUCED	
						不眠症	163	371D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						神経過敏	163		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼瞼浮腫	177	197D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	205		RELATED	GRADE 1	AE	DOSE REDUCED	
						顎骨壊死	205		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	205	441D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	205	231D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	261	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	289	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	296		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	373	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	373		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腰椎骨折	373	25D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	384	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	384		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	391	73D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腰椎骨折	397	3D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						副鼻腔炎	421	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	436	174D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	461	18D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球減少症	464	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	489	171D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	515	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	520		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	534		RELATED	GRADE 3	AE	DOSE REDUCED	
						上気道感染	586	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	604	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	604	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	604	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	609		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						発疹	618	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	688		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	716	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋緊張	716		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	716	15D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	730	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						副鼻腔炎	730	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	762		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						白血球減少症	814	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	898	29D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						呼吸困難	898	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						全身健康状態低下	898	29D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
E-LD	4507-00289	WHITE	10 mg/kg	MALE	6[redacted]	ヘルペスウイルス感染	3	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	5	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						全身健康状態低下	5	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	5	9D	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	7	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	8	38.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	10	25.2H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	10	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	14	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	31	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	38	5D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	43	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	74	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	78	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	92		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	162	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	171	48.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胃腸音異常	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	205	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	207	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	208	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	210	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	232	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	234	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	235	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	238	12D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	239	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	241	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	242	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	283	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	302	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4508-00384	WHITE	10 mg/kg	FEMALE	6[redacted]	疼痛	1	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚色素過剰	1	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚色素過剰	1	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	15	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	28	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						平衡障害	37	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	37	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	37	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	49	65D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	50	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	57	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	57	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚色素過剰	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アシドーシス	66	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	66	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						サイトメガロウイルス検査陽性	66	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	66	9D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	66	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	122	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	177	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	185	14D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						肺炎	189	22D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						発熱	189	19D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	190	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						糖尿病	191	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋緊張亢進	191	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	197	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	199	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						汎血球減少症	225	3D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						気管支炎	239	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						細菌検査陽性	261	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨髄異形成症候群	289		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
E-LD	4509-00356	WHITE	10 mg/kg	MALE	7[redacted]	発声障害	4	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	8	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	22	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	30	20D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ウイルス性下痢	33	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	35	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性腎不全	35	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ウイルス性下痢	35	8D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カルシウム血症	37	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	38	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	40	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	41	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	50	92D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	58	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	114	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	128	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鎖骨下静脈血栓症	136	34D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	144	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						放屁	144	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	146	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	170	169D	RELATED	GRADE 2	AE	DOSE REDUCED	
						糸球体濾過率減少	184	155D	RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	198		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下障害	225		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局在性痙攣	315		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多発ニューロパチー	315		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	338		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						糸球体濾過率減少	338		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高尿酸血症	436	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	437		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	437		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	450		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	450	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	450		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血中尿素増加	459		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4510-00186	WHITE	10 mg/kg	MALE	6[redacted]	発声障害	1	155D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	97	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	99	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋緊張	99	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						声帯障害	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	183	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	203	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	239	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	239	9D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						ウイルス感染	248	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	298	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	298	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	309	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱水	335	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						小腸炎	335	6D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	335	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	352	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カリウム血症	353	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染性大腸炎	353	9D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	391	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	428	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	583		RELATED	GRADE 1	AE	DOSE REDUCED	
						咳嗽	638	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻炎	652	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	722		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	736		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	750	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	764	17D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	767		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	775	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						赤白血病	781		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						貧血	785	2D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	789		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
E-LD	4510-00647	WHITE	10 mg/kg	FEMALE	7[redacted]	低カルシウム血症	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	2	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	3	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	8	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	22	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	22	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	22	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	28	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	29		RELATED	GRADE 2	AE	DOSE REDUCED	
						ニューモシスチス・イロベチイ肺炎	33	29D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺炎	33	29D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						頻脈	33	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	34	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	34	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	34	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	34	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	36	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	36	24.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低カルシウム血症	37	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	38	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低マグネシウム血症	39	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						続発性副甲状腺機能亢進症	40		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	40	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	40	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	41	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	44	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	49	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	49	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	50	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	51	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	51	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	53	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	57	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	71	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	73	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	73	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	73	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	83	9D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						頚部痛	86	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	99	239D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外傷性血腫	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	120	106D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	141	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	141	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	141	616D	RELATED	GRADE 2	AE	DOSE REDUCED	
						低カルシウム血症	155	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	225	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	246	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	309	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	360		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						椎間板突出	385		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						滑液包炎	435	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	436	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血腫	444	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	491	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格硬直	502		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	533	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	533	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	546	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	559	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋緊張低下	589	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	603		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	617	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	617	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	701	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動脈硬化症	735		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4510-00661	WHITE	10 mg/kg	MALE	5[redacted]	悪心	1	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	7	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	7	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ほてり	8	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	9	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	9	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	11	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	11	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	12	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	15	132D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	15	6.6H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	21	56D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	31	46D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	34	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ほてり	34	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	34	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	34	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	41	30M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	48	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	48	2.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	62	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	62	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	62		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	90	42D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	90	2.8H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	104	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						多発ニューロパチー	118		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	132		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	175	19D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						便秘	190	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	190	7D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	194	48.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						下痢	196	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	202		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4514-00607	WHITE	10 mg/kg	MALE	7[redacted]	背部痛	26	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						天疱瘡	71	5D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						天疱瘡	76	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						胃食道逆流性疾患	85		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						天疱瘡	85	29D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						裂孔ヘルニア	96	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨壊死	96	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	119	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	119	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	121	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	121	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	122	26D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血圧	124	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	126	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	127	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	128	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	140	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						潮紅	141	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	141	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	141	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	355	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋緊張亢進	355	158D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	355	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						歯髄炎	359	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	373	11D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻咽頭炎	474	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	521	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	527		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	628	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	632	8D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						熱性感染症	656	10D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪心	660	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重増加	660	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	661	27.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4515-00261	WHITE	10 mg/kg	FEMALE	6[redacted]	そう痒症	2	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	8	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						悪心	13	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嘔吐	13	13D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胃腸炎	15	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						リンパ球減少症	22	120D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	25		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	88	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	99	1M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	127		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非心臓性胸痛	141	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	145	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	147	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	148	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	169	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	190	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	210	138D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						完全房室ブロック	251	27D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						心停止	251	27D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-LD	4515-00416	WHITE	10 mg/kg	MALE	5[redacted]	貧血	1	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	3	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	5	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	5	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	8	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	15	26D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						労作性呼吸困難	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	15	25D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嘔吐	19	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	20	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	21	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹腔内血腫	29	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内出血	29	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	33	38D	RELATED	GRADE 2	AE	DOSE REDUCED	
						発疹	33	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	40	3D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	43	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	47	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	57	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	57	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	57	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	64	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						寝汗	68	59D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	71	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	102	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	105	136D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						紅斑	132	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	164	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	164	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	164	44D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	180	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	201	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	203	38D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脊椎痛	203	38D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発疹	210	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	215	51D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	225		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						感覚鈍麻	232	72D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						筋力低下	232	72D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4516-00177	WHITE	10 mg/kg	MALE	5[redacted]	血中クレアチンホスホキナーゼ増加	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	1	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	1	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	1	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	2	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	2	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	2	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	3	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	8	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	8	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						リンパ球減少症	8	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球数増加	8	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	8	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	11	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	15	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	15	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	15	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	15	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	15	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	16	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	29	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	29	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	29	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	29	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						嘔吐	32	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	33	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	36	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中フィブリノゲン増加	36	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリンＤダイマー増加	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						生殖器病変	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球減少症	36	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	36	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						寝汗	36	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						前立腺炎	36	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アミラーゼ増加	43	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	43	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	43	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	43	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単球増加症	43	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	43	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						プロカルシトニン増加	43		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	45	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	45	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	45	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	45	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	50	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	50	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	50	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	50	35M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	50	10M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低リン酸血症	50	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	50	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数増加	50	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						唾液腺結石	50	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	54	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	60	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	65	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	65	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						放屁	69	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	72	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	72	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	72	14D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						低リン酸血症	72	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	72	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	72	13D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球数増加	72	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	85	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	85	37.4H	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						高血圧	85	15.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	85	3D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						筋肉痛	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	86	2D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	88	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	88	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	88	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アミラーゼ増加	99	77D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	99	14D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						低リン酸血症	99	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球数増加	99	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	113	99D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼の障害	113	99D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	113	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	113	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	113	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	113	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						単球増加症	113	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異物感	113	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓性静脈炎	113	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	121	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	124	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	125	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	127	50D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	127	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	127	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	127	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	127	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	127	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	127	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	132	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	133	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	141	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化器痛	141	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	141	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	141	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	141	3.2H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	155	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	155	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	155	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	155	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						寝汗	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	155	3.3H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	155	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	169	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嘔吐	175	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	176	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	176	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アミラーゼ増加	183	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	183	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	183	28M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	183	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	183	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	197	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	197	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	211	1.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	224	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	224	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単球増加症	224	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	224	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	224	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	224	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	226	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	226	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	226	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	231	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	232	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C一反応性蛋白増加	232	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	232	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	232	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数増加	232	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜炎	232	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アミラーゼ増加	235		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	235	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚消失	240	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	240	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	240	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	240	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	242	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	253	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	253	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単球増加症	253	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	260	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチンホスホキナーゼ増加	267		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	267	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胸痛	281	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	281	31M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	281	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	281	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	281	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	296		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	296		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	296	41D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	296	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血便排泄	310		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	310		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						溢出	311	12D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腹痛	337	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	337		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						単球増加症	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	337		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	4600-00082	WHITE	10 mg/kg	MALE	8[redacted]	貧血	1	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	1	30M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性感覚ニューロパチー	1	54D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	6	16.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	15	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	21	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	22	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	29	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	29	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	29	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	29	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	36	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	36	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	43	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	50	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	50	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	50	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	50	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	5D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	50	5D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						大動脈瘤破裂	54	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4600-00251	WHITE	10 mg/kg	MALE	7[redacted]	低カルシウム血症	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	85D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	8	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	8	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	8	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	9	28D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下気道感染	9	28D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	9	28D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	37	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	37	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						高ビリルビン血症	37	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	37	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	44	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	44	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	44	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	44	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	51	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	51	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	57	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	58	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	65	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	79	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	93	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	93	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	93	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	93	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	93	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	102	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	108	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	108	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	108	42D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	108	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	122	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	139	4D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	143	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	150	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	150	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	160	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	164	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	164	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	164	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	164	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	192	168D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	192	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	220	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	220	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発疹	220	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	234	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	234	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	234	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	234	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	243	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	248	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	261	58D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	262	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	277	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	277	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	277	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高血糖	290	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低ナトリウム血症	290	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4600-00274	WHITE	10 mg/kg	MALE	8[redacted]	貧血	1	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	1	709D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	1	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1	66D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	9	91D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23	687D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	37	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	44	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	51	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	67	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	72	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	72	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	86	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	100	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	100	266D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	135	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	142	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カリウム血症	142	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	142	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	156	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	170	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	184	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	198	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	198	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	213	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	213	497D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	213	41D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	213	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	226	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	228	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	240	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	240	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	269	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	269	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	269	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	269	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	282	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	296	126D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	310	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	323	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	323	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	323	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	338	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	349	10D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高カリウム血症	352	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	380	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	380	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	380	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	394	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高窒素血症	408	302D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	408	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	408	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	422	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	422	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	436	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	436	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	436	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	450	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高カリウム血症	499	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	499	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	506	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	520	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	520	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	534	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	548	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	548	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	548	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	562	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	562	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	562	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	576	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	576	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	590	120D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	604	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	604	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	604	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	618	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	618	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	618	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	639	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	639	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	639	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	639	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	646	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	646	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	646	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	660	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	674	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	674	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	674	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	688	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	688	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	688	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	696		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						肺炎	696	14D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	4600-00363	WHITE	10 mg/kg	FEMALE	[redacted]	アラニンアミノトランスフェラーゼ増加	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	1	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	1	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	1	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高リン酸塩血症	8	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	15	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	15	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	16	98D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	18	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	22	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	29	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	36	64D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	36	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カルシウム血症	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	36	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	43	72D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	43	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中クレアチニン増加	50	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	71	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カルシウム血症	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	86		NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						貧血	100	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	100	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	100	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症性ショック	114	10M	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4600-00504	WHITE	10 mg/kg	MALE	7[redacted]	高血糖	9	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	16	197D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	16	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	24	189D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	30	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	37	176D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	44	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	51	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	69	17D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	72	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高血糖	79	106D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カリウム血症	128	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	128	62D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	170	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	170	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	176	13D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高ビリルビン血症	183	39.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	185	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	212	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	236	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	268	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	281	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						歯痛	281	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	296	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	310	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	324	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	380	112D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	450	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	478	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	492	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	519	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	549	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	549	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	549	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	562	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	590	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	604	154D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	604	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	618	42D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	660	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	660	98D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	758	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	758	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	758	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	758		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	774	9D	RELATED	GRADE 3	AE	DOSE REDUCED	
						背部痛	776		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	786		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	800		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	800		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4601-00678	WHITE	10 mg/kg	FEMALE	6[redacted]	血中アルブミン減少	-8	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	-8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	2	2.0H	RELATED	GRADE 2	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中アルブミン減少	2	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	2	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	2	1.0H	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	9	251D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	9	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	16	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	16	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	25	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	33	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	50	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血中アルブミン減少	79	110D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	79	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性腸炎	99	30.0H	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃腸炎	99	18.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性胃腸炎	99	30.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						背部痛	104	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	120	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	135	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	177	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	204	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	204	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中クレアチニン	232	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	232		RELATED	GRADE 3	AE	DOSE REDUCED	
						血中アルブミン減少	261	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	261	82D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	264	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	275	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	275	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルブミン減少	316	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	316	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	344	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	344		RELATED	GRADE 2	AE	DOSE REDUCED	
						嘔吐	344	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルブミン減少	372	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	400		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	414		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	414		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4602-00426	WHITE	10 mg/kg	MALE	4[redacted]	貧血	2	99D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	2	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	9	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	24	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	37	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	37	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	44	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	58	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	80	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	212	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	239		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	239		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	239		NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	240	26D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4602-00458	WHITE	10 mg/kg	MALE	8[redacted]	貧血	5	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心房細動	5	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						心房細動	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	9	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	20	18D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	25	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	27	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	30	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	30	168D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	37	34D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	37	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	43	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性運動ニューロパチー	43	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	43	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	49	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	50	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性運動ニューロパチー	50	21D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						尿路感染	62	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						痛風	63	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	64	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	64	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋力低下	70	9D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性運動ニューロパチー	70	9D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	78	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	78	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	192	41.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						回転性めまい	195	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	197	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						憩室炎	270	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腹痛	301	14D	NOT RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪性新生物進行	353	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4702-00440	WHITE	10 mg/kg	MALE	5[redacted]	関節炎	2	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	178	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	293	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	303		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症	618	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4703-00257	WHITE	10 mg/kg	FEMALE	5[redacted]	痔出血	15	30M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	263	17D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腎結石症	345	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	374	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上腕骨骨折	404	46D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						帯状疱疹	419	25D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格痛	450	11D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	533		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	4802-00651	WHITE	10 mg/kg	FEMALE	7[redacted]	下痢	14	7.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	23D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	19	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	31	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	35	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	37	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	42	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	44	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	51	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	69	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	69	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	72	8D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	86	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	113	235D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	16D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	142	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	142	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	149	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	183	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						股関節部骨折	245	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
E-LD	4900-00314	WHITE	10 mg/kg	MALE	6[redacted]	食欲減退	20	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	29	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	53	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	201	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	213	24D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔真菌感染	218	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	226	60D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	311	34D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	316		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体液貯留	316	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						錯乱状態	330	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	344	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						錯乱状態	347	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	429	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	487	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	487	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨病変	506	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						背部痛	528		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	528		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	528		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴力低下	570	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	570	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	623	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺炎	676	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	676	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腎不全	681	31D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	4900-00533	WHITE	10 mg/kg	FEMALE	7[redacted]	γ－グルタミルトランスフェラーゼ増加	7	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アラニンアミノトランスフェラーゼ増加	14	21D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	14	15D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中アルカリホスファターゼ増加	14	21D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						γ－グルタミルトランスフェラーゼ増加	28	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						ミオパチー	50	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上肢骨折	129	68D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝酵素上昇	249	24D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脊椎圧迫骨折	252	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋腫瘤	261	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4900-00742	WHITE	10 mg/kg	FEMALE	5[redacted]	脊椎圧迫骨折	-12	2D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高カルシウム血症	1	8D	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋骨格痛	1	28D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪心	1		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嘔吐	1		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	2	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	3		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	14		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	37.5H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	22	37.5H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						急性腎不全	22	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	22	37.5H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	24	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	24	10.4H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	25	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊椎圧迫骨折	30	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	43	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	50	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔ヘルペス	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	57	28D	RELATED	GRADE 3	AE	DOSE REDUCED	
						関節痛	71	0S	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	85	16D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						過量投与	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	85	13D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						不安	87		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	98	3D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	4901-00329	WHITE	10 mg/kg	MALE	6[redacted]	無力症	11	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	13	5D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	17	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	18	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	18		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	30	4D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	40	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ウイルス感染	45		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	48	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	53	3D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	55	4D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	60	3D	NOT RELATED	GRADE 4	AE	DOSE REDUCED	
						好中球減少症	65	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	68	5D	NOT RELATED	GRADE 4	AE	DOSE REDUCED	
						好中球減少症	74	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	75	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	82	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	83	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	89	12D	NOT RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						悪性新生物進行	107	29D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						骨髄機能不全	113	23D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	143		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	143	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4901-00531	WHITE	10 mg/kg	FEMALE	[redacted]	血中尿酸増加	11	15D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	18	8D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						血中アルブミン減少	30	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	30	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	142	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	142	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						血中アルブミン減少	170	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ブドウ糖増加	226	290D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便失禁	257		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	318		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿失禁	350	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	366	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	393	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低換気	410	124D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺の悪性新生物	412	122D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						無力症	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						処置による疼痛	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低アルブミン血症	464	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	471		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						ラ音	478		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	493	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低アルブミン血症	506		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	532	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						全身健康状態低下	532	48.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	4901-00673	WHITE	10 mg/kg	FEMALE	6[redacted]	血中ブドウ糖増加	2	372D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						乳房痛	21	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	56	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス	86		RELATED	GRADE 2	AE	DOSE REDUCED	
						白内障	122	123D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	207		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						齲歯	303	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	330	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	332	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	334	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	334	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	364	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	366	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	366		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	384	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	395	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	4902-00173	WHITE	10 mg/kg	MALE	6[redacted]	咳嗽	1	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	1	83D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	6	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	31	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高尿酸血症	45	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	45	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	45	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	52		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						食欲減退	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						感覚鈍麻	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	52	32D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						口内炎	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						振戦	52	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疾患進行	73	85D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						体液貯留	81	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						汎血球減少症	90	19D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	4902-00213	WHITE	10 mg/kg	MALE	7[redacted]	高血糖	9	13D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低血糖症	22	14.7H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	36	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	140	43D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	182	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	189		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						慢性閉塞性肺疾患	221	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	340	445D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	378	0S	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高血糖	378	12.2H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						創傷	378	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	384	16D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						体重減少	420	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	448	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	505	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	587	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						慢性閉塞性肺疾患	660	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中カリウム増加	688	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中ナトリウム減少	688	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	812		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	840	21D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						高血糖	868	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	5001-00491	WHITE	10 mg/kg	MALE	7[redacted]	そう痒症	5	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	7	149D	RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	7	83D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	7	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						腹痛	14	134D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	14	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	14	35D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	20	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口内炎	20	80D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	28	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	49	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						血小板減少症	49	13D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						口内炎	100	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	103	68D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	103		RELATED	GRADE 2	AE	DOSE REDUCED	
						無力症	142		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						うっ血性心不全	147	24D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						発熱	186	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	5002-00092	WHITE	10 mg/kg	MALE	6[redacted]	浮動性めまい	1	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	1	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	7	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	13	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	29	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	36	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						充血	49	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	49	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						充血	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	57	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋痙縮	67	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	126	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	126	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	189	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	189	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	190	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	190	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						嘔吐	207	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	220	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	223	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	225	21D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	230	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	250	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	268	13D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	281	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	295	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	295	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	307	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	307	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腹部不快感	309	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	309	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	316	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	365	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						出血	365	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	365	154D	RELATED	GRADE 1	AE	DOSE REDUCED	
						下痢	388	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	401	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	421	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	432	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	448	72D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	448	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	462	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	462	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	493	153D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	493	153D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	504	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	505		RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	505	29D	RELATED	GRADE 2	AE	DOSE REDUCED	
						期外収縮	547	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	547	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	585	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	585	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	585	89D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	585	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	609	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	609	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	615	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	673	113D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性ニューロパチー	673	56D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性ニューロパチー	707	79D	RELATED	GRADE 1	AE	DOSE REDUCED	
						咳嗽	714	16D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	729	197D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	729	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	738		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	738		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	743	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	743	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	766	48D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性ニューロパチー	785		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	845	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						関節痛	852	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	855	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	855	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						前立腺腺腫	974	24.0H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	5002-00185	WHITE	10 mg/kg	FEMALE	7[redacted]	貧血	1	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						冷感	1	1.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	2	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						浮動性めまい	2	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	2	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	24.0H	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						真菌感染	3	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	6	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻尿	6	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	8	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	8	51D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎不全	8	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	8	16D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						食欲減退	14	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	14	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						潮紅	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	14	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	14	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	14	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	32	48.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						蕁麻疹	32	48.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	36	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	43	56D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						下痢	44	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	44		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	50	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	50	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	72	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	72	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	72	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	75		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	85	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	95	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	97	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	97	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	99	99D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低マグネシウム血症	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	127	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	127	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	127	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	155	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	155	16D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	155	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	179	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	197	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						坐骨神経痛	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	208	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	211	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						生殖器病変	211	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	228	51D	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						下痢	237	42D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	239	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5002-00336	WHITE	10 mg/kg	MALE	6[redacted]	疲労	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	35	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好酸球増加症	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	71	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	78	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	78	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸障害	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	155	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	169	155D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	187	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	204	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	262	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	290		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	290		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	309	14D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支肺炎	310		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	310	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	323	11D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						アスペルギルス感染	330	23D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	413	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭部損傷	413	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	413	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						深部静脈血栓症	415	10D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺塞栓症	415	10D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血栓症	424	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋痙縮	449	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	478	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘルペスウイルス感染	501	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咽頭炎	504	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経痛	505	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	518	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	533	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	777	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5005-00617	WHITE	10 mg/kg	MALE	7[redacted]	呼吸困難	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	15	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	15		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						そう痒症	15	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	19	8D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						口腔真菌感染	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5006-00343	WHITE	10 mg/kg	FEMALE	7[redacted]	好中球減少症	43	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	43	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	57	32D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						尿路感染	101	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	127	126D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	141	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						無力症	217	36D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						肺炎	240	13D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5007-00598	WHITE	10 mg/kg	FEMALE	6[redacted]	貧血	3	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	3	7D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	4	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	5	37.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	6	29.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	18	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	26	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	32	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	37	14.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	39	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	86	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	143	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	146	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	259	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	301	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	459	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	485	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5008-00292	WHITE	10 mg/kg	MALE	6[redacted]	貧血	2	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒性皮疹	5	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	217D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒性皮疹	8	21D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						神経学的症状	10	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						神経学的症状	34	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	70	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	70	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	112	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	112	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎仙痛	181	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	266	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	294	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	308	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	5008-00352	WHITE	10 mg/kg	MALE	[redacted]	脊椎痛	13	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	14	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	21	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	35	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	35	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	42	63D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	49	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	70		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	70	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨盤痛	70	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	147	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	159	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腸閉塞	189	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	191	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	217	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	222		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	253	21D	RELATED	GRADE 2	AE	DOSE REDUCED	
						便秘	253	21D	RELATED	GRADE 2	AE	DOSE REDUCED	
						結膜炎	273	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	273	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	300	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白内障	378	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						湿性咳嗽	379	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	413	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視神経炎	413		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						黄斑浮腫	432		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						咳嗽	455	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	476	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	557	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	557	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視神経炎	566		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						発熱	612	45D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	677	37D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	677	6D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						多汗症	713	29D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						高血圧	741	91D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	741	119D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	832	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	860		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5008-00648	WHITE	10 mg/kg	MALE	6[redacted]	呼吸困難	1	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸水	5	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						体重減少	21	93D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不安	57	288D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	71	253D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	226	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	242	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経過敏	267	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						重感	267	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	281	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						湿性咳嗽	323	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5010-00193	WHITE	10 mg/kg	MALE	7[redacted]	肝腫大	1	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	2	48.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						多汗症	2	9.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	9.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	3	14.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	4	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	13	48.0H	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	14	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ウイルス性下痢	22	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	43	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						インフルエンザ	53	33D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	53	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	58	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5010-00397	WHITE	10 mg/kg	FEMALE	[redacted]	腎クレアチニン・クリアランス	9	22D	RELATED	GRADE 1	AE	DOSE REDUCED	
						筋肉痛	9	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	30	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	39	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈血栓症	58	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腎クレアチニン・クリアランス	64	53D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	67	461D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン減少	142	29D	RELATED	GRADE 2	AE	DOSE REDUCED	
						無力症	170	358D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	189	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	189	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						期外収縮	200	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低音性連続性ラ音	200	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	235	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	270	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	284	17D	RELATED	GRADE 1	AE	DOSE REDUCED	
						急性胆嚢炎	298		NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						好中球減少症	301	127D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	340	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	357	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	438	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	438	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	438	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	483	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	511	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	511	17D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
E-LD	5012-00105	WHITE	10 mg/kg	FEMALE	5[redacted]	発熱	2	12.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	3	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	3	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	3	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	3	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	3	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	282	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	326	83D	RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	394	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						下痢	478	112D	RELATED	GRADE 1	AE	DOSE REDUCED	
						下痢	590	323D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	726	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						不眠症	814		RELATED	GRADE 2	AE	DOSE REDUCED	
						易刺激性	814		RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	940		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5012-00347	WHITE	10 mg/kg	MALE	6[redacted]	消化不良	205	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	205	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	239	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不眠症	309	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						錯乱状態	373	20D	RELATED	GRADE 2	AE	DOSE REDUCED	
						消化不良	407	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						性器感染	407	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						視力障害	435		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	505	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	505		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						性器感染	575		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	645	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	659		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	659		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	659		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	659		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	701	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	701	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	715		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	730	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	792		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5200-00187	WHITE	10 mg/kg	MALE	8[redacted]	貧血	86	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性浮腫	86	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	170	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	199	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	254	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	331	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	331	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	408	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	408	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチン増加	422		RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	451	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	478		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	493	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	632	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
E-LD	5200-00309	WHITE	10 mg/kg	MALE	8[redacted]	高血糖	54	4D	RELATED	GRADE 3	AE	DOSE REDUCED	
						血小板数減少	324	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	336	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支肺炎	351	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	380		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	492		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	492		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中乳酸脱水素酵素増加	492		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						C－反応性蛋白増加	496	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						粘膜出血	496	17D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						下痢	511	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	526	12D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						髄膜腫	526		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
E-LD	5202-00232	WHITE	10 mg/kg	MALE	7[redacted]	鼻咽頭炎	10	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	10	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	16	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	16	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	29	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	57	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球減少症	113	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	113	30D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球減少症	141	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	175	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリン分解産物増加	182	422D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	198	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	225	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	248	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	280	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	281	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	323	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	351	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	407	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	449	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	477	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	490	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	491	13.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	497	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	535	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	561	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						皮膚潰瘍	561	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	571		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	589	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心雑音	589		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	589	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	617	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	645	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	645	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	648	68D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発声障害	659	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	671	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中甲状腺刺激ホルモン減少	673	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	701		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心内膜炎	703	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	715	1.5H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	715	9D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	729	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	729	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	729	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低アルブミン血症	743	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	743	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口の錯感覚	783	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	785	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	792	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	797	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	799	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	799	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	799		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	806	24.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	827	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	828	48.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	841		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	869		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	870	39D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5202-00316	WHITE	10 mg/kg	MALE	5[redacted]	筋骨格系胸痛	-11	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	5	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膿疱性皮疹	12	88D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	17	55D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	22	48.0H	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	22	4D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						口腔ヘルペス	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	22	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	25	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上気道感染	41	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	99		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	138	130D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	176	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過角化	246	64D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	249	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	298	96D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						狭心症	304	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性冠動脈症候群	312	5D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						咽頭炎	380	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						乳房脂肪腫	420		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	425		RELATED	GRADE 1	AE	DOSE REDUCED	
						女性化乳房	449		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	463	71D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						排尿困難	477	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	512		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	519	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	547	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	547		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	547	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	547	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	564		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	575	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜炎	589	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	602		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	631	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	659	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	667	30D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	701		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	701		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	701		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5202-00619	WHITE	10 mg/kg	FEMALE	[redacted]	上気道感染	4	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	9	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	9	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	96	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	112	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	127	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支炎	135	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						敗血症性ショック	157	15D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	176	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	197	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支肺アスペルギルス症	197	42D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	197		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	198		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺アスペルギルス症	239	94D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	253	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血糖症	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	253	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	267	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	267	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	267	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	281	71D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	281	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	295	111D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	295	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	309	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	309	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	323	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	323	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						挫傷	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	337	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	337		RELATED	GRADE 2	AE	DOSE REDUCED	
						貧血	351	39D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支肺アスペルギルス症	351		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						低アルブミン血症	351	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	351	134D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	351		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳アスペルギルス症	389		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	405	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	502		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						疾患進行	511	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5202-00707	WHITE	10 mg/kg	MALE	5[redacted]	発声障害	1	155D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭炎	53	103D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	73		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	79		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						消化不良	85	28D	RELATED	GRADE 1	AE	DOSE REDUCED	
						鼠径ヘルニア	109		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	119	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	141	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	225	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部腫瘤	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	295	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	307	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜炎	309	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	323	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	326	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	351	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	407	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	421	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	434	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上室性期外収縮	449		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	463	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	465	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	470	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	491	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	492	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	505	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	505	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	519	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	533	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	546	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						喘息	550	9D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	575	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	581	4D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						脊椎痛	594		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	594	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	603		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	603	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	631	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	631	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	631	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	659		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	673		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	673		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5204-00106	WHITE	10 mg/kg	MALE	6[redacted]	腎クレアチニン・クリアランス減少	1	28D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						肺臓炎	43	12D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						四肢静脈血栓症	169	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						静脈炎	617	70D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性虚血	673	23.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	5204-00233	WHITE	10 mg/kg	MALE	7[redacted]	貧血	561	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	673	127D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	814	46D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心筋虚血	845		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	859	2D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	911		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
E-LD	5204-00441	WHITE	10 mg/kg	FEMALE	7[redacted]	背部痛	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	377	10D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						糸球体濾過率減少	603	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						疾患進行	652	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5204-00445	WHITE	10 mg/kg	MALE	6[redacted]	高血圧	1	1.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	1	1.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎クレアチニン・クリアランス減少	8	7D	RELATED	GRADE 1	AE	DOSE REDUCED	
						低カルシウム血症	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	8	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	15	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	22	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	43	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	49	23D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						耳下腺腫大	49	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						労作性呼吸困難	85	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	85	129D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	90		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	99	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	99	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						発熱	102	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	113	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疾患進行	149		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						不全対麻痺	149	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不全対麻痺	161		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	171	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	171	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	174	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	184	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	5204-00555	WHITE	10 mg/kg	MALE	[redacted]	そう痒症	5	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	15	3.9H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	16	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	30	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	30	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上肢骨折	37	24D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						気管支炎	60	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						アスパラギン酸アミノトランスフェラーゼ増加	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	80		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	92		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						聴覚障害	110	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						視力低下	110	52D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	127	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	127	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咽頭炎	155	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						聴覚障害	157		RELATED	GRADE 3	AE	DOSE REDUCED	
						低カルシウム血症	161	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	169	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	211	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	239	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	239	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	261		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	267	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	295	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	351	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						術後創感染	376	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カルシウム血症	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	435	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	435	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	463	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	603	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	631	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	657	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	688		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	757	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	5204-00744	WHITE	10 mg/kg	FEMALE	7[redacted]	体重増加	15	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顆粒球減少症	29	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顆粒球減少症	36	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気圧性中耳炎	45	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	80	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	155	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267	38.2H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	339	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	341	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	388	41.9H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	425	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	473	18D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	501	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5208-00568	WHITE	10 mg/kg	MALE	6[redacted]	胆管炎	5	23D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	11	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	15	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	17	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	19	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	33	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	35	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝損傷	35	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	84		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耐糖能障害	84		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	109	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	112		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	112	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	130	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	190	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5208-00569	WHITE	10 mg/kg	MALE	5[redacted]	貧血	7	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						好中球減少症	7	17D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						血小板減少症	7		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						咽頭炎	8	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	11	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	46	16.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	58	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						リンパ節症	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						咳嗽	79	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	79	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	79		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	91	35D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						好中球減少症	91		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	99		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						大腿骨頚部骨折	107		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
E-LD	5208-00571	WHITE	10 mg/kg	FEMALE	[redacted]	高血圧	8		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						糖尿病	24		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	31	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	40	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	56	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						糸球体濾過率	70	43D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						錯乱状態	72	21D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カルシウム血症	84	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	92		RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	98	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	145	23D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						糸球体濾過率	175	51D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨痛	179		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	189	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						糸球体濾過率	253	57D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						爪真菌症	289		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						糸球体濾過率	323	29D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						気管支炎	385	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	393	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	518	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	521	11D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺炎	581	15D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	5208-00618	WHITE	10 mg/kg	MALE	7[redacted]	貧血	7	64D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	28	72D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	29	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	68		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	71		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高カリウム血症	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	194	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5300-00463	WHITE	10 mg/kg	MALE	5[redacted]	アラニンアミノトランスフェラーゼ増加	8	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	8	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	8D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性膵炎	32	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	36	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	50	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	64	109D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性胆嚢炎	72	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高血糖	172	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	184	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	198	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	226	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	240	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	268	112D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	380	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	394	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	476	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	478	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯牙破折	491	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	506	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	520	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	533	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	562	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	567	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	590	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	674		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5301-00090	WHITE	10 mg/kg	MALE	6[redacted]	アレルギー性皮膚炎	14	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	394	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	422	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	435	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	477	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	493	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	493	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞腫	498		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
E-LD	5301-00116	WHITE	10 mg/kg	MALE	6[redacted]	斑状丘疹状皮疹	12	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	15	21D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発疹	70	46.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	71	3.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						靭帯捻挫	252	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	386	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性運動ニューロパチー	946		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5301-00390	WHITE	10 mg/kg	FEMALE	4[redacted]	傾眠	31	3.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	34	1.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	34	1.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋力低下	39	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	262D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷感染	137	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						蜂巣炎	219	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	325	169D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	507	58D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	564	224D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	603	45.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胆嚢炎	670	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	726	0S	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	726	5M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼刺激	743		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5303-00128	WHITE	10 mg/kg	FEMALE	6[redacted]	尿路感染	5	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	6	37.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	12	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口唇腫脹	12	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	14	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	15	21D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						尿路感染	46	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	73	41D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	417	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歯痛	475	40D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	483	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	492	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	493	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	493	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	503	31D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脱水	506	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好酸球増加症	506	57D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						気道感染	506	15D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	508	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	509		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	534		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5303-00516	WHITE	10 mg/kg	FEMALE	6[redacted]	下痢	73	14D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						下痢	96	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	101		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	UNKNOWN
						敗血症	117	3D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						細菌性尿路感染	117	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	5500-00670	WHITE	10 mg/kg	MALE	5[redacted]	四肢痛	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	14	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	26	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	30	238D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	37		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞腫	46		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	106	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	158	132D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	207	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	256	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨溶解	263		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	268		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	290		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						排尿異常	309	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	309	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5501-00241	WHITE	10 mg/kg	FEMALE	8[redacted]	鼻漏	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	24	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	29	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	50	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低血圧	141	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	197	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	207	47D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支痙攣	323	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	323	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	323	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	379	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	387	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	393	43D	RELATED	GRADE 2	AE	DOSE REDUCED	
						斑状出血	407	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	421	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	435	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	435	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	449	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	477	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	491	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	505	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	505	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	533		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	547	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	575	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内不快感	624		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	637	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心肺停止	672	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5501-00244	WHITE	10 mg/kg	FEMALE	[redacted]	血小板減少症	17	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	22	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	43	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	183	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎球菌性肺炎	257	3D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						無力症	281	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	299	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	323	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	323	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼の異物感	337	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紫斑	337	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈瘤	337	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	379	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	400	8D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						創傷	435	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5501-00337	WHITE	10 mg/kg	MALE	7[redacted]	血中クレアチニン増加	8	50D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						嘔吐	15	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	43	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						静脈不全	99	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	141	260D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	141	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						血腫	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	155	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	168	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	168	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	180	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	183		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						咳嗽	244	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	245	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	267	196D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	337	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	379	9D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	379	9D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						急性腎不全	379	9D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						無力症	393	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	393	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	400		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	400	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	404	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	404	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	404	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	407	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低マグネシウム血症	407	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	407	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	407	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	411	24.0H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺炎	411	17D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						急性腎不全	411	17D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						器質化肺炎	419		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						高カリウム血症	435	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	435	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	435	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球増加症	435	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎不全	435	48.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ミオパチー	449		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						蜂巣炎	463	26D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						蜂巣炎	463		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						褥瘡性潰瘍	463		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	463		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腎不全	463	26D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	463	26D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心房細動	467	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	469		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	509	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5501-00339	WHITE	10 mg/kg	MALE	7[redacted]	貧血	-24	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-24	5D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-3	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肝機能検査異常	7	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	7	8D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	7	14.7H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	8	13.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔カンジダ症	9	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	13	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血腫	19	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	26	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	33	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	40		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						霧視	40	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	47	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低血圧	47	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	47	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	54	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	54		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	68	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	68		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	82		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	96		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						両耳難聴	138		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	138		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						四肢痛	138		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	152		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	152	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	166		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	187		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎前性腎不全	187	12D	NOT RELATED	GRADE 5	SAE	DRUG INTERRUPTED	FATAL
						膿瘍	195		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5501-00375	WHITE	10 mg/kg	MALE	6[redacted]	筋拘縮	15	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						舌痛	29	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃障害	36	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	38	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	50	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	57	113D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	72	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	79	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						陰部ヘルペス	92	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔カンジダ症	92	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	158	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	158	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格硬直	183	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						四肢痛	183	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	226	83D	RELATED	GRADE 2	AE	DOSE REDUCED	
						抑うつ気分	226	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	226	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯の脱落	226	24.0H	RELATED	GRADE 2	AE	DOSE REDUCED	
						筋骨格硬直	253	29D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						四肢痛	253	98D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						背部痛	267	50D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						倦怠感	267	57D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						四肢痛	267	84D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	309	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	316	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	316	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						四肢痛	351	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	351	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	351	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						側腹部痛	421	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	421	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性ニューロパチー	463		RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						四肢痛	463		RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						倦怠感	505		RELATED	GRADE 2	AE	DOSE REDUCED	
E-LD	5501-00615	WHITE	10 mg/kg	MALE	[redacted]	発熱	12	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔障害	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						パーキンソニズム	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚病変	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	22		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	43	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						紫斑	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	71		RELATED	GRADE 3	AE	DOSE REDUCED	
						発声障害	71	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	112		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	127	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	169		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	197	176D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	197	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	253		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	267	22D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	267	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	309	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	337	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						大葉性肺炎	365	6D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	393		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	393		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	401	5D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	5501-00735	WHITE	10 mg/kg	FEMALE	[redacted]	胸痛	10	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	10		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	10		RELATED	GRADE 1	AE	DOSE REDUCED	
						洞性頻脈	15	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	20	5D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						鼻閉	20	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	20	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	29	252D	RELATED	GRADE 3	AE	DOSE REDUCED	
						筋骨格痛	29		RELATED	GRADE 3	AE	DOSE REDUCED	
						眼そう痒症	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低クロール血症	141	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	141	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	155	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	155	275D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	239	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	281		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						視力低下	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	427	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	427	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	430	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸不全	430	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気道感染	430	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						浮動性めまい	477	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						落ち着きのなさ	477	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						浮動性めまい	519		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						落ち着きのなさ	519		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	519		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	652		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	690	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高ビリルビン血症	690	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	5504-00634	WHITE	10 mg/kg	MALE	6[redacted]	貧血	1	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	1	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	9.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	3	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						線維素溶解	3	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	3	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	3	9.8H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	4	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	8	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	9	16.7H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	10	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	10	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	10	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	16	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	16	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	23	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	23	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	30	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	32	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	37	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	39	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	44	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	51	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	52	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嚥下障害	55	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	57	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔粘膜紅斑	57	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	64	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歯膿瘍	64	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯感染	64	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						開口障害	64	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	85	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	101	83D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	101	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						毛包炎	128	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	128	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔粘膜紅斑	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	156	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯髄炎	169	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	169	169D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	184	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔カンジダ症	184	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	197	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	212	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	212	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	212	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						処置後浮腫	212	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歯周炎	225	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	253	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉紅斑	253	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨炎	253	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	309	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面浮腫	309	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨髄炎	309	17D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	309	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	313	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	322	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨髄炎	326	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	337	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	366	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	366	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	376	15D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	379	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	379	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	381	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	385	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	388	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	390	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	392	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	400	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	400	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	400	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胆汁うっ滞	400	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	400	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	400	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	400	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	400	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	407	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	407	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	411		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉潰瘍	411		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下痛	411		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	424	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5505-00076	WHITE	10 mg/kg	MALE	6[redacted]	関節痛	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	1	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	1	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	1	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	2	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	2	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	15	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	23	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	30		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	30		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						振戦	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痙攣	99	9D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	105	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	134	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	169	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						夜間頻尿	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	184		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	194	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血便排泄	194	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	197	48.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						無力症	197		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	197		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	197		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	199	25.6H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	201	3D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						背部痛	202		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	204		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						骨痛	204		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						微小血管症性溶血性貧血	206	6D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						消化器新生物	209	3D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5505-00137	WHITE	10 mg/kg	FEMALE	7[redacted]	貧血	1	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	7	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	9	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	13	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	39	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	43	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	8D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						寝汗	56	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	71	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	85	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	99	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						寝汗	113	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	124	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	127	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	127	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	141		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	155	127D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	155	435D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	155		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	169	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	239	701D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	239		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	267	673D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	267	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	267	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	268	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	282		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	308	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	331	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	331	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	366	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚病変	366	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	393	547D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状出血	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	410	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	414	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						窒息感	414	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	421	519D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	573	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	579	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	579	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						聴力低下	603		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	603		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	603	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳鳴	603	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	617	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	631	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						小腸炎	646	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	659	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	671	11D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						無力症	673	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	673	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹部膨満	688	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	688	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	688	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内損傷	701	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	715	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	729	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						熱感	730	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	730	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	752	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	758	182D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身性浮腫	799	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨壊死	841	48D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脊柱管狭窄症	874	15D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	902	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	925	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	938	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5505-00154	WHITE	10 mg/kg	FEMALE	6[redacted]	貧血	-7	10D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	1	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	1	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	7	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性浮腫	7	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	7	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	25	741D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	28	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	28		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	28	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	35	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	35	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	42	37D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						尿路性敗血症	46	26D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						外傷性血腫	84	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路性敗血症	112	35D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	253	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-LD	5700-00266	WHITE	10 mg/kg	MALE	6[redacted]	発疹	11	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	15	268D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	15	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						背部痛	59	35D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腰椎骨折	85	9D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						皮下血腫	212	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚病変	240		RELATED	GRADE 2	AE	DOSE REDUCED	
						咳嗽	254	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	5801-00592	WHITE	10 mg/kg	MALE	5[redacted]	眼窩蜂巣炎	-6	5D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	29	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						高血糖	58		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						糖尿	141	197D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	338		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	352		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5801-00610	WHITE	10 mg/kg	FEMALE	7[redacted]	悪心	19	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						食欲減退	41		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	41	254D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	53	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	61		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	102	33.6H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						クッシング様症状	169	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	169	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						心房細動	186	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						クッシング様症状	197	124D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋力低下	197	99D	RELATED	GRADE 3	AE	DOSE REDUCED	
						浮腫	197	309D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	295	182D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	295	26D	RELATED	GRADE 2	AE	DOSE INCREASED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	309		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	309	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚炎	323	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	337	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	351	134D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	365	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	379	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	393		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	393	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	421	5D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上室性不整脈	449		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	477	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋力低下	477		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	484	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	505	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	505		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	519		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	631	24.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道感染	649	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5801-00612	WHITE	10 mg/kg	FEMALE	5[redacted]	過敏症	2	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	2	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						過敏症	7	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	7	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過敏症	16	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	16	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	29	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	36	44D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						過敏症	39	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	39	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						サイトメガロウイルス感染	57	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						サイトメガロウイルス感染	68	17D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						細菌感染	82	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5801-00635	WHITE	10 mg/kg	MALE	7[redacted]	振戦	1	15M	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						膀胱移行上皮癌	15	12.2H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						蒼白	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	49	84D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						真菌性肺炎	50	45D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						呼吸窮迫	150	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-LD	5801-00682	WHITE	10 mg/kg	FEMALE	6[redacted]	疲労	1	321D	RELATED	GRADE 1	AE	DOSE REDUCED	
						蒼白	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	39	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼡径部痛	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	91		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	106		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	106		RELATED	GRADE 1	AE	DOSE REDUCED	
						尿路感染	134	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						大腸穿孔	145	289D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	321		RELATED	GRADE 2	AE	DOSE REDUCED	
						肺塞栓症	458	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺塞栓症	463	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5801-00700	WHITE	10 mg/kg	FEMALE	6	貧血	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	15	328D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	57	187D	RELATED	GRADE 3	AE	DOSE REDUCED	
						疲労	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率	57		RELATED	GRADE 2	AE	DOSE REDUCED	
						蒼白	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	239	33D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎クレアチニン・クリアランス減少	244	29D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎尿細管性アシドーシス	252	21D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺炎	322	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						多発ニューロパチー	343		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						浮腫	491		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5900-00151	WHITE	10 mg/kg	FEMALE	7[redacted]	腎機能障害	1	2D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						疲労	3	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	3	739D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	5	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	5	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	8	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	8	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	8	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	11	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	12	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	22	720D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	720D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	33	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	39	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咽頭炎	39	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ミオパチー	50	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ミオパチー	71	181D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						直腸出血	75	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	602D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	155	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	155	587D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	199	543D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						後天性涙道狭窄	209		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	246		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ミオパチー	252	490D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	271		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	292		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	292		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	292	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	310	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	320	15D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	320	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						大腸菌検査陽性	320	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	320	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	322	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						運動性低下	420	322D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	441		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紫斑	448		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	454		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	454	288D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	459	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	463	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						菌血症	472		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	472	270D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	472		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	502	240D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化管運動障害	533		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	547	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	564		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	594	148D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	640	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	648		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	659	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	700	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	700		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	732	9D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎不全	732	10D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
E-LD	5900-00255	WHITE	10 mg/kg	MALE	7[redacted]	腹部不快感	18	69D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎痛	110	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節摩擦音	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	129	240D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	131		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						出血性関節症	131	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格硬直	145		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	165	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	170	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	223	12.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	223	12.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	378		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	395	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	395	200D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						胸痛	411	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	426		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	456	80D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	535		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						皮膚病変	548		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	640		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	640	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	661	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	691	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	703		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	871		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	871		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5900-00524	WHITE	10 mg/kg	MALE	6[redacted]	不安	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	14	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	27		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	27	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	27	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	27	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ライノウイルス感染	53	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	55		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ライノウイルス感染	55		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	55	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	83		RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	83	113D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	83	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	83	16D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ミオパチー	83	16D	RELATED	GRADE 2	AE	DOSE REDUCED	
						振戦	83		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	111	141D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ミオパチー	111	113D	RELATED	GRADE 2	AE	DOSE REDUCED	
						発疹	116		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉塞	126	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	135	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	135	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘルニア	139		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	183		RELATED	GRADE 1	AE	DOSE REDUCED	
						疲労	195		RELATED	GRADE 1	AE	DOSE REDUCED	
						鼻出血	199	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	210		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						急性腎不全	294		NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						血中カルシウム減少	298		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						血中マグネシウム減少	298		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						血中リン減少	298		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						ヘモグロビン減少	298		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						下痢	500	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5900-00572	WHITE	10 mg/kg	MALE	5[redacted]	発熱性好中球減少症	3	30.0H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上腹部痛	12	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	12		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	19		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食道痛	45	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	59		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	84	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	84	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	112	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	154	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	158	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ライノウイルス感染	158	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	273		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						季節性アレルギー	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	301		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	332		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	332		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						足部白癬	363		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	424	109D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	460	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪の障害	485		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	558	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格痛	616	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	674	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5903-00373	WHITE	10 mg/kg	MALE	4[redacted]	疲労	1	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	2	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	2	19.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						カンジダ感染	4	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	9	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	26	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	111	17D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪心	123		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	128	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	154		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5903-00584	WHITE	10 mg/kg	MALE	6[redacted]	振動覚低下	1	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	2	123D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						重感	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	4	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	4	21.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	5	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	5	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	9	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下気道感染	17	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	42		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肉離れ	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	68	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	93	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	98	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						RS ウイルス感染	99	26D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	113	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	124	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	134		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						形質細胞性骨髄腫	169	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-LD	5905-00112	WHITE	10 mg/kg	MALE	5[redacted]	便秘	1	393D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	1	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	5	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	14	2D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	14	2D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	14	14D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						蜂巣炎	15	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						過敏症	22	2.3H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血圧	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	29	35M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過敏症	36	10.5H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発疹	36	30M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						リンパ球減少症	43	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	50	372D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	57	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	68	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口唇炎	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔感染	74	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	113	14D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						うつ病	127	155D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						多汗症	170	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	240	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	254	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	282	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	282	28D	RELATED	GRADE 3	AE	DOSE REDUCED	
						うつ病	310	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	310	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						うつ病	366	111D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	366	27D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						便秘	394	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	394	85D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	477	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	478		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	506	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	506	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	562	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	590	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	603	44D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						異常行動	618		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	646		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	646		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	688	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	814		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	872	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス検査陽性	876	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	5905-00263	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	血中クレアチニン増加	-1	57D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	1	47D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	1	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	9	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	15	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	22	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	28	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	43	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	48	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	50	21D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						爪真菌症	51	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	52	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	114	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	147	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	198	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疼痛	254	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	275	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸困難	275	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	275	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	275	13D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下気道感染	282	40D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	289	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	289	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	319	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	322	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚乾燥	342	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	345	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	352	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	352	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5905-00730	WHITE	10 mg/kg	FEMALE	7[redacted]	皮膚反応	1	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	15	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	15	99D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	15	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	22	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	22	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	29	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胸痛	36	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	58	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	58		RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						背部痛	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	79	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	106	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	113	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5906-00163	WHITE	10 mg/kg	MALE	6[redacted]	味覚異常	1	20M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						霧視	1	20M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	18	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	19	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	28	127D	RELATED	GRADE 1	AE	DOSE REDUCED	
						感覚鈍麻	54	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少性敗血症	128	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	129	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋肉痛	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	196	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	280	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ヘモグロビン減少	294		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	294		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	322		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	5906-00650	WHITE	10 mg/kg	MALE	6[redacted]	耳鳴	9		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	17	54D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	69	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	69	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	71	31D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	85	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中カルシウム減少	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	147	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	150	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	151	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	169	434D	RELATED	GRADE 1	AE	DOSE REDUCED	
						疲労	169	434D	RELATED	GRADE 1	AE	DOSE REDUCED	
						振戦	169	434D	RELATED	GRADE 1	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下気道感染	264	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	295	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						神経痛	310		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	329	350D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	334		RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	334		RELATED	GRADE 2	AE	DOSE REDUCED	
						眼乾燥	361	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	374	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	375	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	389	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	402	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	403	68D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	403	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	403	191D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	421	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染性嚢腫	424	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	426	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	449		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳不快感	451	143D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						異常感	451	137D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						副鼻腔うっ血	451	143D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						変色痰	464	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻閉	505	89D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						眼痛	535	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						レンサ球菌性肺炎	582	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	583	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚疼痛	583	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						レンサ球菌感染	590	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	593	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	603	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						拡張期血圧低下	631	0S	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	637	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	637	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻閉	643	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	650	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	678		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						口腔咽頭痛	694	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	5909-00497	WHITE	10 mg/kg	FEMALE	7[redacted]	末梢性浮腫	28		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	89	7D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						錯乱状態	130	17D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	6000-00315	ASIAN	10 mg/kg	MALE	6[redacted]	斑状丘疹状皮疹	2		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	3	13.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						倦怠感	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	11		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	11		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単純ヘルペス	14	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	19	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	21	16D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						しゃっくり	37	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	57	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹部膨満	92	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						角膜炎	112	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	141	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	155	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	196	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	211	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	252	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	264	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	280	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腸炎	290	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	308	29D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	336	48.0H	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	364	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体内異物	387	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	392	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	434	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	462	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	504	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	6001-00034	ASIAN	10 mg/kg	MALE	7[redacted]	しゃっくり	2	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単純ヘルペス	10	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	256	17D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胸痛	390	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						緑内障	436	56D	RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	442	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染性皮膚嚢腫	505	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	584		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	609	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜出血	651	37D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	694	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	746	17D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						脱水	757	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						上気道の炎症	797	18D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	6001-00333	ASIAN	10 mg/kg	FEMALE	6[redacted]	血圧上昇	1	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	1	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	1	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	1	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	22	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	30	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	370	74D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	6002-00609	ASIAN	10 mg/kg	MALE	8[redacted]	便秘	6		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	8	51D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	15	72D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	19	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	22	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	33	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	35	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	40	243D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						股部白癬	163	181D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿閉	167	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	170		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	170		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿閉	170		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						尿路感染	195	10D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	199		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肝機能異常	204	79D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						足部白癬	224		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	226		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	254	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	254		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	280	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	282	62D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						褥瘡性潰瘍	282	62D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	290	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	317	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-LD	6003-00196	ASIAN	10 mg/kg	FEMALE	6[redacted]	フィブリン分解産物増加	2	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	2	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	3	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	16	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	22		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	22	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	29	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						光視症	29	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	79		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	129	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脊椎圧迫骨折	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃ポリープ	189		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	202	439D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						粘膜の炎症	262		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	301		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻漏	354	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	393		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性結膜炎	402	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道の炎症	402	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	467	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	477	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						基底細胞癌	505	393D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						頚部痛	523		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	594	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	638		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
E-LD	6003-00411	ASIAN	10 mg/kg	MALE	6[redacted]	眼痛	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	1	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	8	35M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腸骨骨折	42		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						下痢	55	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪性新生物進行	107		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
E-LD	6004-00412	ASIAN	10 mg/kg	MALE	6[redacted]	悪寒	1	5M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	1	1.3H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						紅斑	5	115D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	8	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	16	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アフタ性口内炎	21	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	34	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低酸素症	41		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						閉塞性細気管支炎	44		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						末梢性浮腫	119		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6004-00722	ASIAN	10 mg/kg	MALE	6[redacted]	しゃっくり	9	53D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	21		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	28	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	37		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	95	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染性腸炎	111	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						白内障	222		RELATED	GRADE 3	AE	DOSE REDUCED	
						頚部脊柱管狭窄症	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリン分解産物増加	309	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	314	136D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						フィブリンＤダイマー増加	337	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	375	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	526	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	574	26D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	6005-00586	ASIAN	10 mg/kg	MALE	[redacted]	便秘	6		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	6	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	7	64D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	7	46D	RELATED	GRADE 1	AE	DOSE REDUCED	
						白血球数減少	7	45D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						咳嗽	9	76D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	17	195D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊椎圧迫骨折	20		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	24	62D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	31	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺臓炎	40	31D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球数減少	45	26D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板数減少	45	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	176	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膿疱性乾癬	260	246D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口唇炎	262	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹痛	267	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	463		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	483	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	498	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	527	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						インフルエンザ様疾患	686	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6006-00133	ASIAN	10 mg/kg	FEMALE	7[redacted]	気分変化	1	309D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	68D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						蕁麻疹	3	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	17	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	17	9.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	21	51D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						蕁麻疹	23	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						認知障害	44	287D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	99	141D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	131		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼瞼炎	135	175D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	225		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						リンパ球減少症	253		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						発熱	262		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疾患進行	318		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						膀胱炎	331		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						認知症	331	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						認知症	335		RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
E-LD	6006-00210	ASIAN	10 mg/kg	FEMALE	[redacted]	不眠症	2		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	18.1H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	7	57D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						発熱	21	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	22	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	35	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	35	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	37	44D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腎盂腎炎	37	44D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						悪心	38	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						神経因性膀胱	40	40D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						低ナトリウム血症	43	38D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	43	3D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						うつ病	50	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						体重減少	57		RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						うつ病	59	27D	RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						神経因性膀胱	80	71D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						筋力低下	81	70D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	6006-00248	ASIAN	10 mg/kg	FEMALE	6[redacted]	蕁麻疹	7	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	265	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	274	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	276	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						リンパ球減少症	310	43D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
E-LD	6007-00204	ASIAN	10 mg/kg	FEMALE	6[redacted]	発熱	2	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	3		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	3	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	58		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好酸球増加症	58		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	86		RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	114	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						クッシング様症状	184		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	198	104D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口唇感染	260	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	302	9D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	387	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	408	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	466	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	657	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	720	25D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	765		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非定型マイコバクテリア感染	835		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						間質性肺疾患	835		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	868	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	870	15D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	6007-00474	ASIAN	10 mg/kg	MALE	5[redacted]	発熱	10	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	39	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	71	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	71	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	92	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	110	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	127		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	155	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	165		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	213	21D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						肺炎	216	31D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	277	12D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	277	12D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	309		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	362	18D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	362	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	421		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺臓炎	454	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	486	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						糖尿病	519		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	571	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	585	141D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	589	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	625	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大腸炎	726	32D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃炎	739	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	782	18D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
E-LD	6008-00060	ASIAN	10 mg/kg	MALE	7[redacted]	便秘	5	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	6	51D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	6		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	6	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	14	144D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便潜血	71	282D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	157	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	158	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	163	217D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肝機能異常	203	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	203	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	261	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	309	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						手白癬	316	373D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸ポリープ	352	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結腸腺癌	357	24.0H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						挫傷	377	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	379	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚異常	379	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	379	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	379	5D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎球菌性肺炎	379	15D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	379	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	386	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	398	68D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	435	1M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	465	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	465	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腸炎	465	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	468	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	468	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	468	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	469	364D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼脂	506	204D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	597	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	604	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	617	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	685	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	806	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便潜血	807	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	851	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	870	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	915		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	938	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						手白癬	981	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉腫脹	1002			GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	1002	8D		GRADE 1	AE	DOSE NOT CHANGED	
						下痢	1003	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	1009		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6009-00313	ASIAN	10 mg/kg	MALE	6[redacted]	倦怠感	3	559D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	3	475D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	6	472D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	12	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	12		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口内炎	81	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	148	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	155		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	222	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	253		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	253	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	295		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喉頭痛	322	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						近視	344	254D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						齲歯	470	302D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜充血	503	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						核性白内障	598	117D	RELATED	GRADE 3	AE	DOSE REDUCED	
						核性白内障	715	24D	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
E-LD	6010-00049	ASIAN	10 mg/kg	MALE	7[redacted]	譫妄	2		RELATED	GRADE 3	AE	DOSE REDUCED	
						喘鳴	2	1.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	12	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						転倒	12	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	30	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	50	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	57	29D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						注射部位疼痛	57	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性運動ニューロパチー	66		RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性感覚ニューロパチー	66		RELATED	GRADE 2	AE	DOSE REDUCED	
						便秘	71		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	100	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	101	392D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	101		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	137	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	138	31.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						国際標準比増加	138	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						浮動性めまい	139	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						認知障害	148		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	148	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	149	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肝機能異常	155	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						動悸	219	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘息	239	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脱水	239	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	239	7D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						動悸	562	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6010-00387	ASIAN	10 mg/kg	FEMALE	7[redacted]	発疹	3	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						狭心症	4	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低血圧	100	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						白内障	112		RELATED	GRADE 3	AE	DOSE REDUCED	
						便秘	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	324	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	324		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						酸素飽和度低下	408	3.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	438	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						挫傷	477	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過敏症	483	24D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	491	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						蛋白尿	493		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜出血	506	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	616	3D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
E-LD	6010-00547	ASIAN	10 mg/kg	MALE	7[redacted]	多汗症	33	1.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	33	1.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	35		NOT RELATED	GRADE 1	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	43	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	49	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						挫傷	406	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	406		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糖尿病	420		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	476	194D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						肺炎	538	19D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨髄炎	612	82D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	658	36D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	669	46D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-LD	6011-00272	ASIAN	10 mg/kg	FEMALE	7[redacted]	喘息	-61	39D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高血糖	2	551D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						ほてり	10	440D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮下血腫	45	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	85	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						回転性めまい	166	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血糖症	198	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	199	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	239	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜炎	240	237D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋肉痛	250	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	303	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	321		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						膀胱炎	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪破損	435	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス性胃腸炎	457	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	488	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	524	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糖尿病	553	23D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						インフルエンザ	604	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6012-00567	ASIAN	10 mg/kg	FEMALE	7[redacted]	不眠症	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	7	134D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリン分解産物増加	7	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	7	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						咽頭炎	12	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	17	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	17	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	45	147D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	45	0S	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	63	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	84	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	92	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	102	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	108	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	116	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	118	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	131	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	140		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						体重減少	140	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	141	46D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	143	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	144	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	147	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	148	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	152	40D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ステロイド離脱症候群	152	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	152	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	153	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						フィブリン分解産物増加	154	85D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	156	22.9H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	159	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	162	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低ナトリウム血症	163	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	164	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔カンジダ症	166	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	166	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	167	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						体重減少	168		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋力低下	169		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	171	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	176		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	176	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	176	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	177	15D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						敗血症	177	8D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						傾眠	177	8D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						挫傷	178	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	178	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚乾燥	184	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	187		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	192	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	205		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6014-00036	ASIAN	10 mg/kg	MALE	[redacted]	ほてり	1	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肝機能異常	4	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	9	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	14	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	35	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	183	99D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	189		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						心拡大	239	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	252	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	253	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	271	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨髄異形成症候群	281	605D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						齲歯	348	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	397	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	398		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	400	24D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支炎	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肋骨骨折	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	428		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	429		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	458		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	462	116D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-LD	6014-00039	ASIAN	10 mg/kg	MALE	6[redacted]	便秘	11		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	154	56D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性浮腫	154		RELATED	GRADE 1	AE	DOSE REDUCED	
						クッシング様症状	182		RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性ニューロパチー	210	240D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白斑	240		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	269		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	304		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肝機能検査異常	310	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	378	45D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						蕁麻疹	385	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	423		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						末梢性ニューロパチー	450		RELATED	GRADE 1	AE	DOSE INCREASED	
						鼻咽頭炎	545	74D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	741	18D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	774	27D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	811	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	873		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	922	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	949	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6015-00217	ASIAN	10 mg/kg	FEMALE	4[redacted]	発熱	10	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						大葉性肺炎	11	18D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	13	24D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	17	20D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	110	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯周病	141	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	197	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	236	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳梗塞	243	53D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						汎血球減少症	258	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	269	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	272	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳梗塞	298	54D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						白血球減少症	309	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	309	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脳梗塞	359	16D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						一過性脳虚血発作	405	23.7H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	659		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	698	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-LD	6016-00114	ASIAN	10 mg/kg	FEMALE	[redacted]	便秘	3	532D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	8	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎	10	14D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道の炎症	121	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	139	32D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	170	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						胃炎	196	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						熱傷	310	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	325	56D	RELATED	GRADE 2	AE	DOSE REDUCED	
						腎クレアチニン・クリアランス減少	394	14D	RELATED	GRADE 1	AE	DOSE REDUCED	
						腎クレアチニン・クリアランス減少	422	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						リンパ球減少症	450	8D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	520	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						便秘	584		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	604	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎クレアチニン・クリアランス減少	618	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						腎クレアチニン・クリアランス減少	646	15D	RELATED	GRADE 1	AE	DOSE REDUCED	
						腎クレアチニン・クリアランス減少	674	22D	RELATED	GRADE 1	AE	DOSE REDUCED	
						上気道感染	674	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						萎縮性胃炎	730	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	744	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						倦怠感	744		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	744	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						萎縮性胃炎	758		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	786	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	898	43D	RELATED	GRADE 1	AE	DOSE REDUCED	
LD	1401-00563	WHITE	0	MALE	5[redacted]	振戦	1	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	3	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8	25D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	17	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	40	4D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	50	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						呼吸困難	57	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						節足動物咬傷	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	64	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	64		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	64	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	71	24.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	80		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	1403-00246	WHITE	0	FEMALE	6[redacted]	過敏症	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	7	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						そう痒症	78	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過敏症	94	20D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	100		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脊髄圧迫	113		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	1403-00424	WHITE	0	FEMALE	[redacted]	不安	1	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1	622D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	64	462D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱毛症	92	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	92		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	168	22D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						労作性呼吸困難	219		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	225	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	225	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	225	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	225	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	246	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	246		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	260	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠時無呼吸症候群	267	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	268	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	311		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	311	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低γグロブリン血症	312	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	312	24.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支炎	354	29D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						乳酸アシドーシス	382	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大葉性肺炎	382	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						パラインフルエンザウイルス感染	382	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うっ滞性皮膚炎	383	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うっ血性心不全	384		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	384	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	387	42D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	456	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	456	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢動脈狭窄	504	59D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中甲状腺刺激ホルモン増加	524		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						第一度房室ブロック	525		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耳垢栓塞	538	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低γグロブリン血症	538		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	538	86D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						クロストリジウム検査陽性	562	110D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚潰瘍	563	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿路感染	563	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心臓損傷	569		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢動脈狭窄	573		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚潰瘍	577	82D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	595		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	595		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	609	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	623	77D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						疲労	623	77D	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						低カリウム血症	623	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	623	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	623	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	650	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	699		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	699		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	1411-00001	WHITE	0	FEMALE	8[redacted]	背部痛	1	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	1	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1	98D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	15	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	31	138D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	44		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						うつ病	44		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	7D	RELATED	GRADE 3	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	57	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	71	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	99	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	126	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	155	71D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	155	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	169	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	225		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	225	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	239	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	275	77D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	279	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	309	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	316	90D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	346	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	365	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						股関節部骨折	404	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	406		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	1411-00058	WHITE	0	MALE	7[redacted]	眼痛	1	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	5	225D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿意切迫	9	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	12	134D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	12	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	19	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	20	210D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	131		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿意切迫	131	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						血小板減少症	131	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿意切迫	145		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	187	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	198	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	201		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	243		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	243	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	243	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	251	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	271	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	271	85D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	271	330D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	285		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						顎膿瘍	369	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	369	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	396	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	460	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	488		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	488	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鉄欠乏	580		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	1414-00010	WHITE	0	MALE	6[redacted]	腎不全	8	48.0H	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	16	274D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚異常	39	62D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	72	197D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	111	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	128	141D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	156	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						裂傷	163	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	176	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心房細動	282	29D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	289	9D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						眼帯状疱疹	329		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
LD	1414-00099	WHITE	0	MALE	6[redacted]	高カルシウム血症	3	4D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
LD	1414-00234	WHITE	0	MALE	8[redacted]	発声障害	9	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋力低下	9	22D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	16		RELATED	GRADE 3	AE	DOSE REDUCED	
						深部静脈血栓症	23	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	58	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						遠隔転移を伴う肺癌	61		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	1414-00295	WHITE	0	MALE	5[redacted]	便秘	8	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	15	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	15	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	15	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	15	50D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	20	3D	RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						横紋筋融解症	39	5D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						皮膚病変	64	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	1431-00072	WHITE	0	MALE	7[redacted]	背部痛	3		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋肉痛	3	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						非心臓性胸痛	3	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	8	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非心臓性胸痛	23	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	33	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	35	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	46	5D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	46	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						急性腎不全	46	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	51	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜痛	57	28D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	70	106D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カルシウム血症	84	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	98	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	103	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	133	12D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アラニンアミノトランスフェラーゼ増加	154	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	154	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	156	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	175		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	212	7D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						嘔吐	262	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	268		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	340	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	348		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	351	10D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						血小板減少症	351	10D	RELATED	GRADE 3	AE	DOSE REDUCED	
						関節痛	391	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋肉痛	391		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	399	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	472	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	543	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非心臓性胸痛	543	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	1431-00386	BLACK OR AFRICAN AMERICAN	0	MALE	5[redacted]	筋痙縮	108	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	130	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	152		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	152		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	152		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	165	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	165	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	194	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	248		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血糖症	266	7.3H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	1442-00667	WHITE	0	FEMALE	5[redacted]	脊椎圧迫骨折	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	27	18D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						背部痛	27	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸困難	27	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	27	28D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	28	102D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	28	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多尿	28	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	31		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	36	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						菌血症	48	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	48	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	48	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	48	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	67	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	83	13D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						敗血症性ショック	83	13D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カルシウム血症	85	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	85	8.8H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低血圧	85	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	86	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	87	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	87	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	92	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	126	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	126	37.4H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	126		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						敗血症	126	5D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						不整脈	127	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低血圧	127	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	129	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	1447-00018	WHITE	0	MALE	8[redacted]	背部痛	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	1	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						口唇潰瘍	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	1	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻脈	1	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						斑状皮疹	10	12D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						排尿困難	86	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	86	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						尿路感染	86	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	94	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	107	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	107	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	149	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	149	1.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	149	152D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経過敏	171		NOT RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	241	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	241		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	262	56D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						低カリウム血症	279	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	295	2D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	301		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	1447-00026	WHITE	0	MALE	8[redacted]	発疹	6	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肋骨骨折	40	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						非心臓性胸痛	42	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	84		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	84		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	84	173D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	127		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	141	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	150		RELATED	GRADE 2	AE	DOSE REDUCED	
						腹痛	201		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	211		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						異常な夢	337	60D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						丘疹	392		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	414	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歩行障害	470		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	1452-00056	WHITE	0	MALE	7[redacted]	上気道感染	6	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性副鼻腔炎	55	49D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	57	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	76	28D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						好中球減少症	113		RELATED	GRADE 2	AE	DOSE REDUCED	
						血小板減少症	113		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	1473-00431	WHITE	0	FEMALE	6[redacted]	呼吸困難	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1	672D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						排尿躊躇	29	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	57	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	57	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						活動性低下	84	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	84	589D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	112	561D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	140		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						舌変色	140		RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	222	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃食道逆流性疾患	377		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	388	284D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	488	16D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低酸素症	490	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						記憶障害	532	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低酸素症	637		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	644		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	664		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	672		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	672	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						記憶障害	672		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	672		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疼痛	672		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	686		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	710	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	710	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	750	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	750	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	753	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	770	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	1480-00630	WHITE	0	FEMALE	8[redacted]	悪心	5	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	8	14.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	15	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	15		RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	20	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	24	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	36		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	43	2D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						転倒	45	22.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	56		RELATED	GRADE 2	AE	DOSE REDUCED	
						ヘモグロビン減少	56	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	71	28.0H	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						胃腸出血	86	2D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	106	1M	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2400-00029	WHITE	0	FEMALE	5[redacted]	悪心	3	83D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	3	3D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	3	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	4	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	4	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	4	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	5	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	5	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	7	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	11	174D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	13	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	21	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	21	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	21	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	28	98D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	36	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	41	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	47	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	47	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	47	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	56	95D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	56		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	56	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	60	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格痛	65	63D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	77	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	96	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	103	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	104	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入部位内出血	123	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	123	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	126	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	140	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	140		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	151		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	176	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	185	57D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	186	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腰椎骨折	211	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	2400-00113	WHITE	0	MALE	6[redacted]	記憶障害	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						陰嚢血瘤	4	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	4	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	5	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	5	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	5	28.4H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カリウム血症	6	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	8	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	10	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	12	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高ビリルビン血症	13	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	18	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	29	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						耳感染	46	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	49	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	90D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	64	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	68	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	70	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症	113	28D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カルシウム血症	139		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	140		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疾患進行	140	56D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						傾眠	140		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	140	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	2401-00518	WHITE	0	FEMALE	[redacted]	不眠症	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	3	9D	RELATED	GRADE 2	AE	DOSE REDUCED	
						酒さ	4	37D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	5	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						酒さ	41	216D	RELATED	GRADE 2	AE	DOSE REDUCED	
						血小板数減少	48	5OD	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	55	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						悪寒	60	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	60	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	60	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	80		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	83	436D	RELATED	GRADE 1	AE	DOSE REDUCED	
						膀胱癌	91	400D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	95		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	105	388D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	126	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	133	11D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						大葉性肺炎	136	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						脱毛症	188	173D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ほてり	223		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	312	107D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿失禁	313	40D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔真菌感染	347	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	349	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿失禁	352	47D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	419	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不随意性筋収縮	435	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	463	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	492	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	492	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	498	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節硬直	503	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	503	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						真菌性尿路感染	508	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	523	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	542	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	564	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	564	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						爪破損	615		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	664	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ大腸炎	672	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	692		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	696		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	726	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨障害	733		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	766		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	2403-00023	WHITE	0	FEMALE	7[redacted]	発疹	2	5D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						口内乾燥	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	14	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	14	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	18	449D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	21		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋痙縮	24	33D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節硬直	25	104D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	25	159D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	29	100D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口の錯感覚	29	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36	246D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面浮腫	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	69	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	82	116D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	96	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						健忘	106	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	114	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						角膜瘢痕	128	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						片頭痛	137		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	141		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節腫脹	197		RELATED	GRADE 1	AE	DOSE REDUCED	
						浮動性めまい	204	218D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	263	47D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	281	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	295	56D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	351		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	365	81D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	419	59D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	435	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	445		RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	466		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						聴力低下	477	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼡径部痛	512	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	575		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	590		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	642		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	659		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	756	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						うっ血性心不全	760	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	821		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鉄欠乏	830		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	889		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疼痛	889		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	2403-00030	WHITE	0	MALE	8[redacted]	貧血	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格硬直	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	2	26D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						側腹部痛	6	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	6	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						挫傷	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	16	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	16	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	19		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	19	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	20		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	21		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	21		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	24	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	26		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	26		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	28	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	36	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	40		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	40		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						食欲減退	43		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	43		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	49	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2403-00109	WHITE	0	MALE	8[redacted]	下痢	10	34D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						靭帯捻挫	14	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	18	3D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脱水	18	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血便排泄	18	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	19		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	20	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	23	63D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	29	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	29	8D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						関節腫脹	29	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	29	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心臓瘤	39		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	52	69D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	71	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発声障害	78	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	82	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歩行障害	82	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	85	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	85		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低体温	85	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						起立性低血圧	85	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	85		RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	85	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腸球菌性尿路感染	86	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	92	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	92	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨盤骨折	100		NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						下痢	117	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	2403-00175	WHITE	0	FEMALE	[redacted]	背部痛	2	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚異常	5	219D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	9	161D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	11	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格不快感	20	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						灼熱感	22		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						灼熱感	22		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	29	195D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	12D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	57	154D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						基底細胞癌	85	79D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						紅斑	85	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	113		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						小結節	113	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	211	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	218		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	223	590D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	303	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	309		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	309		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	331	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	402		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	402		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						ビタミンB12欠乏	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	447		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈湖	617		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	681		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	771		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	781		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	813		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	838		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状出血	884		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑	894		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚色素過剰	897		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	2403-00473	WHITE	0	FEMALE	[redacted]	背部痛	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	9	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						多汗症	9		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	23		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	36	10D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪寒	41	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	41	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	42		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	42	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	57	127D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射消失	57		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	57		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	68	74D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	69		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	71	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	104	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腟出血	104	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						収縮期血圧上昇	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	171	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						細菌性関節炎	202	44D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						肺炎	202	44D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
LD	2405-00326	WHITE	0	MALE	6[redacted]	悪寒	6	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	6		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	21		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	26	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	28	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	43	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	43	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	49		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	60	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心筋虚血	60	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性心筋梗塞	99	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						心筋梗塞	122		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						急性腎不全	122	13D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2405-00448	BLACK OR AFRICAN AMERICAN	0	FEMALE	7[redacted]	便秘	2	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	2	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	2	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	16	20D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嚥下障害	17	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	17	17D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節腫脹	17	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	17	17D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	17	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	17	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	17	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	22	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	12D	NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						急性腎不全	22	12D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						嘔吐	22	12D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	23	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	36	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	37	27D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						嘔吐	37	27D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						貧血	51	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	51	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	64		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性浮腫	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	64		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	124		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						急性腎不全	124	53D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2407-00005	WHITE	0	MALE	7[redacted]	体位性めまい	22	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	37	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	37	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	71	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	71	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	83	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	83	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	83	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	83	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	144	159D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	206	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腱炎	242	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	277		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋痙縮	277		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋痙縮	277		RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	303		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						副鼻腔炎	402	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						夜間頻尿	416		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	444	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	493	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	505	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	570	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚢胞	581		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	630	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	701		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	728	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	734		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						間質性肺疾患	735	17.2H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	735	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						間質性肺疾患	737	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	742	40.6H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	742	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	764	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	765	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高コレステロール血症	887		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	918	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肉離れ	1014		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歯感染	1114		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	2407-00016	WHITE	0	MALE	7[redacted]	尿閉	18	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	18	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	19		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻尿	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	49	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹部膨満	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						間代	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	130	10D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	137		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	147	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱水	150	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	150	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	154		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						陰茎浮腫	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						陰嚢浮腫	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	159	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	159		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						貧血	160	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胸水	162		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クロストリジウム検査陽性	164		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不安	166		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	166		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	168		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪性新生物進行	171	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2407-00020	WHITE	0	FEMALE	[redacted]	不眠症	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8	147D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	28	188D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	43	374D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	46	200D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	46	95D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	46	95D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内痛	63	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	66	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	66	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	66	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	66	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	81	336D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過換気	84	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	109	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	112	305D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	132	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カリウム血症	140	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	169	110D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	169		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	169	78D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	174	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						平衡障害	199	218D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不全片麻痺	199		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	201		RELATED	GRADE 3	AE	DOSE REDUCED	
						筋痙縮	206	211D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	244	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	246	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						幻聴	246	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						幻視	246	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	249	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	249	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	249	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低マグネシウム血症	249	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血液量減少症	249	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	249	5D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	249	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	249	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						嘔吐	249	5.3H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						男性外性器蜂巣炎	251	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	255	68D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	278	152D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	283	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	292	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	294	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	294	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	301	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	301	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	301	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	308	11D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						喘鳴	308	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	323	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	323	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	323	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	333	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼡径部痛	333	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	350	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	354		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	389	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪寒	389	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸窮迫	389	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	390	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	390	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	390	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外陰腟痛	391	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱水	405	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	405	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	405	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						外陰腟不快感	405	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	417	4D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	418	3D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	488	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	559	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	602	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	606		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	616		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	628	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	977		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	2407-00202	WHITE	0	FEMALE	[redacted]	眼感染	11	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	11	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	14	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	14	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中アルカリホスファターゼ増加	14	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	14	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋痙縮	14	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	18	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	18	207D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	22	62D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	41	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	41	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	47	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	47	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	47	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						潮紅	57	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	105	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腱炎	132	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射消失	140	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	159	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	183	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格痛	192	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	224	29D	RELATED	GRADE 3	AE	DOSE REDUCED	
						下気道感染	270	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯感覚	273	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格不快感	336		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	361	80D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	379	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	420		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	441	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位内出血	448	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	464	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	516	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	547	37D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						処置後出血	572	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
LD	2407-00219	WHITE	0	MALE	6[redacted]	嚢胞	71	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	140	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	238		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	365	5D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	369		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						譫妄	370	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						髄膜転移	370	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	2407-00284	WHITE	0	MALE	6[redacted]	気管支炎	1	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	28	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	43	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	49	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	49		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	85		RELATED	GRADE 3	AE	DOSE REDUCED	
						疲労	140		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	140		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	174	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	182	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	233		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	258	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	276	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	276	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎	276	11D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	276	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						カンジダ感染	282		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	289	11D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	295	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	299		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	300		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	334	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	2407-00590	WHITE	0	MALE	6[redacted]	貧血	6	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	13	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						無力症	14		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪床出血	14	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	20	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	27	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	27	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	35	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						蜂巣炎	35	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						表在性血栓性静脈炎	35	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	40		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	48	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	66		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	66	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	66		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸時疼痛	66	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	67	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						レンサ球菌性菌血症	67	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿閉	67		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	68	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯乱状態	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	69		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	70	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道うっ血	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						構語障害	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血便排泄	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚変色	72		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	74		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	74		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	75	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	76		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	77		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格痛	77		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						点状出血	78		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						落ち着きのなさ	79		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	80		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便失禁	80	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	80	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	81	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						十二指腸胃逆流	81	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肛門周囲痛	81		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	82		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	83	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結腸腺癌	84	251D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						貧血	84	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						水分過負荷	87	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	87		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンジダ感染	88		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	89	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	90	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カルシウム増加	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム減少	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頻脈	90		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	91	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊髄圧迫	91		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						低マグネシウム血症	94	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	95	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	124	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	3400-00153	WHITE	0	MALE	7[redacted]	胃食道逆流性疾患	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	45	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	48	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	51		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	68	10D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						呼吸困難	82	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	93		RELATED	GRADE 2	AE	DOSE REDUCED	
						肺塞栓症	97	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						肺感染	109	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						直腸出血	145		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	193	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	214	276D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	257	13D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						末梢性浮腫	281		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	286	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	316	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	323	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	490	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	494	7D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						背部痛	501		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	526	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	533	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	540	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体位性めまい	547	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						起立性低血圧	547	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	3400-00160	WHITE	0	MALE	7[redacted]	発声障害	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯感覚	47	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	126	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼充血	141	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	141	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	195		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						膀胱炎	253	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	323		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						擦過傷	345	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	351	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	554	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	587		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	589		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	615	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	618		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺膿瘍	646		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						転倒	671	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ミオパチー	671		RELATED	GRADE 2	AE	DOSE REDUCED	
						転倒	684	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	701	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	701		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	750	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	750	24.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺膿瘍	750	9D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						腎不全	750	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	752	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺膿瘍	764	7D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	766	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	767		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	3400-00161	WHITE	0	MALE	6[redacted]	黄色板腫	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	105	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	112		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心筋虚血	123	8D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						気管支肺炎	130	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	3400-00179	WHITE	0	MALE	6[redacted]	関節痛	5		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	5	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	26	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	101	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	114	433D	RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	125	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失語症	181	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高コレステロール血症	193		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						緑内障	277		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	301		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性冠動脈症候群	318	4D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						滑液包炎	360		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	450		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						扁桃潰瘍	464	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						扁桃癌	493	335D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
LD	3400-00697	WHITE	0	FEMALE	7[redacted]	筋痙縮	9	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	25	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	50	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	57	548D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺腫瘤	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	191	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	246	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	307	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	321	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						メレナ	321	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	366	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	366	148D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						憩室炎	386		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ミオパチー	394	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	407	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	407	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨髄炎	438	100D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球数減少	478		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	478	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	484	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	506	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	534		RELATED	GRADE 4	AE	DOSE REDUCED	
						骨髄異形成症候群	562		RELATED	GRADE 4	SAE	DRUG WITHDRAWN	UNKNOWN
						疼痛	562		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚有棘細胞癌	601		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						貧血	605	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	607		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						転倒	608	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	3404-00565	WHITE	0	MALE	5[redacted]	下痢	4	21.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	16	42D	RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	26	60D	RELATED	GRADE 3	AE	DOSE REDUCED	
						顎骨壊死	53		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔膿瘍	95	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	106	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	169	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	192		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	253	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	337		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	337		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	531	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	573	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	703		RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						上気道感染	710	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	3406-00355	WHITE	0	MALE	6[redacted]	睡眠障害	2		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	6	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	14	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	23	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	30		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	56	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	62		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	64	23D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						吸収不良	64		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膵炎	64		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						嘔吐	66	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重減少	66		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	69		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋虚血	69	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	71	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	87		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	87		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	117	102D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	148		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	3407-00236	WHITE	0	MALE	5[redacted]	背部痛	-12	7D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						発疹	1	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	4	17D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						蜂巣炎	4	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	4	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪囲炎	14	45.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腿骨頚部骨折	46	59D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						発熱	47	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	50	24.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						術後創感染	91	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	3408-00449	WHITE	0	MALE	7[redacted]	疲労	2	589D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発声障害	3	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膝蓋骨骨折	14	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						橈骨骨折	14	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	43	33D	RELATED	GRADE 2	AE	DOSE REDUCED	
						咳嗽	75	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	75	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	92	268D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	98	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	110	250D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	141	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	161	280D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						勃起不全	216		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血腫	306	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	350	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						脱水	350	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						国際標準比増加	350	16.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿閉	350		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						感染	351	13D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						良性前立腺肥大症	370	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						体重減少	373		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	504	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	590		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	590	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷	620		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	721	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	721	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	729	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	3409-00147	WHITE	0	FEMALE	7[redacted]	潮紅	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	6	114D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	6		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	113		RELATED	GRADE 2	AE	DOSE REDUCED	
						うつ病	113		RELATED	GRADE 2	AE	DOSE REDUCED	
						不眠症	113		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	113	55D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	120	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	120		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	140		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	168		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	168		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	272	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	305	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高コレステロール血症	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	323	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外傷性切断	323		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						運動失調	332		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	332		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	332	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						内出血発生の増加傾向	333		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	450	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	456	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面痛	456	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	456	76D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膝蓋骨骨折	456	76D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	476	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嗜眠	476	56D	RELATED	GRADE 3	AE	DOSE REDUCED	
						卵巣嚢胞	552	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	655	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						形質細胞腫	696		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
LD	3410-00487	WHITE	0	MALE	7[redacted]	歯痛	1	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	3	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嗜眠	4	82D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	4		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	6	140D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲亢進	22		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	30	98D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	41	131D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	44	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嗜眠	85	61D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	120		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	142		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	145	53D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嗜眠	145	53D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						胸部不快感	149		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモフィルス感染	149	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	167	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						歯肉炎	169	155D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	176		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	176		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						裂傷	190	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	190	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	190	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	197		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嗜眠	197		RELATED	GRADE 2	AE	DOSE REDUCED	
						裂傷	204	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						裂傷	217	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	305	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	392	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	396	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	415	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯感染	421	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	447	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	447	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腫瘤	456	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼刺激	477		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	488	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	495		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	504		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	526		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便意切迫	596		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿意切迫	596		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉痛	617		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	634	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	696		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	720	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	770	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						肺炎	773		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						インフルエンザ	777	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						インフルエンザ	784		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
LD	4003-00407	WHITE	0	MALE	7[redacted]	呼吸困難	1	477D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内乾燥	3	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	4	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	6	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	21	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						局所腫脹	33	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	66	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸不全	84	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						埋込み部位膿瘍	92	8D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	92	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚症	98	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪真菌症	98	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ブドウ球菌性菌血症	119	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						痛風性関節炎	136	91D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						細菌性関節炎	141	7D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	169	39D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	208	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	223	156D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	240	71D	RELATED	GRADE 1	AE	DOSE REDUCED	
						インフルエンザ	267	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血腫	317	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肋骨骨折	317	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						創傷感染	323	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	332	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	339	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	361	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	362	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	379	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	393	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心不全	400	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						皮膚有棘細胞癌	401	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血栓性静脈炎	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	421	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						瘻孔分泌物	455	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋骨格痛	472	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	489	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	533		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	547	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	589	210D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	631	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	645	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	659	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						過換気	661		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						日光性角化症	662		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	663	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						四肢痛	670	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	673		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	687	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						四肢痛	687		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節痛	701	4D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						関節痛	705	63D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						てんかん重積状態	742	8D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						擦過傷	743	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚消失	743	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	787	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎骨壊死	799	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						顎骨壊死	802	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	4100-00296	WHITE	0	FEMALE	4[redacted]	上腹部痛	1	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	1	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疼痛	1	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	1	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	2	47D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	4	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	15	51D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	15	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	22	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						単ニューロパチー	37	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング症候群	51	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	51	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	58	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	65	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	65	10D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	93	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4100-00683	WHITE	0	MALE	8[redacted]	発熱	7	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	45	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	62	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	62	24D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	99		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	124	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	127	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	155	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	169	8D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						浮腫	253	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大赤血球症	281	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	365	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害者	463		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	477		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血尿	533	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	574	32D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4102-00494	WHITE	0	FEMALE	4[redacted]	うつ病	1	170D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹痛	20	23D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	20	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						胃食道逆流性疾患	24	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	50		RELATED	GRADE 2	AE	DOSE REDUCED	
						歩行障害	113	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	113	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						小腸炎	163	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	171	83D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	171	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	183		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	197	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	253	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	253	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	25D	RELATED	GRADE 1	AE	DOSE REDUCED	
LD	4105-00260	WHITE	0	MALE	6[redacted]	上腹部痛	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	15	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	15	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン減少	29	8D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	50	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	61		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性浮腫	85	533D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	113	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	113	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	148	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上気道感染	163		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	181	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	253		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	281	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						浮動性めまい	281		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分動揺	281		RELATED	GRADE 1	AE	DOSE REDUCED	
						深部静脈血栓症	289	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	401	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	421	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	421	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	421	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	453	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	474	11D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	477	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚部痛	485	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	533	71D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上気道感染	536	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	552	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	645	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎結石症	662	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	686		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	697	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	701	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	707	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						抜歯	708	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性腎不全	729	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	730	47.9H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						急性腎不全	730		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	736	23.8H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎球菌性肺炎	744	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎球菌性肺炎	745	10D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺炎球菌性肺炎	745	9D	NOT RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						貧血	747	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喀血	754	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低換気	754		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	754		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カリウム血症	778	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	782	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	813	26D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	827		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	855	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						聴力低下	855		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	883	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	897	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4106-00171	WHITE	0	FEMALE	3[redacted]	圧迫骨折	18	21D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						便秘	24	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アレルギー性鼻炎	57	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	58	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	83	31D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	114	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	126		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	364	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4200-00331	WHITE	0	MALE	7[redacted]	疲労	1	266D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	82	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	99	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低リン酸血症	127	63D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支炎	176	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心房細動	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血管腫	204	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低リン酸血症	211	10D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低リン酸血症	239	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気管支炎	253	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	267	42D	RELATED	GRADE 3	AE	DOSE REDUCED	
						低リン酸血症	281	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	295	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	309	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨膿瘍	351	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	393	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	421	42D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	449	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道感染	449	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
LD	4200-00505	WHITE	0	MALE	4[redacted]	創傷感染	36	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発疹	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈炎	53	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	57	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	71	56D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血栓性静脈炎	110	31D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	127	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	141	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	155	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	159	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	159	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎	163	22D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肝酵素上昇	190	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	211	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4200-00641	WHITE	0	FEMALE	7[redacted]	関節痛	-9	35D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						カテーテル留置部位感染	1	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	8	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路感染	15	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	20	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外傷性骨折	42		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						骨髄炎	64	56D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						疾患進行	112	9D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4201-00278	WHITE	0	MALE	5[redacted]	発熱	4	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	9	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	11	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	15	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	39	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	41	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	45	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	49	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	60	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	68	51D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	119		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	130	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	136	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	144	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	144	10D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺炎	144	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症	144	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	145	3D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						カテーテル留置部位感染	146	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	148	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	4201-00360	WHITE	0	FEMALE	7[redacted]	筋痙縮	10	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	42	22D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	42	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	42	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						精神緩慢	43	10D	RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	43	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	56	43D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	56	8D	RELATED	GRADE 4	AE	DOSE REDUCED	
						痙攣	64	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	70	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	70	63D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	72	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	89	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	112	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						体重減少	112	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	124	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	126	56D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						白血球減少症	126	29D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	126	14D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	126	14D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	140	15D	RELATED	GRADE 3	AE	DOSE REDUCED	
						顎骨壊死	140	238D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	140	28D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	168	14D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	182	205D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	182	98D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	196	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	210	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	229	45D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	243	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	243	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	252	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	280	14D	RELATED	GRADE 4	AE	DOSE REDUCED	
						血小板減少症	294	93D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						顔面骨骨折	333		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						回転性めまい	334	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	336	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	336	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						顎骨壊死	378	20D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	387	4D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	387	3D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	387	5D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	392	98D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						顎骨壊死	398		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	406	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	422	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	434	56D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						無力症	440	28D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	488	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	490	14D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	490	70D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低カリウム血症	490	70D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	490	14D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	504	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	515	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	532	120D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	560	92D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	4201-00421	WHITE	0	MALE	6[redacted]	回転性めまい	6	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						歩行障害	33		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	43	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						中毒性皮疹	78	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	85	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						咳嗽	93	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咽頭炎	99	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	102	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	113		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						無力症	116		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	116		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	120		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	123		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	124		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4201-00432	WHITE	0	FEMALE	[redacted]	感情的苦悩	2	51D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	2	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	4	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	13	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	13	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						精神緩慢	16	10D	RELATED	GRADE 2	AE	DOSE REDUCED	
						不眠症	16	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						精神緩慢	26	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	76	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	77	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	92	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	104	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	115	88D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	117	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	148	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	165	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	199	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	225	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	230	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	230	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	258	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	270	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	272	326D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	286	262D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	318	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	356		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	457	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	478	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	491	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	505	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	530	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	530	118D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上腹部痛	531	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	598	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	648	65D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	648		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	742	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	742	24D	RELATED	GRADE 3	AE	DOSE REDUCED	
						筋力低下	765		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脳血管発作	779		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
LD	4201-00589	WHITE	0	FEMALE	7[redacted]	ウイルス感染	35	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	36	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	41	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支肺炎	41	22D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	44	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	65	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	99	162D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	29D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	134	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	176	34D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	210	16D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	212	33D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	255	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺塞栓症	280	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血栓性静脈炎	348	11D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						静脈血栓症	348	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支炎	369		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						塞栓症	369		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						左室不全	369		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						尿路感染	370	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						全身健康状態低下	398	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4202-00479	WHITE	0	MALE	6[redacted]	疲労	1	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	11	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	15	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	49	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	71	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	76	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	78	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	99	128D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ブドウ球菌性敗血症	174	19D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ブドウ球菌性敗血症	202	25D	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						ウイルス性胃腸炎	236	12D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						大葉性肺炎	236	12D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						心内膜炎	257	62D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	306	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4202-00658	WHITE	0	MALE	6[redacted]	腫脹	4	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	29	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	53	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	141	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	155	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						病的骨折	174	63D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						処置後合併症	185	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腸出血	361	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	400	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	408	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	492	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴覚障害	548		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腱断裂	560	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腱断裂	603	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨盤痛	618		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						医療機器位置異常	625	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						医療機器位置異常	646	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4202-00699	WHITE	0	FEMALE	6[redacted]	痙攣	22	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	23	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	23	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	127	456D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	127	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	209	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不眠症	225	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	393		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	467	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	495	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	548		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	583	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	631	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4301-00285	WHITE	0	FEMALE	4[redacted]	浮動性めまい	6	80D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						動悸	6	80D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						振戦	6	80D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						不安	12	74D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	19	0S	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						うつ病	29		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						舌痛	30	109D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	30		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	33	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	72	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	73	4.4H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	73	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	88	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	107	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	139	40.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸時疼痛	139	25.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	139	2D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	156	372D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	156		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	156	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	163	442D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	170	32D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚感染	177	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	198	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重増加	198		RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	356	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	357	9D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						膣の炎症	364	87D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	395	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	415	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状出血	422	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣分泌物	422	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	473	60D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	478	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	533	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						カンピロバクター胃腸炎	535	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						カンピロバクター検査陽性	538	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						限局性感染	583	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢膿瘍	590	8D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	605		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	634	6D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4301-00502	BLACK OR AFRICAN AMERICAN	0	FEMALE	5[redacted]	疲労	1	252D	RELATED	GRADE 1	AE	DOSE REDUCED	
						ヘモグロビン減少	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	1	337D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	8	91D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	12	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	15	10.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	23	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣の炎症	23	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	29	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	50		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	50	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						子宮痛	50	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣出血	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						痔核	69	28.5H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						うつ病	71	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	76		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	85	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	106	174D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	106	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	113	77D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	147	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	147	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	159	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	159	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	181	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	211	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	211	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	226	54D	RELATED	GRADE 1	AE	DOSE REDUCED	
						筋痙縮	244	93D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	244		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	279		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	281		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	281	37D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	295	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	372	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	378	127D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性皮膚炎	401	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚炎	403	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	421		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔真菌感染	442	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	458	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	494		RELATED	GRADE 2	AE	DOSE REDUCED	
						気管支炎	531	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	560	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						皮膚乾燥	566	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	568		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	599	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	617		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	663		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	663		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4302-00409	WHITE	0	MALE	6[redacted]	C－反応性蛋白増加	1	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	1	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	4	14D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ヘモグロビン減少	5	25.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						単ニューロパチー	5	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						四肢痛	5	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚疼痛	5	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	5	40.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	7	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	13	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	85	22D	RELATED	GRADE 2	AE	DOSE REDUCED	
						発熱	109	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	110	17.8H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	116	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						ヘモグロビン減少	117	38.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	155	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	158	9D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						鼻出血	159	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	169	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	176		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	182	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	183		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	190		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	190		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	190	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	191	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						尿失禁	191		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	192		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	202	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	202	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	202	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	205		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	207	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	212	15D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	219	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4401-00044	WHITE	0	MALE	6[redacted]	悪心	1	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	15	613D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比異常	19	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	22	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	22	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						攻撃性	54	101D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	54	574D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						うつ病	54	574D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						精神運動亢進	54	101D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						錯乱状態	57	19D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
LD	4401-00065	WHITE	0	FEMALE	[redacted]	無力症	29	64D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	47	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						冷汗	82	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	85	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	85	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不眠症	111		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	237	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	250	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	250	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	267	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	302	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	336	338D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	365	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	422	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	463	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	463	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	472	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	560	25D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心窩部不快感	590	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	645	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋梗塞	663	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						無力症	673	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	688		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	889	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	953	29D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	4401-00143	WHITE	0	MALE	6[redacted]	背部痛	1	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						平衡障害	8	79D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊髄障害	8	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋骨格痛	16	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	22	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	22	98D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	26	228D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	26	187D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	26	117D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	26	200D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠障害	26	172D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発声障害	41	130D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下痛	43	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	87		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	104	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	104	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	112	87D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腹痛	126	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クロストリジウム・ディフィシレ感染	178	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不眠症	198	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	198	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	226	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						末梢性感覚ニューロパチー	240	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	253		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4401-00164	WHITE	0	MALE	7[redacted]	無力症	8	103D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	8	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	15	154D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	15	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	30	42D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低リン酸血症	71	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	71	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	71	84D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	111	87D	RELATED	GRADE 2	AE	DOSE REDUCED	
						ほてり	111	31D	RELATED	GRADE 1	AE	DOSE REDUCED	
						悪心	111	31D	RELATED	GRADE 1	AE	DOSE REDUCED	
						振戦	111	31D	RELATED	GRADE 1	AE	DOSE REDUCED	
						肺障害	137	4D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発声障害	141		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	141	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	155	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	169		RELATED	GRADE 1	AE	DOSE REDUCED	
						中毒性皮疹	183	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	252	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	281	13D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						無力症	282	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	294	16D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胃腸炎	295	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						無力症	311		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						真菌感染	311	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	336	55D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	336	13D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						紅斑	366	40D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						リンパ球減少症	378	13D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低リン酸血症	519	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	616	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	616	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						皮膚乾燥	803		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅色症	803		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚脆弱性	864		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4401-00243	WHITE	0	MALE	6[redacted]	リンパ球減少症	22	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食道炎	22	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	36	20D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯感覚	43		RELATED	GRADE 3	AE	DOSE REDUCED	
						リンパ球減少症	70	12D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	99	40D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱尿道吻合部狭窄	174	48.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎結石症	188	67D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性腎盂腎炎	188	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低リン酸血症	239	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	239	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腎結石症	254	48.0H	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						挫傷	281	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	323	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						膀胱尿道吻合部狭窄	334	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋骨格痛	368	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	4402-00057	WHITE	0	MALE	4[redacted]	筋痙縮	2	139D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	8	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	29	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨壊死	72		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						血小板減少症	295	63D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	358	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	387	141D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	387	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	387	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	414	35D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	449	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	462	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	470	52D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	522	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	526	112D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	526		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	528	26D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	554	62D	RELATED	GRADE 2	AE	DOSE REDUCED	
						呼吸困難	589	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脳虚血	607	8D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						貧血	616	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨髄異形成症候群	756		RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
LD	4402-00095	WHITE	0	MALE	6[redacted]	気管支障害	285	12D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						慢性閉塞性肺疾患	285		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	285		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	286	50D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支障害	308	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						前立腺腺腫	326	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿閉	326	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						尿閉	329	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	336	180D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	337	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						前立腺腺腫	337	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						不眠症	371	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	385	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	503	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	531	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節炎	546	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支炎	606	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	629	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	657	28D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						骨痛	657	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	657	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	685		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4402-00639	WHITE	0	MALE	6[redacted]	歯膿瘍	20	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯膿瘍	42	41D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						無力症	54	140D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯膿瘍	83	20.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	194	27D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	221	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4406-00245	OTHER	0	MALE	5[redacted]	消化不良	2	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠障害	2	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	6	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	26	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	26	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	26	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	54		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	54	56D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						回転性めまい	54	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	135	132D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血小板減少症	135	86D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						胆嚢炎	196	8D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4409-00545	OTHER	0	MALE	7[redacted]	リンパ球減少症	8	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						熱感	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	81	34D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	136	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無気肺	143		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺塞栓症	143	17D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						無力症	144	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	144		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	144		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喀血	149	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	154	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	155	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	155	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						喀血	161	12D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						リンパ球減少症	163	2D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	163	32D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	164	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4414-00457	WHITE	0	MALE	7[redacted]	貧血	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カルシウム血症	1	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚びらん	9		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	8D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身健康状態低下	58	41D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						肝機能異常	58		NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						腎不全	58		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	4501-00391	WHITE	0	MALE	5[redacted]	疲労	4		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼刺激	19	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	19	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肉離れ	53	47D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						齲歯	129	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	141	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						女性化乳房	141		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	141	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	142	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	176	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	203	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	218	25D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アシドーシス	225	71D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						C－反応性蛋白増加	225		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						心電図異常	225	15D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						フィブリンＤダイマー増加	225	71D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	225	18D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						肺塞栓症	225	17D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						肺塞栓症	225	17D	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						頻脈	225	18D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血栓症	225	71D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						心房中隔欠損症	227	11D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチンホスホキナーゼ増加	227	3D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						糸球体濾過率減少	227	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						肺高血圧症	227	11D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中カリウム増加	228	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						γ－グルタミルトランスフェラーゼ増加	231	65D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						糸球体濾過率減少	232	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中カリウム減少	239	66D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	239	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						瘢痕	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	312		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4501-00437	WHITE	0	MALE	5[redacted]	末梢性浮腫	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	3		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	3		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血小板減少症	42		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	49	8D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	56		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性心筋梗塞	77	16D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						呼吸困難	77	16D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道感染	77	16D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肝腫大	78	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中カリウム減少	82	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						ヘモグロビン減少	84	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						蒼白	93	433D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	105	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						女性化乳房	126		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	128		RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	128		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	160	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	168	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	187		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	367	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4505-00199	WHITE	0	MALE	4[redacted]	便秘	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	14	51D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	16	21D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						多発ニューロパチー	34	80D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	71	239D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						発声障害	141	169D	RELATED	GRADE 1	AE	DOSE REDUCED	
						上気道感染	169	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	239	323D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	324	153D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	344	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外骨腫	351	3D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	358	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						側腹部痛	392	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道の炎症	397	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						感染	414	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	449	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	449		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	477		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						抑うつ気分	564		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	575	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						表皮内悪性黒色腫	589	21D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						鼻咽頭炎	617	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4506-00490	WHITE	0	MALE	6[redacted]	悪寒	2	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						皮膚疼痛	2	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	3	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						感染	8	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	8	7D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	34	8D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カルシウム血症	41	14.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カルシウム血症	43	7D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						発熱	43	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
LD	4506-00644	WHITE	0	MALE	6[redacted]	耳そう痒症	1	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	1	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	1	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	6	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	13	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						悪心	15	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	30	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	49	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	50	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						労作性呼吸困難	57		RELATED	GRADE 1	AE	DOSE REDUCED	
						労作性呼吸困難	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	57	65D	RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						攻撃性	85	296D	RELATED	GRADE 2	AE	DOSE REDUCED	
						捻髪音	85	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	109	538D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	113	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不眠症	128	48.0H	RELATED	GRADE 3	AE	DOSE REDUCED	
						インフルエンザ様疾患	134	48.0H	RELATED	GRADE 3	AE	DOSE REDUCED	
						上気道感染	139	46D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						インフルエンザ	142	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						喘鳴	156	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	184	197D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	248	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	324	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	348	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	352	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	432	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺感染	432	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						日常生活動作障害者	443	64D	RELATED	GRADE 2	AE	DOSE REDUCED	
						ウイルス性胃腸炎	443	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						上気道感染	686		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4511-00252	OTHER	0	FEMALE	4[redacted]	口腔ヘルペス	6	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	50	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	283	11D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4512-00059	WHITE	0	MALE	6[redacted]	貧血	-2	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	-2	37D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	-2	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	-2	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	-2	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	1	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	15	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	22	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	29	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	36		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	43	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	71		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	71	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	71	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ニューモシスチス・イロベチイ肺炎	71	9D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						発熱	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	71	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	73	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	74	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	74	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	75	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	76	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	77	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	78	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	78	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79	15.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	79	32.9H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	79	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	80	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	80	24.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	4512-00218	WHITE	0	FEMALE	6[redacted]	ヘルペス後神経痛	4	41D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	8	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	8	119D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	45		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	50	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	50	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	57	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	57	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	57	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	72	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	72	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	81	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	85	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						労作性呼吸困難	113		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	127		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	127	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	127	98D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	127	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	128	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹部膨満	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	155	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	155		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	159		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	163	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	191	4D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4514-00664	WHITE	0	MALE	7[redacted]	過敏症	6	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	15	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	15	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	27	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎機能障害	27	200D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	83	366D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	107	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	111		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	111	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	216	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	216	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	219	8D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						幻覚	220	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	220	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠障害	223	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓性静脈炎	224	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	230	120D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	248	17D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						C－反応性蛋白増加	363		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	443		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	460		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	482	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪床の炎症	559	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肩回旋筋腱板症候群	559		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						漿液腫	608		NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						尿路閉塞	659	37D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						末梢性浮腫	743			GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4514-00710	WHITE	0	FEMALE	[redacted]	嚥下痛	22	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔真菌感染	22	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	81	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	125	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸障害	154	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	158	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	158	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腎機能障害	158	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						亜イレウス	158	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						深部静脈血栓症	164	41D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						眼出血	220	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	260	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	281	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						頭蓋脳損傷	331	48.0H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						裂傷	331	48.0H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						麻痺性イレウス	382	3D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	428	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	477	92D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼出血	505	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス感染	511	30D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	582	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	680		RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	680		RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	711		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	736		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
LD	4516-00366	WHITE	0	FEMALE	5[redacted]	そう痒症	4	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アミラーゼ増加	15	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中尿素増加	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	15	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	15	42D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	15	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	15	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	15	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	15	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						気道感染	15	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						交通事故	17	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						交通事故	17	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						交通事故	17	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	19	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	19	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						脱毛症	22	106D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						浮動性めまい	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	22	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						痔核	29	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	29	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	29	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	29	240D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	36	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	36	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球数増加	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	42	16D	RELATED	GRADE 2	AE	DOSE REDUCED	
						筋力低下	42	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						単球減少症	43	24.4H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中尿素増加	44	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	44	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脊椎痛	44	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	49	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	57	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グリコヘモグロビン増加	57	183D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	57	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	57	45.5H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						甲状腺機能亢進症	57	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	57	45.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	57	45.5H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						単球減少症	57	45.5H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						自己免疫性甲状腺炎	59	279D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中尿素増加	59	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	59	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	59	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	71	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						浮動性めまい	71	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	71	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	71	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	71	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	71	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	71	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	71	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	71	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪囲炎	71	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	81	48D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低マグネシウム血症	84	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	84	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	92	48D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	92	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	92	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	92	358D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失語症	99	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	99	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	99	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	99	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	99	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						易刺激性	99	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	99	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球数増加	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿閉	99	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	113	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	113	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	113	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						上腹部痛	128	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	128	42D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	128	53D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	128	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	128	55D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	128		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	141	29D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	141	13D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						低リン酸血症	141	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						変形性脊椎症	141	236D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	155	113D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	155	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上腹部痛	169	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	169	99D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	181	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	181	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						活性化部分トロンボプラスチン時間延長	183	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	183	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	183	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	183	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	183	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	183	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	183	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						徐脈	197	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						毛包炎	197	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	197	141D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚乾燥	212	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	212	13D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	212	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	212	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	225		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	225	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	225	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	225	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	240	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	240	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	240	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	240	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	240	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						インフルエンザ	240	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	240	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	240	28D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	240	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	240	29D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						消化管感染	254	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	267	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	268	97D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	282	187D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	282	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	282	95D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	282	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						グルタミン酸脱水素酵素増加	282	159D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	282	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	282	112D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	282	96D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	282	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	296	154D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	296	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	296		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	296	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	296	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	296	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	296	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	310	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好酸球数増加	324	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	324	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	324	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	324	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球数増加	324	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	324	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	324		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						自己免疫性甲状腺炎	338		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	338	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	338	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	338	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						滑液包炎	339	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	351	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	351	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	351	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	351		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	354	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	366	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	366	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	366	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	366	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	366	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	376	9D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	377	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中コリンエステラーゼ減少	377		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						C－反応性蛋白増加	377	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	377	88D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸水	377	89D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜炎	377	31D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						変形性脊椎症	377	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	377	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	380	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	380	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						滑液包炎	380	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	380	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	380	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	380	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳性ナトリウム利尿ペプチド前駆体Ｎ端フラグメント増加	380	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数増加	380	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	385	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	385	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	385	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	385	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	392	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	392	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	392	33.4H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						C－反応性蛋白増加	394	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	394	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	394	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	394	56D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	408	33D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	408	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	408	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数増加	408	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸膜炎	408	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	408	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	422	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	422	43D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	422	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	422	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						変形性脊椎症	422		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	422	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	436	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	436	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	436	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	441	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中アルカリホスファターゼ増加	441		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脳性ナトリウム利尿ペプチド増加	441		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	441	8D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						フィブリンＤダイマー増加	441		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	441	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	441	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	441	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸膜炎	441	25D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脾臓梗塞	441		RELATED	GRADE 2	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						回転性めまい	441	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	444	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	446	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心膜炎	448	13D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹部膨満	450		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	450		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						C－反応性蛋白増加	450		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	450		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	450		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	450		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低リン酸血症	450	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	450	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						単球増加症	450	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋力低下	450		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	450		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	457	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	461	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	461		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心膜炎	461		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	465		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心不全	465		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	465		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	465		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	465		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						上腹部痛	469		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	469		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	469		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心内膜炎	482	229D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						骨髄異形成症候群	854		RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
LD	4517-00649	WHITE	0	MALE	6[redacted]	前立腺癌	1		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						脊椎痛	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発疹	2	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						口腔ヘルペス	6	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	34	24.0H	RELATED	GRADE 1	AE	DOSE REDUCED	
						発疹	35	8D	RELATED	GRADE 1	AE	DOSE REDUCED	
						そう痒症	63	106D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	65	24.0H	RELATED	GRADE 1	AE	DOSE REDUCED	
						剥脱性皮膚炎	77	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注意力障害	77	119D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	77	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						落ち着きのなさ	77	119D	RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	91	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	111	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	133	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	140	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	140	91D	RELATED	GRADE 2	AE	DOSE REDUCED	
						悪心	140	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	140	56D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						落ち着きのなさ	196	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	230	49D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	279		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪の障害	279	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	315	140D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	315	140D	RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						悪心	315	140D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	376	58D	RELATED	GRADE 1	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上腹部痛	437		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	468		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	468		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4517-00660	WHITE	0	MALE	8[redacted]	疲労	21	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	34	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	34	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭蓋脳損傷	34	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	34	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	34	24.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	48	35D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	82	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	82	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	108		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						落ち着きのなさ	108		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	112	146D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	139	33D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	139	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	171	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼内炎	173	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						高血圧	187	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						上室性不整脈	200		RELATED	GRADE 3	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						結節性不整脈	200		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						心室性不整脈	200		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血中クレアチニン	214	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	214	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	229		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	229	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	278		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	278		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	285	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	313		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4600-00078	WHITE	0	MALE	7[redacted]	貧血	2	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	2	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	2	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	2	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	8	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	71	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	75	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	85	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	85	20D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カリウム血症	85	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						イレウス	98		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						閉塞性臍径ヘルニア	98		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						血中クレアチニン増加	99	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高カリウム血症	99	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低カルシウム血症	99	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						敗血症性ショック	104	12.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4600-00165	WHITE	0	MALE	7[redacted]	血中クレアチニン増加	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	1	328D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1	328D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						薬疹	6	10D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	6	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	8	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	15	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	21	245D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	22	307D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	28	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	42	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	48	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	48	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高血糖	56	41D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	56	41D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	56	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	83	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	97	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	111	218D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	111	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	112	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	125	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	139	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	167	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	195	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	208	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	223	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	257	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	266	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	279	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	279	19D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						低アルブミン血症	279	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	279	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	298	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4600-00221	WHITE	0	FEMALE	5[redacted]	骨痛	1	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	1	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	30	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	36	248D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	48	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カルシウム血症	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	50	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	57	808D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	99	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						股関節部骨折	107	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低ナトリウム血症	113	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	129	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	143	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	143	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	143	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	228	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	255	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	284	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	284	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	284		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高カルシウム血症	284	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	284	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	403	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	571	112D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	698	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	753	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	809	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	809	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	865	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	865	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						γ－グルタミルトランスフェラーゼ増加	865		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	865		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	872		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	4600-00381	WHITE	0	FEMALE	6[redacted]	骨痛	1	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	1	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	5	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	8	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	15	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	27	7.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	30	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	77	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	99	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	126	3D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	155	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
LD	4600-00496	WHITE	0	MALE	5[redacted]	アラニンアミノトランスフェラーゼ増加	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中尿酸増加	1	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	4	17.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	29	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	57	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	85	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	113	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	127	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	169	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	169	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	197	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	236	36.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	239	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	253	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	267	126D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	283	54D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	309	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高尿酸血症	351	117D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ナトリウム血症	449	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	478	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	478	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	505	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	533	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	533	16D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	533	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	540	9D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	540	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	549		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高尿酸血症	549		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	549		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						骨髄異形成症候群	566		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	4601-00680	WHITE	0	FEMALE	6[redacted]	気管支炎	-18	10D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血中カルシウム減少	9		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	10	12.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						左室機能不全	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						一過性脳虚血発作	15	5D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	26		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	26		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中カリウム減少	40		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	40		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下部消化管出血	47	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						上部消化管出血	47	4D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	51	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	51	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						漿膜炎	52	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						頭蓋脳損傷	155	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						交通事故	155	4D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						軟部組織損傷	155		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	4601-00689	WHITE	0	MALE	7[redacted]	貧血	-2	28.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	8		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	10	40.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	11	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	11	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	14	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						食欲減退	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						嘔吐	17	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	30	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	47	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	69	9.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						軟部組織損傷	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	104		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	104		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	109	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	192	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺塞栓症	203	46.0H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						脳出血	213	31D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4601-00691	WHITE	0	FEMALE	8[redacted]	糸球体濾過率	1	7D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	1	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器細菌感染	6	10D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	13	44D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器感染	41	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						膀胱炎	58	10D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中クレアチニン	77	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	79	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	79	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	93	41D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	105	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	119		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	148	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中クレアチニン	148	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	148	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	162		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	177	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	204	69D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						泌尿生殖器感染	218	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						尿路感染	218	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血中クレアチニン	219	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン	246	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	288	83D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	316	83D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失禁	344		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	344		NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						尿路感染	344	20D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						血中クレアチニン	366	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	374	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	400		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	400	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	466	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	470	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	475	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心停止	589	11.5H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4601-00694	WHITE	0	FEMALE	5[redacted]	潮紅	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	23		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						膣分泌物	44	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ節症	344	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹部リンパ節腫脹	352	55D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路閉塞	352		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						子宮内膜癌	407		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	4700-00322	WHITE	0	MALE	5[redacted]	貧血	8		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						急性腎不全	8	15D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	8		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腫瘍崩壊症候群	8	14D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	11	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						敗血症	34	34D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4700-00520	WHITE	0	FEMALE	5[redacted]	敗血症	7	16D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4702-00460	WHITE	0	MALE	7[redacted]	副腎機能不全	1	84D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	7	15.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						結膜炎	12	372D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	107		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副腎機能不全	167	14D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						気管支炎	169	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						丹毒	236	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						丹毒	266	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢動脈狭窄	266		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	333	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	364	24.5H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	511	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部ヘルニア	513		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	532	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						錯乱状態	542		RELATED	GRADE 1	AE	DOSE REDUCED	
						白内障	570		RELATED	GRADE 3	AE	DOSE REDUCED	
						結膜炎	570	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						橈骨骨折	581	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						うつ病	606		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	616	10.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚損傷	647	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	658		RELATED	GRADE 2	AE	DOSE REDUCED	
						死亡	691	17.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	4901-00191	WHITE	0	MALE	7[redacted]	高血糖	2	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	4	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	9	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋痙縮	16	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	16	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						耳痛	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	20		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	35	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	36	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	50	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	56	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	63	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	69		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						発熱	73	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	75		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						悪性新生物進行	75	17D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺炎	75		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						尿路感染	82	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						心房細動	85	24.0H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4901-00404	WHITE	0	FEMALE	8[redacted]	下痢	2	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	16	2.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	20	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	43	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	53	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	78	10D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	92	102D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	92	12D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	103	46D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	154	39D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	154	20D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						咽頭炎	154	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃潰瘍	168	12D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	182	12D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4901-00656	WHITE	0	MALE	6[redacted]	鼻咽頭炎	8	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	16		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	21	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム増加	38	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	39		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	39		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	44	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	51	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						深部静脈血栓症	61	3D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	67	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	67	76D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	69	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	72	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発疹	72		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	72	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	74	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	77	5D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	77	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	81	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	81	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	86	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	93	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	93	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	100		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	102		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						意識消失	125	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白内障	131	94D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	149	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	153	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	156	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	156	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	161	39D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	161	5D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	161	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	185	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	191	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	191	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	199	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	213	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼充血	224		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	227	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	241	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	255	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	269	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	297	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	326	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	326	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	338	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	352	17D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	369	19D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	369		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						疾患進行	387	4D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	4901-00659	WHITE	0	FEMALE	[redacted]	疲労	5		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	7	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	66		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	66		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	138	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						肺炎	144	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ヘモグロビン減少	167	31D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	167	59D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	217	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	267	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯痛	275		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	330		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱毛症	370		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	370		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸椎骨折	438	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						背部痛	441	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	454		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	475	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	514	7D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺炎	514	7D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	4901-00738	WHITE	0	MALE	[redacted]	骨盤痛	3	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脱水	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	29	252D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	95		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	120		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	124	40D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節腫脹	197	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	216	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	234	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	274	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルブミン減少	281	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	288	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視神経萎縮	307		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルブミン減少	309		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	320		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	333	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	334	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	393	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	456		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	463	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	549	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	549	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	596	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ウイルス感染	610	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	655	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	4903-00192	WHITE	0	MALE	7[redacted]	貧血	1	24.2H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	15	25.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	51	4D	RELATED	GRADE 4	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						好中球減少症	57	42D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	82		RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	85	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	96	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	99	8D	RELATED	GRADE 1	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						好中球減少症	102	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	106	7D	RELATED	GRADE 4	AE	DOSE REDUCED	
						発熱性好中球減少症	113	29.2H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	127	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	141	5.1H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	155	5D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						貧血	166	5.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	183		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						ヘモグロビン減少	183	12D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	185	9D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症	185	10D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						痛風	188	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	195	1.5H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	4905-00302	WHITE	0	MALE	7[redacted]	発熱	212	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性冠動脈症候群	241	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺炎	249	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肝酵素上昇	257	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	261	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺塞栓症	281	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	296	330D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5000-00145	WHITE	0	MALE	6[redacted]	難聴	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	64	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	68	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	308	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	463	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						四肢痛	537	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	575	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	603	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	645	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						インフルエンザ様疾患	692	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	730	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	782	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						浮腫	870	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5000-00603	WHITE	0	FEMALE	[redacted]	便秘	15	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	22	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	43	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	97	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	99	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	125	269D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	146	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	169		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	225	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	267	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腓骨部筋萎縮症	274		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	293	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	365		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	519	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	608	24.1H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	608	12.8H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						呼吸困難	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心房細動	707	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5003-00328	WHITE	0	MALE	6[redacted]	発声障害	-1	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	20D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						良性前立腺肥大症	13		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						前立腺炎	21	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	33	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						感染	35	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	66	13D	NOT RELATED	GRADE 1	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
LD	5003-00469	WHITE	0	MALE	8[redacted]	下痢	1	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	8	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨盤痛	18	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	19	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	21	19D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	22	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	64	23D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	66	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	66	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	101	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	107	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	129	613D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	129	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	131	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	134	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	157	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	163	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	164	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	170	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	182	20D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高血圧	182	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	185	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血尿	193		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	196	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	196	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	210	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	210	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	254	119D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	424	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	465	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	470	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	479	9D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						平衡障害	505		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	522		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	550	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						慢性閉塞性肺疾患	568	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺塞栓症	569	9D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						尿閉	570	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	599	98D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	620		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭炎	648	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	662	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						複視	678	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	680	39D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	690	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便秘	718		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						全身健康状態低下	742	47D	RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5005-00230	WHITE	0	MALE	6[redacted]	起立性低血圧	39	12.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	127	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						毛細血管脆弱	169	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン	170	30D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						悪性新生物進行	182	18D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5007-00172	WHITE	0	MALE	7[redacted]	肺臓炎	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	84	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	177	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	191	99D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	198	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	202	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	241	15D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肋骨骨折	252		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	255	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						静脈炎	259	37.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	262		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	279	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5007-00369	WHITE	0	MALE	6[redacted]	貧血	1	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	22	147D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	43	33.6H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	44	3D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	85	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	85	9.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	113	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						国際標準比増加	127	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	197	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	211	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	240	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	281	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	281	42D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	294	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	309	112D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	323	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						静脈炎	330	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	351	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	365	57D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						無力症	393		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						貧血	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	504	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	536		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	547		RELATED	GRADE 1	AE	DOSE REDUCED	
						鼻出血	692		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	692		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腸出血	700	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5010-00398	WHITE	0	MALE	7[redacted]	発熱	4	29D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	8	26D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						軸索型ニューロパチー	26		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	30		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	43	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	47	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	78	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	169	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疾患進行	246	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5010-00638	WHITE	0	FEMALE	6[redacted]	貧血	-20		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	22	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	36	26.0H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨痛	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	169		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5012-00277	WHITE	0	MALE	6[redacted]	背部痛	1	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	1	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	15	13D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	69	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	97	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	104	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	111	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	167	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	181	15D	RELATED	GRADE 4	AE	DOSE REDUCED	
						好中球減少症	195	22D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	216	61D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						肺臓炎	233	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	5014-00358	WHITE	0	FEMALE	6[redacted]	好中球減少症	27	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	36	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	43	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	71	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	71	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚腫瘤	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	99	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ節症	103		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	108	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	117	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						労作性呼吸困難	125		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸水	126	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	5014-00519	WHITE	0	MALE	6[redacted]	心房細動	6		NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						悪寒	6	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	6	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						呼吸困難	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						乏尿	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						肺臓炎	6		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						肺塞栓症	6	29.8H	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	6	48.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸性アルカローシス	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						敗血症性ショック	6		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						頻脈	6	48.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球数減少	7	24.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						白血球数減少	7	24.0H	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
LD	5200-00126	WHITE	0	FEMALE	7[redacted]	気管支炎	-17	11D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	113	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	183	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	197	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						高尿酸血症	197	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支肺炎	204	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	239	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	253		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支肺炎	332	4D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5200-00420	WHITE	0	MALE	6[redacted]	貧血	-9	3D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	22	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	43	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						体重減少	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	127	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
LD	5202-00455	WHITE	0	MALE	5[redacted]	白血球減少症	22	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	25	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	29	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	43	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	43	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	43	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						うつ病	57	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	57		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						頻脈	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	71		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	99	16D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	99		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	114		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	114		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5202-00708	WHITE	0	FEMALE	6[redacted]	白血球減少症	9	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						リンパ球減少症	9	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	9	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						疲労	47		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	74	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	99	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	109	329D	RELATED	GRADE 1	AE	DOSE REDUCED	
						筋力低下	109		RELATED	GRADE 2	AE	DOSE REDUCED	
						リンパ球減少症	211	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	211	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	239	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	253	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	253	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	267	127D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	291	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	309	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	309	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	321	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	360	75D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	365	70D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	365	85D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	407	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	434	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	434	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副腎機能不全	437		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	437	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	437	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	439	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アフタ性口内炎	443		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	450		RELATED	GRADE 1	AE	DOSE REDUCED	
						白血球減少症	456	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	456	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	456	190D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸潰瘍	477	4D	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アラニンアミノトランスフェラーゼ増加	491	99D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	519	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	519	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	569	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	589	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	596	79D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	631	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	631	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道感染	631	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	638	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	638	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	659		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	5204-00168	WHITE	0	FEMALE	7[redacted]	糸球体濾過率減少	85		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	99	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	155	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アラニンアミノトランスフェラーゼ増加	169	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	169	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	323	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カリウム血症	561	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	757		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						洞不全症候群	811	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						動脈硬化症	812		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	812		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						左室機能不全	812		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高コレステロール血症	816		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						洞不全症候群	816	4D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
LD	5204-00215	WHITE	0	MALE	7[redacted]	不全片麻痺	15	48.0H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不全片麻痺	16	56D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不全片麻痺	71		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	5204-00349	WHITE	0	FEMALE	7[redacted]	糸球体濾過率減少	15	182D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						糸球体濾過率減少	197	56D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	200	53D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	252	4.5H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
LD	5204-00371	WHITE	0	MALE	7[redacted]	肺炎	215	25D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						形質細胞性骨髄腫	510	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5204-00672	WHITE	0	FEMALE	5[redacted]	貧血	-5	48.0H	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	2	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	2	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	19	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	19	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	24		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	29	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	36	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	37	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱毛症	39		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	45		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	54		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	57	323D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	57	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	71	16D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	79	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	113	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	127	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	156	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	175	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	183	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	205		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	211	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	211	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	225	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	253	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	295	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	379	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	407	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	463	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	477	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	570	76D	RELATED	GRADE 2	AE	DOSE REDUCED	
						下痢	645		RELATED	GRADE 1	AE	DOSE REDUCED	
LD	5204-00711	WHITE	0	FEMALE	5[redacted]	気管支炎	105	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	108	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	113		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	113		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胃炎	152	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咽頭炎	391	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管の炎症	393	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血圧	449		RELATED	GRADE 3	AE	DOSE REDUCED	
						末梢性浮腫	449	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						咽頭炎	528	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膀胱炎	588	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢損傷	617	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						足骨折	633	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咽頭炎	714	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
LD	5205-00709	WHITE	0	MALE	5[redacted]	不眠症	2	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	10	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	15	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過敏症	19	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	22	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	31	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	32	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	35	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	35	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						疲労	38	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	52		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	54	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	54	20D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	59	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						耳鳴	87	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	94	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	99	16D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	101	114D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳鳴	102		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	115	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気道感染	117	48.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	119	10D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						期外収縮	140	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	142	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	142	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	148	98D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	148	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血便排泄	149	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	156	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						期外収縮	168	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	169	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	170	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	171	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	178	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
LD	5205-00733	WHITE	0	FEMALE	7[redacted]	皮膚病変	1	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	2	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	2	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	2	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	8	372D	RELATED	GRADE 1	AE	DOSE REDUCED	
						霧視	8	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	24	63D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	25	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	28	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	46	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	58	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	71		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	90	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						多汗症	91	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						寝汗	91	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	115	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	120	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	120	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						無力症	129	180D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						寝汗	129	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	130	419D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						炎症	137	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	140	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼部不快感	140	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻痛	140	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	141	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	143	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	154	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	168	352D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低γグロブリン血症	168	226D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	176	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴力低下	183		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力低下	183	498D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	191	258D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	196	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格痛	203	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭不快感	203	79D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	203	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抑うつ気分	211	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	211		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	217	178D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球尿	225	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	226	169D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	240		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	241	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	253	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球尿	253	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	263	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						内出血発生の増加傾向	268	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腸憩室	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸ポリープ	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						静脈瘤	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼の異常感	282	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	282	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	288	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性上気道感染	294	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋肉痛	296	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	308	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	309	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	317	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ざ瘡	323	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	323	113D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	323	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	333	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	344	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	351	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	351	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	351	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						γ－グルタミルトランスフェラーゼ増加	351	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アフタ性口内炎	353	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球尿	364	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	365	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	366	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	367	18D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	367	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						外陰腟痛	371	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	379	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アフタ性口内炎	380	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血圧上昇	380	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	380	98D	RELATED	GRADE 2	AE	DOSE REDUCED	
						消化管感染	384	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血圧上昇	393		RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	393	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						咳嗽	394	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						放屁	394		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	407	253D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	407	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃ポリープ	408		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	408		RELATED	GRADE 2	AE	DOSE REDUCED	
						頭痛	419	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	420		RELATED	GRADE 2	AE	DOSE REDUCED	
						低γグロブリン血症	420	85D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	420	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	421	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						流涙増加	428	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	428	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	434	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	436	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	449	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	449	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						非心臓性胸痛	450	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						恥骨上痛	450	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	451	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	451	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	463		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	464	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	465	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	477	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	478		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						内出血発生の増加傾向	478	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	478	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	495	186D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	499	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	504		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸部不快感	505	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	505	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節硬直	519		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	532	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯感覚	532	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	533	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋骨格痛	553	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						眼痛	556	61D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	559	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	561	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	563	13D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	565	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白内障	574	106D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						寝汗	575	98D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	575	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	588	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	588	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	603	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	603		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	615	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	641	19D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼そう痒症	647		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	647		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭不快感	647		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	660		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻部障害	666	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	672	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	678	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋痙縮	679		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無感情	688		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						臍径ヘルニア	700		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	702	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	702		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	703		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	715		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5207-00304	WHITE	0	FEMALE	5[redacted]	血小板数減少	8	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	8	556D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	556D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	29	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	50	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	126	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耐糖能障害	156		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	207	10D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	209	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	213	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	226	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						潮紅	280	87D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	309	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	316	29D	RELATED	GRADE 1	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						クッシング様症状	337		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	337	100D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性上気道感染	378	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	407	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	421	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						筋痙縮	435	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	449	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	474	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	477	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						結膜炎	490	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	532	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	533	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5208-00478	WHITE	0	MALE	6[redacted]	好中球減少症	49	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	71	33D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						表在性血栓性静脈炎	85	9D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						咽頭炎	168	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	183	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	236	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	253	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	365	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	379	29D	RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						結膜炎	380	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	407	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	448	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	462	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	477	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	490	99D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	588	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	616	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	630	29D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	672	44D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5208-00645	WHITE	0	MALE	5[redacted]	医療機器関連感染	-15	7D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	8	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	21	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	50	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						耐糖能障害	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	50	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	50	8D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	50	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	57	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	57	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	71		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中カルシウム減少	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	71		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	71		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						不全対麻痺	73		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						脊椎圧迫骨折	73		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						疾患進行	117	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5208-00737	WHITE	0	FEMALE	6[redacted]	低カルシウム血症	50	91D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	85	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	98	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	204	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	281	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						糸球体濾過率減少	295	15D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	365	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	420	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						心房細動	427		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						膣出血	431	14D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支炎	473	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	488	17D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	504		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						筋力低下	556		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5301-00712	WHITE	0	FEMALE	5[redacted]	好中球減少症	43	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	281	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	295	17D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	295	72D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	311		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疾患進行	311		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
LD	5302-00223	WHITE	0	FEMALE	7[redacted]	咽頭炎	8	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						尿路感染	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						間質性肺疾患	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	85	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	92	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	104	122D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	127	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	155	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞腫	183	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	183	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞腫	197	35D	NOT RELATED	GRADE 5	SAE	DRUG INTERRUPTED	FATAL
						血栓性静脈炎	197	35D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞腫	205	27D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	215	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						対麻痺	226	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						形質細胞腫	230	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	5303-00141	WHITE	0	MALE	6[redacted]	尿路感染	1	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	23	100D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	49	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	57	154D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	84D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	148	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	211	28D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肥満	211		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	225		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	239	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	253		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨血管腫	367	33D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腹痛	413	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹膜炎	417	22D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5303-00169	WHITE	0	MALE	5[redacted]	労作性呼吸困難	28	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	34	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	70	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						狭心症	79		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	85	240D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上室性頻脈	93	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	128	393D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	173	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	325		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯膿瘍	326	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	329	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔ヘルペス	360	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	375	23D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						筋断裂	431		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	507		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	521	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						霧視	549	28D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気管支炎	612	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結膜炎	676	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯膿瘍	683	17D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						霧視	695	21D	RELATED	GRADE 2	AE	DOSE REDUCED	
						白内障	715	196D	RELATED	GRADE 2	AE	DOSE REDUCED	
						気管支炎	717	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						急性肺水腫	721	8D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心房細動	721	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	743	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	851	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	880	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	883	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						糸球体濾過率減少	883	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	911		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	911	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	925		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5303-00443	WHITE	0	FEMALE	5[redacted]	浮動性めまい	11	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						起立性低血圧	13	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						外傷性骨折	19		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						術後貧血	29	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						術後貧血	50	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	190	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	266	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	266	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	298	61D	RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	358	92D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						末梢性ニューロパチー	449		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5303-00528	WHITE	0	MALE	5[redacted]	錯感覚	37	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						原発巣不明の悪性新生物	43	32D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5500-00086	WHITE	0	MALE	6[redacted]	貧血	1	56D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						無力症	1		RELATED	GRADE 2	AE	DOSE REDUCED	
						背部痛	1		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						血小板減少症	1	56D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	5	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						敗血症性ショック	5	12D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						外傷性血尿	6	11D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						好中球減少症	21	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻出血	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	35	22D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						上気道感染	63	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	70	16D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	70	79D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	85	106D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	99	15D	RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	105	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	127	22D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	162	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	176	38D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						うつ病	204		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	204	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	213	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	220	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	227	111D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	241	119D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	241	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	262	8D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	275	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	288		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	327	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	337	23D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	359		RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	5500-00121	WHITE	0	FEMALE	7[redacted]	貧血	1	84D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	1	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	15	22D	RELATED	GRADE 2	AE	DOSE REDUCED	
						血腫	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	183	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	351	43D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔ヘルペス	351	29D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低音性連続性ラ音	351	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膿性痰	351	43D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	372	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	378	120D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大腿骨骨折	408	14D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
LD	5500-00350	WHITE	0	FEMALE	[redacted]	貧血	1	50D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						骨痛	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	1	166D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球減少症	6		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	36	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	50	126D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	57	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道感染	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	78	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	78	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	78	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	78	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	126		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	166	36D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	175	385D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	175	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管気管支炎	175	6D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板減少症	180	123D	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						貧血	194	8D	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						発熱	201	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	202	17D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						貧血	224		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	5500-00379	WHITE	0	MALE	5[redacted]	末梢性ニューロパチー	-14	442D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	8	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	20	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						リステリア症	24	8D	RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						痛風	29	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						静脈炎	29	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	31	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	31	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	32		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	32	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	39	55D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血栓性静脈炎	135	38D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	214	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	221	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膿性痰	221	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外傷性難聴	242		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						老人性難聴	242		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	333	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	354	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下痛	354	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	375		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中尿酸増加	388	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5501-00342	WHITE	0	MALE	7[redacted]	浮動性めまい	21	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	29	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	34	8D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	85	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	113		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	131		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	153	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	153	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	155	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不整脈	202	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨盤痛	225		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						激越	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	253	5D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ラ音	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						縮瞳	274	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳症	283	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5501-00557	WHITE	0	MALE	7[redacted]	発疹	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内潰瘍形成	22	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	50	177D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚潰瘍	57		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	71	9D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	71	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						臨床検査異常	71	9D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	71	10D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	99	63D	RELATED	GRADE 1	AE	DOSE REDUCED	
						呼吸困難	106		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カルシウム血症	106	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						蜂巣炎	117		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	117	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脱水	127	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心不全	162	8D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						腎不全	162	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気道感染	172	19D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						心不全	190	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血腫	190		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	190	134D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸不全	190	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	191	14D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						気道感染	201	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	218	106D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						不安	223	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	223	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	227	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心不全	227	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低血圧	227	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎不全	227	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口腔カンジダ症	239	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	260		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						喀血	260	8D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						出血性素因	260	8D	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	267		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						痔出血	267	15D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						皮膚剥脱	267		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	269	3D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						全身健康状態低下	288		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						発熱	295	18D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心不全	355	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5501-00671	WHITE	0	MALE	5[redacted]	貧血	8		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	8		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中クレアチニン増加	29	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血中クレアチニン増加	45	27D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5502-00125	WHITE	0	FEMALE	6[redacted]	無力症	8	31D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	15	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						深部静脈血栓症	24	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	57	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻咽頭炎	78	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	86	6D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	99	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	113	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	118	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	120	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	120	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	141	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎	145	11D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	160	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低ナトリウム血症	170	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	174	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						体重減少	174	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	183	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痔出血	185	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳症	187	20D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	206	19D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
LD	5503-00423	WHITE	0	MALE	7[redacted]	不安	7		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	20	22.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						失神寸前の状態	21	3.3H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						好中球減少症	42	15D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						関節痛	70	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	98	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	98		RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						気道感染	103	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						敗血症性ショック	124	8D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血尿	132	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	140	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	140	10D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症性ショック	146	14D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						形質細胞性骨髄腫	161	18D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						敗血症性ショック	161		RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
LD	5504-00300	WHITE	0	FEMALE	7[redacted]	無力症	8	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	8	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	8	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	8	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻出血	13	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高血糖	13	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	13	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						点状出血	13	24.0H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	14	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	16	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	16	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球減少症	16	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	16	5D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	21	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	21	15D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高血糖	36	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	36	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	36	19D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	48	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						不整脈	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	48	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	48	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	48	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋虚血	48	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	48	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						貧血	55	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	55	4D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	57	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	57	54D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	59	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	59	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	59	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	61	24D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	64	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	64	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	64	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	64	7D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	71	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	78	69D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	78	69D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	85	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	85	21D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	85	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	85	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	85	36D	NOT RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						心拍数増加	98	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	106	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎痛	106	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	118	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	121	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	121	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	129	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	129	18D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	134	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	134	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	142	5D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						白血球減少症	142	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	142	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	146	11.8H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5506-00427	WHITE	0	FEMALE	6[redacted]	失神	5	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	6	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	8	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸部不快感	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	43	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	54	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	57	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔ヘルペス	64	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	78	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	88	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口唇潰瘍	92	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔内不快感	92	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						皮膚炎	116	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	122	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						裂肛	132	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	174	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	212	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	216	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	245	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	248	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	278	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	298	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	300	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	300	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						爪損傷	300	87D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	303	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎骨壊死	306		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	327	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	339		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	342	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血管性脳症	342		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	364	33D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						異常感覚	370	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						錯感覚	370	175D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	399	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	419	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	419	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	419	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	433	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	436	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	446	42D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	460	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	463	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	474	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	488	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	488	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						好中球減少症	488	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	495	36D	RELATED	GRADE 1	AE	DOSE REDUCED	
						薬疹	527	32D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						薬疹	531	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						単純ヘルペス	540		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	540	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	563	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						関節痛	570	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	573	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	580	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	587	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	594	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下痛	615	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	625	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	632		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨壊死	633	6D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						消化不良	643	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	643		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	671		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	671	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	671	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5801-00562	WHITE	0	FEMALE	5[redacted]	貧血	8	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼部腫脹	27	45D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感覚鈍麻	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蒼白	29	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	35	7.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	43	5D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	43	14D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						疲労	48	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疾患進行	72		NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5803-00745	WHITE	0	FEMALE	8[redacted]	貧血	15	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	22	141D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	22	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	23	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						抱合ビリルビン増加	36	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	36	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	50	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	57	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						抱合ビリルビン増加	71	51D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	71	51D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	71	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	82	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	82	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	98		NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
LD	5900-00290	WHITE	0	MALE	5[redacted]	高血糖	1	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	23		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	23	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	29	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎仙痛	50	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	85	51D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	113		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	136	33D	RELATED	GRADE 2	AE	DOSE REDUCED	
						くしゃみ	156		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	169		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	193	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	193		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						硬膜下血腫	253	15D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5906-00305	WHITE	0	MALE	6[redacted]	不眠症	10	641D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼痛	15	636D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						医療機器関連敗血症	49	7D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	64	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	183	468D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	183	644D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	184	11D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	191	77D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						四肢痛	213	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	250	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	337	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						尿閉	346	35.3H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						疲労	372	279D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	421	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						心電図異常	477	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑	487	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	497	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	529	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	529	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						傾眠	534	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	561	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						敗血症	581	6D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						C－反応性蛋白増加	650	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	657	170D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	5907-00148	WHITE	0	MALE	6[redacted]	徐脈	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	8	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	8	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	10	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	10	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腎臓痛	11	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	12	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	15	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	15	4D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						徐脈	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性腎不全	15	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	15	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	16	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	17	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚感染	19	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						アスパラギン酸アミノトランスフェラーゼ増加	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	22	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	23	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	23	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚感染	24	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	29	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	43	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	43	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	43	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	43	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						慢性腎不全	43	44D	NOT RELATED	GRADE 2	AE	DOSE INCREASED	
						血小板減少症	43	44D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	68	53D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ミオパチー	68	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	99	57D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	113	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	113	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						慢性腎不全	113	43D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						好中球減少症	141	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						結膜出血	149	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	155	24D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						慢性腎不全	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	178	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	180	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	182	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	183	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	183	43D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	183	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中ビリルビン増加	183	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	183	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	187	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						口腔咽頭痛	189	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	191	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	207	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	225	36D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	248	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	248	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	253	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	253	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	253	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	254	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中リン減少	260	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	260	8D	RELATED	GRADE 1	AE	DOSE REDUCED	
						血小板減少症	260	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	267	183D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	281	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	309	126D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	351	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	351	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	351	183D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	393	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	413	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	413	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	422	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	435	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	435	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	446		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	478	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	488	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯感染	520		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯牙破折	530		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	536	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	561		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						下痢	561	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	571	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	603	48.0H	RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						血小板減少症	605	12D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血小板減少症	617		RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						骨髄異形成症候群	632	207D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						気管支肺炎	820	19D	RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	5907-00200	WHITE	0	MALE	6[redacted]	背部痛	12	123D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	13	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性感覚ニューロパチー	13	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	15	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	26	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	41	560D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	41	367D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	54	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	64	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	67	40D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	134	36D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	135	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	187	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	194	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺感染	211	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	211	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	235	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	235	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腱炎	261	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	282	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	330		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	331	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	348		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	348	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	361	120D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	369	85D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	379	46D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						パラインフルエンザウイルス感染	383	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	425	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	425		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	427		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	464	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胆石症	481		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	481	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	509	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	523	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板減少症	551	15D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						下気道感染	556	3D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	556	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	565	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						RS ウイルス感染	633	9D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	5907-00594	WHITE	0	MALE	5[redacted]	不眠症	1	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	1	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発声障害	2	34D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	2	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	3	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	8	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						関節痛	11	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	11	47D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	14	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	18	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	57	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						振戦	57	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	84	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	109	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	109	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	122	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	140	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎関節症候群	147	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	168	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	196	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	209	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	245	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ性肺炎	245	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	247	48.0H	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						インフルエンザ	252	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						インフルエンザ	259		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	279	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	280	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						筋肉痛	284	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	321	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪真菌症	366		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性上気道感染	387	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	392		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	462	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	489	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	494	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						上気道感染	564	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	574	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						伝染性紅斑	577	26D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高血圧	602	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	644	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	668	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	672		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						振戦	672	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	700	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						足部白癬	714	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	719		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺感染	763	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
LD	5909-00534	WHITE	0	MALE	7[redacted]	便秘	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	41	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	46	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	46	5D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						結膜炎	47	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ	148	8D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	211	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	212	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						しゃっくり	237		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	237		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	249		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	250	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	307		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	351		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	359		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	390		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	390		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						流涙増加	420		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	425		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	451		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	477	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	504		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	512		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	543	187D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						炎症	601		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						爪感染	601		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	603		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	630	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚異常	663	67D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						好中球減少性敗血症	687	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下気道感染	706	13D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
LD	5909-00606	WHITE	0	MALE	7[redacted]	不眠症	14	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膵炎	101	3D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						鼻部不快感	123		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	140	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						齲歯	148	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口唇感染	188	23D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎骨壊死	224		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	252	15D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	280	99D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ節炎	287		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	287	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	292		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	304		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	308		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	378	148D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部脊柱管狭窄症	407	23D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	407	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	414	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少性敗血症	414	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	414	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳虚血	415		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	420		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	468		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨髄炎	476		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面腫脹	476	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	507		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節硬直	507		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	507		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	525	78D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	602	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	657		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	658		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5910-00318	WHITE	0	MALE	6[redacted]	末梢性ニューロパチー	3	54D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	6	753D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	7	32D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	12	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	45	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	46		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	55		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	57	168D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	108	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	112	9D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						低カルシウム血症	120		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	120	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	121		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	133	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	148	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	162	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	173	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気分変化	176		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	176	7D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	176	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	183	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	190	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	204	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						皮膚感染	206	518D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	211	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性ニューロパチー	225	28D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	239	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	253	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	281	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						蜂巣炎	333	73D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	364	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	365	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	377	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	385	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	429	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	447	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	470	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	495	138D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	531		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						挫傷	561		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	588		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胆汁酸吸収不良	602		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ビタミンD欠乏	602		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	618		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	632	101D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						擦過傷	672	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	678		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						H1N1インフルエンザ	679	14D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						背部痛	692		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	731		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯感染	751	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						激越	768		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	783		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	799		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	5910-00549	BLACK OR AFRICAN AMERICAN	0	FEMALE	4[redacted]	便秘	1	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						動悸	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	4	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	8	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	8	8D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	46	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	57	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	81	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	81	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	85	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	98	45D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下気道感染	104	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	109	17D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋骨格痛	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	137	18D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	137	6D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						ウイルス性胃腸炎	140	17D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発熱	140	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	150	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	150	7D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気分変化	162	29D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	165	96D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	190	29D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						足関節部骨折	203	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
LD	5910-00559	WHITE	0	FEMALE	8[redacted]	霧視	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	2	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	12	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	13	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	13	24D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	18		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	20	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	36	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	42	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	48	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	49	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	51	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻炎	82	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脳血管発作	97	4D	RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						パラインフルエンザウイルス感染	97	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	5910-00588	WHITE	0	MALE	6[redacted]	悪寒	3	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						振戦	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	39	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	50	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	50	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	50	108D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	51	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	85		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						易刺激性	85	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	87	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	87		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						激越	141		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						体重増加	143		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	154	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	164	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	167	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中マグネシウム減少	190	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	192	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						小脳症候群	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼振	197		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモジデリン沈着症	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						局所腫脹	302	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	323	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	325	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	424		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	443	35D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						神経皮膚炎	449		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋梗塞	523	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
LD	5910-00665	WHITE	0	FEMALE	7[redacted]	背部痛	2		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	8	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8	637D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	9	26D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻出血	11	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎機能障害	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	22	64D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	27		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	34	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	36	99D	RELATED	GRADE 1	AE	DOSE REDUCED	
						上腹部痛	41	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿路感染	57	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カンピロバクター胃腸炎	77	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	84	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感染	85	23D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節腫脹	85	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	102		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	127	8D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						背部痛	140		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳垢栓塞	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						外陰腟不快感	153	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	155		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	173	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	181	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	197	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	197	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						平衡障害	198		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嵌入爪	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	198	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	198		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						顎痛	226	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顎関節症候群	233		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	253	240D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	253		RELATED	GRADE 2	AE	DOSE REDUCED	
						尿路感染	271	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	294		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	365	71D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格痛	382	60D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	421	85D	RELATED	GRADE 2	AE	DOSE REDUCED	
						尿路感染	421		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	442	35D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	465	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	465	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下気道感染	466	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球数減少	466	11D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板数減少	466	11D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						急性腎不全	466	54D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						急性腎不全	466	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ヘモグロビン減少	471	24.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋骨格痛	476		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	493	68D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	519		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	521		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	540		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嗜眠	561		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						悪心	561	85D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	561		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ミオパチー	575		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	582	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	636	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	645		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	645	15D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	645		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	645	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板数減少	645		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						白血球数減少	645		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						限局性感染	656	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胆汁酸吸収不良	708		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	712		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	727		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6000-00636	ASIAN	0	MALE	6[redacted]	しゃっくり	2	176D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	2	20D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						倦怠感	2	169D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	3	26D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						便秘	8	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	12	31D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	16	154D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮脂欠乏症	17	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						光視症	21	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	22	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						高血糖	29	18D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						末梢性ニューロパチー	29	18D	RELATED	GRADE 2	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						アスパラギン酸アミノトランスフェラーゼ増加	32	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	33	145D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼乾燥	38	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	59	160D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						腎クレアチニン・クリアランス減少	141	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6004-00206	ASIAN	0	MALE	5[redacted]	発声障害	2	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	50	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	272	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	273	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血栓症	393		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気管支炎	430	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血管運動性鼻炎	430	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	633	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						横紋筋融解症	636	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	644	86D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	865	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	6004-00311	ASIAN	0	MALE	6[redacted]	体重増加	85		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						痰貯留	169	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						転倒	196	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	318	48D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						うっ血性心不全	320	313D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	421	113D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻咽頭炎	619	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ性肺炎	623	41D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						心房細動	630	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						起立性低血圧	645	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6005-00312	ASIAN	0	MALE	5[redacted]	倦怠感	8	134D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	12	676D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	22	666D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	43	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	128	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	128	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						皮膚硬結	157	69D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	169	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	589	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不快感	606	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						白内障	645	24D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	669	19D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						皮膚乳頭腫	729	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6005-00705	ASIAN	0	MALE	6[redacted]	便秘	17	152D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	56	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	155	28D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						上気道の炎症	167	31D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						心房細動	183		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						肝機能異常	193	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高脂血症	197	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	221	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						引っかき傷	223	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						変形性脊椎症	234		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6006-00149	ASIAN	0	FEMALE	8[redacted]	高血圧	29	560D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	43	18D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	99	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	99	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	134	64D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔ヘルペス	141	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔ヘルペス	222	60D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	279	31D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	353	55D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						糖尿病	505	296D	RELATED	GRADE 2	AE	DOSE REDUCED	
						爪真菌症	521		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	722	37D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ヘルペス後神経痛	763	26D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	769	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚炎	781	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6007-00310	ASIAN	0	FEMALE	6[redacted]	不眠症	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	4	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	8	260D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	8	373D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						感覚鈍麻	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	22	8D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	29	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白内障	50	362D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	99	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	155		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						胃腸炎	178	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	183		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	184	378D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	293	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	337	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	339	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	412	17D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	432	18D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	449	113D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	458	13D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						胃腸炎	458	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	503	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	6008-00042	ASIAN	0	MALE	6[redacted]	下痢	33	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	33	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	65		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						高尿酸血症	65		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	70	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	82	0S	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
LD	6009-00250	ASIAN	0	MALE	7[redacted]	鼻咽頭炎	26	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	32	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	32	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						C－反応性蛋白増加	36	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低アルブミン血症	36	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	46	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	75	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	99	364D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蕁麻疹	104	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	131	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	160	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紫斑	190	148D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮下組織膿瘍	276	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道の炎症	288	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	295	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	371	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	463	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	477	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	491	42D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	509	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	533	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	547	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白内障	549		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	561	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	570	13D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	575	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球数減少	589	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	589	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	600	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板数減少	603	5D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板数減少	608	30D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	608	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球数減少	617	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発疹	621	81D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	638	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	6010-00220	ASIAN	0	MALE	7[redacted]	発疹	12	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						間質性肺疾患	15	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	22		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	37		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	41	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	71	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	114	28D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発疹	143	13D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性感覚ニューロパチー	160	309D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	173	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						不眠症	190		RELATED	GRADE 1	AE	DOSE REDUCED	
						白内障	199		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	220	20D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						間質性肺疾患	239	48.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						間質性肺疾患	241	22D	RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						歯の脱落	253	55D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面浮腫	288		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6011-00118	ASIAN	0	FEMALE	7[redacted]	高血糖	4		RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						接触性皮膚炎	6	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	12		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	15	57D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						そう痒症	68		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚嚢腫	99	46D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	113		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口腔咽頭痛	124	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						振戦	127	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	151	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低リン酸血症	183	169D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低γグロブリン血症	239	351D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	253	372D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胃腸炎	263	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嵌入爪	270	205D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						水疱	341	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃腸炎	379	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	379	57D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						急性腎不全	379	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						急性腎不全	386	36D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						発疹	399	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性腎不全	422		NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
LD	6012-00093	ASIAN	0	MALE	6[redacted]	不眠症	1	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	3		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	3	21.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	29.7H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肝機能異常	4		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	12	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	17	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	20	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	34	158D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						良性前立腺肥大症	81		RELATED	GRADE 1	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						下痢	136	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	158	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	219	93D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	220	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	223	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	263	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	271	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	315	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	321	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	342	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼瞼浮腫	352	37D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	381	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6012-00388	ASIAN	0	MALE	7[redacted]	発疹	21	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	23	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	31	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	39		RELATED	GRADE 4	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						鼻咽頭炎	46	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部不快感	54	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	73	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	79	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	93	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	126	10D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球数	129	17D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	129	124D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	189		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	6013-00444	ASIAN	0	MALE	6[redacted]	気管支炎	13	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	15	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	22	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	22	93D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	22	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	150	21D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	170	51D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	226	216D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	282		NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血中アルカリホスファターゼ増加	296	156D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	324	152D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	352	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						夜間頻尿	360	92D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	366	76D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重減少	366		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腫瘍熱	381	29D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発疹	410	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	414	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						健忘	427	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
LD	6014-00043	ASIAN	0	FEMALE	4[redacted]	動悸	1		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						齲歯	3	55D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	4		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	5		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹部不快感	6		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	6		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						味覚減退	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	31		RELATED	GRADE 2	AE	DOSE REDUCED	
						視力低下	77		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	95	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	149	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	155	24D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺炎	155	22D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						ウイルス性胃腸炎	186	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	212	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	214		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						傾眠	214		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						圧迫骨折	253		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	261	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アフタ性口内炎	271	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	271	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	283		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	299	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	299		RELATED	GRADE 1	AE	DOSE REDUCED	
						深部静脈血栓症	304	420D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	305	21D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						鼻咽頭炎	325	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	351	15D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嚥下障害	379		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	386	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						記憶障害	393		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	449	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						貧血	491	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						鼻咽頭炎	528	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	528		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	564	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	662	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						好中球減少症	697		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						放射線性食道炎	709		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6014-00614	ASIAN	0	FEMALE	[redacted]	不眠症	1	736D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	3	30D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	3	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	7	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	7	730D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	12	725D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚減退	13	724D	RELATED	GRADE 2	AE	DOSE REDUCED	
						顔面浮腫	18	719D	RELATED	GRADE 1	AE	DOSE REDUCED	
						好中球減少症	57	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻咽頭炎	85	18D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	140	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼の障害	398		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白内障	429	140D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						歯周炎	445	5D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	506	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白内障	569	113D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						好中球減少症	631	22D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	659		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	694	18D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	704		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						処置による疼痛	704	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	707	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注射部位反応	710		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	712		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	714		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	716		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
LD	6016-00365	ASIAN	0	MALE	6[redacted]	歯肉炎	12	18D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						便秘	15	630D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	36	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	96	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道の炎症	103	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	162	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	242	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	246	8D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						好中球減少症	250	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						末梢性浮腫	365	43D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	407	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						眼瞼浮腫	439		RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	449		RELATED	GRADE 1	AE	DOSE REDUCED	
						下痢	500	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ウイルス性胃腸炎	507	6D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	580	10D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腎クレアチニン・クリアランス減少	582	36D	RELATED	GRADE 1	AE	DOSE REDUCED	
						筋肉痛	600	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎クレアチニン・クリアランス減少	631	29D	RELATED	GRADE 1	AE	DOSE REDUCED	
						便秘	645		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
LD	6018-00501	ASIAN	0	MALE	7[redacted]	しゃっくり	2	113D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎機能障害	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	9		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	13	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						緑内障	212		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疾患進行	259		NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						便秘	261		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						歯周炎	265		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	282		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
NOT TREATED	1401-00564	BLACK OR AFRICAN AMERICAN		FEMALE	6[redacted]	肺炎		4D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NOT TREATED	1442-00157	WHITE		MALE	6[redacted]	肺扁平上皮癌			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NOT TREATED	2401-00264	WHITE		MALE	8[redacted]	脱水			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						硬膜下血腫		13.4H	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
NOT TREATED	4414-00625	WHITE		FEMALE	7[redacted]	心房細動			NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						心不全			NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						敗血症			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NOT TREATED	4503-00258	WHITE		MALE	7[redacted]	痙攣		8D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						意識レベルの低下		8D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性腎不全		26D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						敗血症		28D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NOT TREATED	4508-00174	WHITE		MALE	6[redacted]	血栓性静脈炎		7D	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
NOT TREATED	4510-00269	WHITE		FEMALE	7[redacted]	結腸腺癌			NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NOT TREATED	4901-00747	WHITE		MALE	6[redacted]	肺炎		4D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NOT TREATED	5011-00374	WHITE		MALE	6[redacted]	形質細胞性骨髄腫		11D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺臓炎		11D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
NOT TREATED	5505-00075	WHITE		FEMALE	8[redacted]	胆道仙痛		27.6H	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NOT TREATED	5900-00353	BLACK OR AFRICAN AMERICAN		FEMALE	3[redacted]	下痢		48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧		3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腸管穿孔		10D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						処置による疼痛			NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱		7D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐		48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐		48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
NOT TREATED	5910-00253	WHITE		FEMALE	6[redacted]	好中球減少症		8D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						副鼻腔炎		4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
NOT TREATED	6005-00212	ASIAN		MALE	6[redacted]	大腿骨頚部骨折		133D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
NOT TREATED	6018-00602	ASIAN		MALE	6[redacted]	疾患進行			NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

APPENDIX 46　重篤な有害事象を発現した被験者の一覧（005 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
BMS 20mg/kg + Ld	0001 00201	JAPANESE	20 mg/kg	MALE	[redacted]	顆粒球減少症	20	6 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	20	6 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	50	36 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	15	6 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	20	66 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	99	15 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	127	15 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	141	43 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	197	18 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	217	8 D	RELATED	GRADE 2	AE	NONE	
						第一度房室ブロック	9	8 D	NOT RELATED	GRADE 1	AE	NONE	
						便秘	17	4 D	NOT RELATED	GRADE 1	AE	NONE	
						齲歯	33	7 D	NOT RELATED	GRADE 1	AE	NONE	
						下痢	7	1 D	NOT RELATED	GRADE 1	AE	NONE	
						下痢	19	3 D	NOT RELATED	GRADE 1	AE	NONE	
						下痢	168	3 D	NOT RELATED	GRADE 2	AE	NONE	
						おくび	2	1 D	RELATED	GRADE 1	AE	NONE	
						おくび	8	3 D	RELATED	GRADE 1	AE	NONE	
						肛門周囲痛	14	7 D	NOT RELATED	GRADE 1	AE	NONE	
						口内炎	21	8 D	NOT RELATED	GRADE 1	AE	NONE	
						口内炎	105	8 D	RELATED	GRADE 1	AE	NONE	
						嘔吐	17	2 D	NOT RELATED	GRADE 1	AE	NONE	
						倦怠感	2	111 D	NOT RELATED	GRADE 1	AE	NONE	
						倦怠感	214	46 D	NOT RELATED	GRADE 1	AE	NONE	
						発熱	19	6 D	NOT RELATED	GRADE 1	AE	NONE	
						胆石症	220		NOT RELATED	GRADE 2	SAE	NONE	DID NOT RESOLVE
						感染	17	13 D	NOT RELATED	GRADE 2	AE	DRUG WAS INTERRUPTED	
						鼻咽頭炎	147	22 D	NOT RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	177	20 D	NOT RELATED	GRADE 1	AE	NONE	
						口腔カンジダ症	33	8 D	NOT RELATED	GRADE 1	AE	NONE	
						アラニンアミノトランスフェラーゼ増加	214	25 D	NOT RELATED	GRADE 3	SAE	NONE	RESOLVED
						アスパラギン酸アミノトランスフェラーゼ増加	214	18 D	NOT RELATED	GRADE 3	SAE	NONE	RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中アルカリホスファターゼ増加	214	46 D	NOT RELATED	GRADE 2	SAE	NONE	RESOLVED
						γ－グルタミルトランスフェラーゼ増加	214		NOT RELATED	GRADE 3	SAE	NONE	DID NOT RESOLVE
						筋骨格痛	17	2 D	NOT RELATED	GRADE 1	AE	NONE	
						味覚異常	183	2 D	RELATED	GRADE 1	AE	NONE	
						頭痛	214	2 D	NOT RELATED	GRADE 1	AE	NONE	
						末梢性ニューロパチー	154	106 D	RELATED	GRADE 1	AE	DOSE WAS REDUCED	
						傾眠	155	1 D	NOT RELATED	GRADE 2	AE	NONE	
						不眠症	8	66 D	NOT RELATED	GRADE 1	AE	NONE	
						鼻出血	28	1 D	NOT RELATED	GRADE 1	AE	NONE	
						皮膚乾燥	133	22 D	NOT RELATED	GRADE 1	AE	NONE	
						発疹	31	7 D	NOT RELATED	GRADE 1	AE	NONE	
						潮紅	2	1 D	RELATED	GRADE 1	AE	NONE	
						潮紅	37	2 D	RELATED	GRADE 1	AE	NONE	
						潮紅	114	1 D	RELATED	GRADE 1	AE	NONE	
BMS 20mg/kg + Ld	0001 00203	JAPANESE	20 mg/kg	FEMALE	6[redacted]	白血球減少症	118	15 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	245	3 D	RELATED	GRADE 1	AE	NONE	
						白血球減少症	247	13 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	15	44 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	118	42 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	201	16 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	245	3 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	247	13 D	RELATED	GRADE 3	AE	NONE	
						下痢	248	3 D	NOT RELATED	GRADE 1	AE	NONE	
						胸痛	17		NOT RELATED	GRADE 1	AE	NONE	
						倦怠感	11	47 D	NOT RELATED	GRADE 1	AE	NONE	
						気管支肺炎	242	3 D	NOT RELATED	GRADE 2	AE	NONE	
						気管支肺炎	244	16 D	NOT RELATED	GRADE 3	SAE	DRUG WAS INTERRUPTED	RESOLVED
						創傷	200	17 D	NOT RELATED	GRADE 1	AE	NONE	
						ヘモグロビン減少	22	69 D	RELATED	GRADE 3	AE	NONE	
						ヘモグロビン減少	90	217 D	RELATED	GRADE 4	AE	DOSE WAS REDUCED	
						味覚異常	11	18 D	NOT RELATED	GRADE 2	AE	NONE	
						味覚異常	104	203 D	RELATED	GRADE 1	AE	NONE	
						発疹	15	3 D	NOT RELATED	GRADE 1	AE	NONE	
						潮紅	3	1 D	RELATED	GRADE 1	AE	NONE	
						潮紅	148	135 D	RELATED	GRADE 1	AE	NONE	
BMS 10mg/kg + Ld	0002 00102	JAPANESE	10 mg/kg	MALE	5[redacted]	白血球減少症	5	7 D	RELATED	GRADE 2	AE	NONE	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球減少症	269	23 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	306	28 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	393	11 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	548	24 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	680	11 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	5	21 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	68	14 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	152	17 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	269	12 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	292	14 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	320	14 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	393	25 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	464	12 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	488	14 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	516	14 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	548	70 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	663	17 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	751	10 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	803	28 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	943	3 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	54	14 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	110	14 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	138	14 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	306	14 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	548	24 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	680	11 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	733	18 D	RELATED	GRADE 2	AE	NONE	
						口内炎	592	12 D	RELATED	GRADE 1	AE	NONE	
						発熱	476	1 D	RELATED	GRADE 1	AE	NONE	
						肝炎	596	31 D	RELATED	GRADE 2	SAE	DRUG WAS INTERRUPTED	RESOLVED
						季節性アレルギー	1.00E+03		RELATED	GRADE 1	AE	NONE	
						単純ヘルペス	597	8 D	RELATED	GRADE 1	AE	NONE	
						インフルエンザ	1.00E+03	10 D	NOT RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	210	13 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	253	17 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	361	16 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	555	6 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	588	18 D	RELATED	GRADE 2	AE	DRUG WAS INTERRUPTED	
						鼻咽頭炎	623	9 D	RELATED	GRADE 1	AE	NONE	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻咽頭炎	836	2 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	931	21 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	1.00E+03	5 D	RELATED	GRADE 1	AE	NONE	
						アラニンアミノトランスフェラーゼ増加	943	14 D	RELATED	GRADE 1	AE	NONE	
						アスパラギン酸アミノトランスフェラーゼ増加	943	3 D	RELATED	GRADE 1	AE	NONE	
						血中アルカリホスファターゼ増加	943	14 D	RELATED	GRADE 1	AE	NONE	
						陰茎潰瘍形成	594	12 D	RELATED	GRADE 1	AE	NONE	
						発疹	773	129 D	NOT RELATED	GRADE 1	AE	NONE	
						発疹	940	7 D	NOT RELATED	GRADE 1	AE	NONE	
BMS 20mg/kg + Ld	0003 00204	JAPANESE	20 mg/kg	FEMALE	[redacted]	白血球減少症	28	7 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	42	14 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	463	15 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	491	15 D	RELATED	GRADE 2	AE	NONE	
						白血球減少症	757	15 D	RELATED	GRADE 2	AE	NONE	
						リンパ球減少症	7	35 D	RELATED	GRADE 3	AE	NONE	
						リンパ球減少症	99	14 D	RELATED	GRADE 1	AE	NONE	
						リンパ球減少症	757	15 D	RELATED	GRADE 1	AE	NONE	
						好中球減少症	42	14 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	449	15 D	RELATED	GRADE 2	AE	NONE	
						好中球減少症	491	15 D	RELATED	GRADE 2	AE	NONE	
						白内障	346	132 D	RELATED	GRADE 1	AE	NONE	
						白内障	478	10 D	RELATED	GRADE 3	SAE	DRUG WAS INTERRUPTED	RESOLVED
						結膜出血	840	16 D	NOT RELATED	GRADE 1	AE	NONE	
						眼脂	603	141 D	RELATED	GRADE 1	AE	NONE	
						便秘	11	215 D	RELATED	GRADE 1	AE	NONE	
						便秘	442	8 D	RELATED	GRADE 1	AE	NONE	
						齲歯	410	124 D	RELATED	GRADE 1	AE	NONE	
						歯肉びらん	827	15 D	NOT RELATED	GRADE 1	AE	NONE	
						疲労	11	4 D	RELATED	GRADE 1	AE	NONE	
						疲労	42	8 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	405	5 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	473	19 D	RELATED	GRADE 1	AE	NONE	
						鼻咽頭炎	565	5 D	NOT RELATED	GRADE 2	AE	NONE	
						歯周炎	507	195 D	RELATED	GRADE 1	AE	NONE	
						歯周炎	701		RELATED	GRADE 2	AE	DOSE WAS REDUCED	
						擦過傷	686	16 D	NOT RELATED	GRADE 1	AE	NONE	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	449	15 D	RELATED	GRADE 2	AE	NONE	
						アミラーゼ増加	449	29 D	NOT RELATED	GRADE 3	AE	NONE	
						アミラーゼ増加	561	29 D	NOT RELATED	GRADE 3	AE	NONE	
						アミラーゼ増加	21	3 D	NOT RELATED	GRADE 3	AE	NONE	
						アスパラギン酸アミノトランスフェラーゼ増加	449	15 D	RELATED	GRADE 2	AE	NONE	
						腎クレアチニン・クリアランス減少	35		NOT RELATED	GRADE 1	AE	DOSE WAS REDUCED	
						体重減少	449	29 D	RELATED	GRADE 2	AE	NONE	
						体重減少	533		NOT RELATED	GRADE 2	AE	NONE	
						高トリグリセリド血症	140	15 D	RELATED	GRADE 2	AE	NONE	
						低アルブミン血症	575	15 D	RELATED	GRADE 1	AE	NONE	
						低アルブミン血症	603	15 D	RELATED	GRADE 1	AE	NONE	
						味覚異常	171	27 D	RELATED	GRADE 1	AE	NONE	
						皮膚乾燥	365	183 D	NOT RELATED	GRADE 1	AE	NONE	

APPENDIX 47　重篤な有害事象を発現した被験者の一覧（1703 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
10 mg/kg	1520	BLACK OF AFRICAN HERITAGE	10 mg/kg	Female	4[redacted]	貧血	1	8 D	NOT RELATED	GRADE 2	AE	NONE
						血中重炭酸塩減少	1	183 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	5	11 D	NOT RELATED	GRADE 2	AE	NONE
						発熱	5	1 D	E	GRADE 3	AE	NONE
						貧血	8	105 D	L	GRADE 2	AE	NONE
						血中乳酸脱水素酵素増加	8	281 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	8	15 D	L	GRADE 2	AE	NONE
						リンパ球減少症	8	15 D	L	GRADE 3	AE	NONE
						カテーテル留置部位疼痛	15	25 D	NOT RELATED	GRADE 1	AE	NONE
						低リン酸血症	15	29 D	NOT RELATED	GRADE 3	AE	NONE
						血小板減少症	15	8 D	L	GRADE 1	AE	NONE
						血中クレアチニン増加	22	8 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	22	22 D	L	GRADE 2	AE	NONE
						高血糖	29	43 D	D	GRADE 2	AE	NONE
						高ナトリウム血症	29	15 D	NOT RELATED	GRADE 1	AE	NONE
						失神	35	2 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						腎嚢胞	40	CONT.	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	43	15 D	L	GRADE 1	AE	NONE
						血中アルカリホスファターゼ増加	43	15 D	L	GRADE 1	AE	NONE
						低アルブミン血症	43	15 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	43	56 D	E,L	GRADE 2	AE	NONE
						傾眠	47	11 D	NOT RELATED	GRADE 2	AE	NONE
						脱水	50	51 D	NOT RELATED	GRADE 3	AE	INTERRUPTED
						血中アルカリホスファターゼ増加	57	15 D	D	GRADE 1	AE	NONE
						高カリウム血症	57	15 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	85	15 D	NOT RELATED	GRADE 2	AE	NONE
						末梢性浮腫	96	13 D	D	GRADE 1	AE	NONE
						高カルシウム血症	99	57 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	99	134 D	D	GRADE 2	AE	NONE
						リンパ球減少症	99	28 D	L	GRADE 2	AE	NONE
						低カリウム血症	108	5 D	NOT RELATED	GRADE 3	AE	NONE
						筋痙縮	113	106 D	L,D	GRADE 2	AE	NONE
						血中カルシウム増加	127	29 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	127	14 D	L	GRADE 3	AE	NONE
						背部痛	132	24 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						リンパ球減少症	141	14 D	L	GRADE 1	AE	NONE
						低カリウム血症	155	15 D	NOT RELATED	GRADE 3	AE	NONE
						リンパ球減少症	155	14 D	L	GRADE 3	AE	NONE
						好中球数増加	155	15 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	161	58 D	E,L,D	GRADE 3	AE	NONE
						リンパ球減少症	169	15 D	E,L	GRADE 3	AE	NONE
						血中重炭酸塩減少	183	36 D	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	183	22 D	E,L	GRADE 2	AE	NONE
						一過性脳虚血発作	192	3 D	NOT RELATED	GRADE 3	SAE	NONE
						リンパ球減少症	204	15 D	L	GRADE 2	AE	NONE
						副甲状腺機能亢進症	218	CONT.	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	218	15 D	NOT RELATED	GRADE 2	AE	NONE
						関節痛	224	504 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	224	22 D	NOT RELATED	GRADE 1	AE	NONE
						筋骨格痛	224	CONT.	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	224	23 D	D	GRADE 1	AE	NONE
						発疹	224	23 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	232	15 D	L	GRADE 2	AE	NONE
						上気道感染	250	67 D	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	260	15 D	E,L	GRADE 2	AE	NONE
						高血糖	274	15 D	L	GRADE 2	AE	NONE
						リンパ球減少症	274	57 D	L	GRADE 2	AE	NONE
						腹痛	285	CONT.	L,D	GRADE 1	AE	NONE
						白血球減少症	330	15 D	L	GRADE 2	AE	NONE
						リンパ球減少症	330	57 D	E,L	GRADE 3	AE	NONE
						上気道感染	331	28 D	NOT RELATED	GRADE 2	AE	NONE
						胃食道逆流性疾患	344	CONT.	D	GRADE 1	AE	NONE
						下痢	368	96 D	L,D	GRADE 1	AE	NONE
						背部痛	386	57 D	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	386	43 D	E,L	GRADE 2	AE	NONE
						好中球減少症	428	120 D	L	GRADE 1	AE	NONE
						リンパ球減少症	442	15 D	L	GRADE 3	AE	NONE
						胃炎	454	10 D	L,D	GRADE 3	AE	DELAYED
						高血糖	456	50 D	D	GRADE 2	AE	NONE
						リンパ球減少症	456	8 D	L	GRADE 2	AE	NONE
						悪心	477	CONT.	E	GRADE 1	AE	NONE
						末梢性浮腫	491	29 D	D	GRADE 1	AE	NONE
						ほてり	497	CONT.	D	GRADE 2	AE	NONE
						多汗症	497	CONT.	D	GRADE 2	AE	NONE
						低カルシウム血症	505	29 D	D	GRADE 2	AE	NONE
						低カリウム血症	505	15 D	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						無呼吸	537	1 D	NOT RELATED	GRADE 3	AE	NONE
						大発作痙攣	537	1 D	NOT RELATED	GRADE 2	AE	NONE
						血中クロール増加	547	15 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	547	15 D	NOT RELATED	GRADE 3	AE	NONE
						白血球減少症	547	15 D	L	GRADE 2	AE	NONE
						好中球減少症	547	15 D	L	GRADE 2	AE	NONE
						末梢性浮腫	575	281 D	NOT RELATED	GRADE 1	AE	NONE
						不安	576	CONT.	D	GRADE 2	AE	NONE
						うつ病	576	CONT.	D	GRADE 2	AE	NONE
						背部痛	589	CONT.	NOT RELATED	GRADE 2	AE	NONE
						便秘	589	267 D	L	GRADE 1	AE	NONE
						下痢	589	267 D	L	GRADE 1	AE	NONE
						錯感覚	603	126 D	L	GRADE 1	AE	NONE
						嘔吐	644	1 D	NOT RELATED	GRADE 1	AE	NONE
						頭痛	692	1 D	NOT RELATED	GRADE 2	AE	NONE
						爪変色	701	70 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	710	31 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	727	CONT.	NOT RELATED	GRADE 2	AE	NONE
						足骨折	727	1 D	NOT RELATED	GRADE 1	AE	NONE
						心雑音	743	CONT.	NOT RELATED	GRADE 1	AE	NONE
						進行性高血圧	776	2 D	NOT RELATED	GRADE 3	SAE	NONE
						大発作痙攣	776	2 D	NOT RELATED	GRADE 2	SAE	NONE
						低カリウム血症	776	2 D	NOT RELATED	GRADE 3	SAE	NONE
						頚部腫瘤	799	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						錯乱状態	826	1 D	D	GRADE 1	AE	NONE
						嘔吐	826	1 D	L	GRADE 1	AE	NONE
						脱水	837	4 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	837	4 D	NOT RELATED	GRADE 3	AE	NONE
						低カリウム血症	841	15 D	NOT RELATED	GRADE 3	AE	NONE
						疲労	863	CONT.	L,D	GRADE 2	AE	NONE
						体重増加	863	31 D	D	GRADE 2	AE	NONE
10 mg/kg	1524	WHITE	10 mg/kg	Female	[redacted]	血中重炭酸塩減少	1	8 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	1	8 D	D	GRADE 1	AE	NONE
						高ナトリウム血症	1	8 D	NOT RELATED	GRADE 1	AE	NONE
						高血圧	1	1 D	E	GRADE 1	AE	NONE
						低アルブミン血症	1	8 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	1	CONT.	L,D	GRADE 1	AE	NONE
						リンパ節症	7	2 D	NOT RELATED	GRADE 1	AE	NONE
						活性化部分トロンボプラスチン時間延長	8	8 D	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	8	2 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	8	22 D	D	GRADE 2	AE	NONE
						リンパ球減少症	8	CONT.	L	GRADE 3	AE	NONE
						アラニンアミノトランスフェラーゼ増加	15	22 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	15	15 D	NOT RELATED	GRADE 2	AE	NONE
						食欲減退	15	8 D	E	GRADE 1	AE	NONE
						浮動性めまい	15	8 D	NOT RELATED	GRADE 1	AE	NONE
						低アルブミン血症	15	22 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	22	15 D	E,L	GRADE 2	AE	NONE
						総蛋白減少	22	8 D	NOT RELATED		AE	NONE
						血中重炭酸塩減少	29	8 D	NOT RELATED	GRADE 1	AE	NONE
						労作性呼吸困難	29	29 D	L	GRADE 1	AE	NONE
						高血糖	29	8 D	D	GRADE 3	AE	NONE
						低酸素症	29	7 D	L	GRADE 2	AE	NONE
						末梢性浮腫	29	8 D	NOT RELATED	GRADE 1	AE	NONE
						肺塞栓症	32	4 D	L	GRADE 3	SAE	NONE
						アラニンアミノトランスフェラーゼ増加	36	8 D	L	GRADE 2	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	36	8 D	L	GRADE 1	AE	NONE
						高血糖	36	8 D	D	GRADE 2	AE	NONE
						アラニンアミノトランスフェラーゼ増加	43	15 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	43	29 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	43	8 D	D	GRADE 3	AE	NONE
						高血糖	50	92 D	D	GRADE 2	AE	NONE
						白血球減少症	50	8 D	L	GRADE 2	AE	NONE
						筋痙縮	50	1 D	L	GRADE 1	AE	NONE
						総蛋白減少	50	8 D	D		AE	NONE
						坐骨神経痛	50	1 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	57	15 D	L	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	71	43 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	85	14 D	NOT RELATED	GRADE 2	AE	NONE
						血中重炭酸塩減少	98	16 D	NOT RELATED	GRADE 1	AE	NONE
						総蛋白減少	98	16 D	NOT RELATED		AE	NONE
						背部痛	99	CONT.	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	127	15 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	127	29 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						血小板減少症	127	15 D	L	GRADE 1	AE	NONE
						高血糖	141	CONT.	D	GRADE 1	AE	NONE
						網膜変性	148	CONT.	NOT RELATED	GRADE 2	AE	NONE
						肺腫瘤	197	CONT.	NOT RELATED	GRADE 1	AE	NONE
						副鼻腔炎	204	18 D	L	GRADE 2	AE	NONE
10 mg/kg	1530	WHITE	10 mg/kg	Female	5[redacted]	高血糖	1	15 D	D	GRADE 1	AE	NONE
						腹部膨満	11	47 D	L	GRADE 1	AE	NONE
						便秘	11	19 D	L	GRADE 1	AE	NONE
						高血糖	22	162 D	D	GRADE 2	AE	NONE
						リンパ球減少症	22	15 D	E,L	GRADE 2	AE	NONE
						そう痒症	29	29 D	L	GRADE 1	AE	NONE
						低ナトリウム血症	36	15 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	43	15 D	L	GRADE 2	AE	NONE
						アラニンアミノトランスフェラーゼ増加	50	8 D	L	GRADE 1	AE	NONE
						下痢	50	1 D	L	GRADE 2	AE	NONE
						白血球減少症	50	8 D	L	GRADE 1	AE	NONE
						腹痛	51	2 D	L	GRADE 1	AE	NONE
						下痢	52	1 D	L	GRADE 2	AE	NONE
						下痢	57	57 D	L	GRADE 1	AE	NONE
						白血球減少症	57	29 D	L	GRADE 2	AE	NONE
						筋痙縮	57	29 D	L,D	GRADE 1	AE	NONE
						血中乳酸脱水素酵素増加	85	15 D	NOT RELATED		AE	NONE
						血小板増加症	85	15 D	L		AE	NONE
						発熱	104	1 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	105	9 D	L,D	GRADE 2	AE	NONE
						血中重炭酸塩減少	113	15 D	NOT RELATED	GRADE 1	AE	NONE
						高ナトリウム血症	113	15 D	NOT RELATED	GRADE 1	AE	NONE
						湿性咳嗽	146	58 D	NOT RELATED	GRADE 2	AE	NONE
						鼻漏	146	52 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	153	5 D	E,L,D	GRADE 3	SAE	INTERRUPTED
						発熱	153	1 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	182	2 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	183	1 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	188	2 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	188	2 D	NOT RELATED	GRADE 1	AE	NONE
						副鼻腔炎	225	15 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	253	15 D	L	GRADE 1	AE	NONE
						高血糖	253	29 D	D	GRADE 2	AE	NONE
						浮動性めまい	262	1 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						腹部膨満	265	45 D	L	GRADE 1	AE	NONE
						高血糖	281	15 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	295	70 D	L	GRADE 1	AE	NONE
						下痢	295	71 D	L	GRADE 1	AE	NONE
						高血糖	295	30 D	D	GRADE 1	AE	NONE
						低クロール血症	295	CONT.	NOT RELATED	GRADE 1	AE	NONE
						多汗症	323	CONT.	D	GRADE 2	AE	NONE
						高血糖	337	15 D	D	GRADE 2	AE	NONE
						高血糖	351	CONT.	D	GRADE 1	AE	NONE
						リンパ球減少症	351	CONT.	L	GRADE 2	AE	NONE
						不安	365	CONT.	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	365	28 D	D	GRADE 2	AE	NONE
						下痢	393	CONT.	L	GRADE 1	AE	NONE
						疲労	393	CONT.	L,D	GRADE 1	AE	NONE
						上気道感染	393	15 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	421	CONT.	NOT RELATED	GRADE 1	AE	NONE
						呼吸困難	421	15 D	NOT RELATED	GRADE 1	AE	NONE
						錯感覚	449	CONT.	L	GRADE 1	AE	NONE
						血小板減少症	533	15 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	592	CONT.	NOT RELATED	GRADE 2	AE	NONE
						脱毛症	629	CONT.	L	GRADE 1	AE	NONE
						ヘルニア	645	CONT.	NOT RELATED	GRADE 2	AE	NONE
						末梢性ニューロパチー	701	CONT.	L	GRADE 2	AE	NONE
						副鼻腔うっ血	785	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	834	22 D	NOT RELATED	GRADE 1	AE	NONE
						慢性閉塞性肺疾患	885	CONT.	NOT RELATED	GRADE 2	AE	NONE
						腹部膨満	897	CONT.	D	GRADE 1	AE	NONE
						呼吸困難	897	57 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	981	28 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	988	22 D	D	GRADE 2	AE	NONE
						下痢	1008	9 D	NOT RELATED	GRADE 3	AE	NONE
						下痢	1017	CONT.	L	GRADE 2	AE	NONE
						網膜裂孔	1046	31 D	NOT RELATED	GRADE 2	AE	NONE
10 mg/kg	1601	WHITE	10 mg/kg	Female	5[redacted]	ほてり	1	1 D	E	GRADE 1	AE	INTERRUPTED
						発熱	1	2 D	E	GRADE 1	AE	NONE
						湿性咳嗽	2	35 D	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	8	4 D	NOT RELATED	GRADE 3	AE	NONE
						便秘	15	10 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	15	CONT.	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						悪心	15	8 D	E,L,D	GRADE 1	AE	NONE
						副鼻腔炎に伴う頭痛	15	10 D	NOT RELATED	GRADE 1	AE	NONE
						血管穿刺部位出血	15	8 D	D	GRADE 1	AE	NONE
						悪心	24	19 D	L	GRADE 1	AE	NONE
						霧視	24	6 D	D	GRADE 1	AE	NONE
						便秘	29	15 D	NOT RELATED	GRADE 1	AE	NONE
						浮動性めまい	29	29 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	36	8 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	50	8 D	L	GRADE 1	AE	NONE
						活性化部分トロンボプラスチン時間延長	57	15 D	NOT RELATED	GRADE 3	AE	NONE
						便秘	57	134 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	57	15 D	L	GRADE 2	AE	NONE
						寝汗	57	29 D	NOT RELATED	GRADE 1	AE	NONE
						動悸	57	29 D	NOT RELATED	GRADE 1	AE	NONE
						霧視	57	43 D	D	GRADE 1	AE	NONE
						頭痛	85	64 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	85	64 D	L	GRADE 1	AE	NONE
						悪心	85	15 D	L	GRADE 1	AE	NONE
						歯痛	85	64 D	NOT RELATED	GRADE 1	AE	NONE
						失神	93	3 D	L	GRADE 3	SAE	NONE
						徐脈	94	3 D	L	GRADE 3	SAE	NONE
						注射部位出血	99	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	127	50 D	NOT RELATED	GRADE 1	AE	NONE
						ほてり	141	8 D	NOT RELATED	GRADE 1	AE	NONE
						霧視	148	CONT.	D	GRADE 1	AE	NONE
						下痢	162	29 D	NOT RELATED	GRADE 1	AE	NONE
						鼻咽頭炎	162	15 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	176	29 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	204	CONT.	NOT RELATED	GRADE 2	AE	NONE
						不眠症	218	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	278	11 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	288	29 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	316	10 D	L	GRADE 1	AE	NONE
						悪心	316	10 D	L	GRADE 1	AE	NONE
						低カルシウム血症	473	27 D	NOT RELATED	GRADE 2	AE	NONE
						血小板減少症	473	153 D	L	GRADE 1	AE	NONE
						動悸	475	CONT.	D	GRADE 1	AE	NONE
						高血糖	499	15 D	D	GRADE 1	AE	NONE
						白血球減少症	499	15 D	D	GRADE 1	AE	NONE
						リンパ球減少症	499	155 D	D	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						高血糖	527	113 D	D	GRADE 1	AE	NONE
						下痢	528	459 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	528	CONT.	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	541	15 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	583	29 D	L,D	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	611	140 D	NOT RELATED	GRADE 2	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	611	15 D	NOT RELATED	GRADE 2	AE	NONE
						鼻炎	622	32 D	NOT RELATED	GRADE 2	AE	NONE
						血小板減少症	639	196 D	L	GRADE 1	AE	NONE
						リンパ球減少症	667	CONT.	D	GRADE 4	AE	NONE
						白血球減少症	707	15 D	L	GRADE 3	AE	NONE
						好中球減少症	707	15 D	L	GRADE 3	AE	NONE
						貧血	777	17 D	NOT RELATED	GRADE 2	AE	NONE
						白血球減少症	807	15 D	D	GRADE 3	AE	NONE
						好中球減少症	807	15 D	L	GRADE 3	AE	NONE
						好中球減少症	834	72 D	L	GRADE 2	AE	NONE
						血小板減少症	834	44 D	L	GRADE 2	AE	NONE
						ウイルス性肺炎	856	22 D	L,D	GRADE 3	SAE	DELAYED
						下痢	986	2 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	991	11 D	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	1001	18 D	NOT RELATED	GRADE 2	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	1001	18 D	NOT RELATED	GRADE 1	AE	NONE
						血中アルカリホスファターゼ増加	1001	18 D	NOT RELATED	GRADE 1	AE	NONE
						耳感染	1003	16 D	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	1016	3 D	NOT RELATED	GRADE 2	AE	NONE
						聴力低下	1018	CONT.	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	1078	4 D	NOT RELATED	GRADE 2	AE	DELAYED
						血中クレアチニン増加	1081	16 D	NOT RELATED	GRADE 1	AE	NONE
						脱水	1113	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	1141	CONT.	NOT RELATED	GRADE 1	AE	NONE
						白血球数減少	1141	CONT.	NOT RELATED	GRADE 2	AE	NONE
						血中クレアチニン増加	1197	15 D	NOT RELATED	GRADE 1	AE	NONE
						血中尿素増加	1197	15 D	NOT RELATED	GRADE 1	AE	NONE
						ヘマトクリット減少	1197	CONT.	L	GRADE 1	AE	NONE
						白血球数増加	1197	15 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						アラニンアミノトランスフェラーゼ増加	1211	16 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	1211	CONT.	L	GRADE 1	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	1211	16 D	NOT RELATED	GRADE 1	AE	NONE
						低カルシウム血症	1211	16 D	NOT RELATED	GRADE 1	AE	NONE
						血小板数減少	1211	CONT.	L	GRADE 1	AE	NONE
						高血糖	1226	CONT.	D	GRADE 1	AE	NONE
						好中球数増加	1226	CONT.	D	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	1240	CONT.	NOT RELATED	GRADE 1	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	1240	CONT.	NOT RELATED	GRADE 1	AE	NONE
						血中アルブミン減少	1240	43 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	1240	CONT.	NOT RELATED	GRADE 1	AE	NONE
						坐骨神経痛	1240	CONT.	NOT RELATED	GRADE 1	AE	NONE
						低血圧	1254	15 D	NOT RELATED	GRADE 1	AE	NONE
						高血圧	1268	15 D	NOT RELATED	GRADE 1	AE	NONE
						血中アルブミン減少	1296	15 D	NOT RELATED	GRADE 1	AE	NONE
						血中尿素増加	1310	15 D	NOT RELATED	GRADE 1	AE	NONE
						高血圧	1324	15 D	NOT RELATED	GRADE 1	AE	NONE
10 mg/kg	1602	BLACK OF AFRICAN HERITAGE	10 mg/kg	Male	5[redacted]	敗血症	2	21 D	D	GRADE 2	SAE	DELAYED
						頻脈	2	3 D	NOT RELATED	GRADE 2	SAE	NONE
						不安	29	15 D	D	GRADE 1	AE	NONE
						蜂巣炎	29	36 D	D	GRADE 2	AE	DELAYED
						リンパ球減少症	29	1060 D	D	GRADE 1	AE	NONE
						浮腫	43	22 D	D	GRADE 1	AE	NONE
						頻脈	64	43 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	92	29 D	D	GRADE 1	AE	NONE
						食欲減退	92	15 D	NOT RELATED	GRADE 1	AE	NONE
						浮腫	92	15 D	D	GRADE 1	AE	NONE
						末梢性浮腫	120	31 D	D	GRADE 1	AE	NONE
						浮動性めまい	134	15 D	NOT RELATED	GRADE 1	AE	NONE
						霧視	148	CONT.	D	GRADE 1	AE	NONE
						咳嗽	150	13 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	151	26 D	D	GRADE 1	AE	NONE
						食欲減退	176	15 D	L	GRADE 1	AE	NONE
						味覚異常	176	29 D	L	GRADE 1	AE	NONE
						食欲減退	190	15 D	L	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						毛包炎	210	23 D	L	GRADE 1	AE	NONE
						血便排泄	215	18 D	NOT RELATED	GRADE 1	AE	NONE
						期外収縮	232	29 D	NOT RELATED	GRADE 1	AE	NONE
						気道感染	339	4 D	L,D	GRADE 1	AE	NONE
						上気道感染	540	29 D	L,D	GRADE 2	AE	NONE
						関節痛	610	43 D	NOT RELATED	GRADE 2	AE	NONE
						背部痛	610	43 D	NOT RELATED	GRADE 2	AE	NONE
						湿性咳嗽	652	29 D	L,D	GRADE 1	AE	NONE
						下痢	708	100 D	NOT RELATED	GRADE 1	AE	NONE
						呼吸困難	708	29 D	NOT RELATED	GRADE 2	AE	NONE
						インフルエンザ	708	29 D	NOT RELATED	GRADE 1	AE	NONE
						インフルエンザ様疾患	708	CONT.	E	GRADE 1	AE	DELAYED
						関節痛	736	CONT.	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	736	29 D	NOT RELATED	GRADE 1	AE	NONE
						低血圧	764	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	778	15 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	862	29 D	D	GRADE 2	AE	NONE
						悪心	924	51 D	L,D	GRADE 1	AE	NONE
						失神	924	2 D	NOT RELATED	GRADE 3	AE	NONE
						疲労	974	CONT.	L	GRADE 2	AE	NONE
						好中球数増加	974	15 D	D	GRADE 1	AE	NONE
						浮腫	974	CONT.	D	GRADE 2	AE	NONE
						貧血	988	29 D	L	GRADE 1	AE	NONE
						高血糖	1002	43 D	D	GRADE 1	AE	NONE
						高血糖	1058	CONT.	D	GRADE 1	AE	NONE
10 mg/kg	2105	WHITE	10 mg/kg	Male	4[redacted]	発熱	2	7 D	E,L	GRADE 2	AE	NONE
						便秘	4	61 D	NOT RELATED	GRADE 1	AE	NONE
						錯感覚	14	CONT.	NOT RELATED	GRADE 1	AE	NONE
						骨痛	15	22 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	16	14 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	30	14 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	42	9 D	NOT RELATED	GRADE 1	AE	DELAYED
						術後創感染	50	18 D	D	GRADE 3	SAE	INTERRUPTED
						医療機器による疼痛	53	3 D	NOT RELATED	GRADE 2	AE	NONE
						気胸	53	4 D	NOT RELATED	GRADE 2	AE	NONE
						ブドウ球菌性創感染	68	43 D	D	GRADE 2	AE	NONE
						背部痛	162	168 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	189	141 D	NOT RELATED	GRADE 1	AE	NONE
						骨減少症	287	CONT.	NOT RELATED	GRADE 1	AE	NONE
						無力症	330	42 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						背部痛	330	81 D	NOT RELATED	GRADE 2	AE	NONE
						骨痛	411	3 D	NOT RELATED	GRADE 3	AE	NONE
						骨痛	414	22 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						骨痛	436	29 D	NOT RELATED	GRADE 3	AE	NONE
						骨痛	465	CONT.	NOT RELATED	GRADE 2	AE	NONE
10 mg/kg	2306	BLACK OF AFRICAN HERITAGE	10 mg/kg	Female	5[redacted]	下痢	8	1 D	E,L,D	GRADE 1	AE	NONE
						血小板減少症	9	14 D	E,L,D	GRADE 1	AE	NONE
						悪心	10	6 D	E,L,D	GRADE 1	AE	NONE
						便秘	11	4 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	22	22 D	E,L,D	GRADE 1	AE	NONE
						好中球減少症	22	15 D	E,L,D	GRADE 3	AE	NONE
						血小板減少症	22	8 D	E,L,D	GRADE 3	AE	NONE
						血小板減少症	29	15 D	E,L,D	GRADE 1	AE	NONE
						好中球減少症	36	16 D	E,L,D	GRADE 1	AE	NONE
						貧血	43	CONT.	E,L,D	GRADE 2	AE	NONE
						血小板減少症	43	9 D	E,L,D	GRADE 2	AE	NONE
						好中球減少症	51	CONT.	E,L,D	GRADE 2	AE	NONE
						血小板減少症	51	7 D	E,L,D	GRADE 1	AE	NONE
						不眠症	57	CONT.	E,L,D	GRADE 1	AE	NONE
						悪心	108	CONT.	NOT RELATED	GRADE 2	AE	NONE
						発熱性好中球減少症	139	11 D	NOT RELATED	GRADE 3	SAE	NONE
						下痢	169	3 D	NOT RELATED	GRADE 3	SAE	NONE
10 mg/kg	2404	WHITE	10 mg/kg	Female	6[redacted]	貧血	1	8 D	E,L	GRADE 2	AE	NONE
						悪寒	8	1 D	E	GRADE 1	AE	NONE
						靱帯捻挫	15	1 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	29	8 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	71	CONT.	NOT RELATED	GRADE 1	AE	NONE
						口腔カンジダ症	95	5 D	E,L	GRADE 1	AE	NONE
						背部痛	113	113 D	NOT RELATED	GRADE 1	AE	NONE
						季節性アレルギー	123	5 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	141	85 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	226	56 D	NOT RELATED	GRADE 2	AE	NONE
						背部痛	226	56 D	NOT RELATED	GRADE 2	AE	NONE
						四肢痛	261	3 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	264	CONT.	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	267	23 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	281	43 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	290	3 D	NOT RELATED	GRADE 2	AE	NONE
						疲労	292	CONT.	NOT RELATED	GRADE 1	AE	NONE
						口内炎	295	15 D	E,L	GRADE 2	AE	NONE
						下痢	309	27 D	NOT RELATED	GRADE 1	AE	DELAYED
						ウイルス感染	330	22 D	NOT RELATED	GRADE 1	AE	DELAYED
						下痢	335	3 D	NOT RELATED	GRADE 3	AE	DELAYED
						好中球減少症	339	6 D	E,L	GRADE 3	AE	NONE
						湿性咳嗽	347	5 D	NOT RELATED	GRADE 1	AE	NONE
						ほてり	348	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	358	1 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	359	CONT.	NOT RELATED	GRADE 1	AE	NONE
						痔核	359	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	365	CONT.	NOT RELATED	GRADE 3	AE	NONE
						胃腸出血	374	21 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						代謝性アシドーシス	374	4 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						心房細動	376	19 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						急性腎不全	376	19 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						消化管穿孔	416	6 D	NOT RELATED	GRADE 5	SAE	NONE
						代謝性アシドーシス	419	3 D	NOT RELATED	GRADE 5	SAE	NONE
10 mg/kg	2412	WHITE	10 mg/kg	Female	6[redacted]	寝汗	2	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	6	1 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	13	CONT.	NOT RELATED	GRADE 1	AE	NONE
						便秘	18	7 D	L,D	GRADE 1	AE	NONE
						悪心	24	2 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	39	4 D	D	GRADE 2	AE	NONE
						副鼻腔炎に伴う頭痛	41	10 D	NOT RELATED	GRADE 1	AE	NONE
						寝汗	42	2 D	D	GRADE 1	AE	NONE
						発声障害	45	41 D	D	GRADE 1	AE	NONE
						疲労	45	5 D	D	GRADE 2	AE	NONE
						霧視	45	41 D	D	GRADE 1	AE	NONE
						貧血	50	22 D	L	GRADE 2	AE	NONE
						悪心	54	2 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	66	5 D	D	GRADE 2	AE	NONE
						寝汗	68	2 D	D	GRADE 1	AE	NONE
						発疹	69	31 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	71	1 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	73	27 D	L,D	GRADE 2	AE	NONE
						低カリウム血症	85	15 D	NOT RELATED	GRADE 3	AE	NONE
						低カリウム血症	99	15 D	NOT RELATED	GRADE 1	AE	NONE
						血小板減少症	99	36 D	L	GRADE 1	AE	NONE
						味覚異常	106	CONT.	D	GRADE 1	AE	NONE
						貧血	113	8 D	E,L	GRADE 2	AE	DELAYED
						低カリウム血症	113	8 D	NOT RELATED	GRADE 3	AE	NONE
						好中球減少症	113	8 D	E,L	GRADE 3	AE	DELAYED
						下痢	120	141 D	L	GRADE 1	AE	NONE
						好中球減少症	120	29 D	L	GRADE 1	AE	NONE
						末梢性浮腫	127	36 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	176	15 D	L	GRADE 2	AE	NONE
						好中球減少症	176	15 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	190	15 D	L	GRADE 3	AE	NONE
						血小板減少症	190	15 D	L	GRADE 3	AE	NONE
						貧血	204	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	204	15 D	L	GRADE 2	AE	NONE
						血小板減少症	204	42 D	L	GRADE 1	AE	NONE
						貧血	218	CONT.	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	218	15 D	NOT RELATED	GRADE 3	AE	NONE
						霧視	226	CONT.	D	GRADE 1	AE	NONE
						低カリウム血症	246	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	246	36 D	L	GRADE 2	AE	NONE
						血小板減少症	246	22 D	L	GRADE 2	AE	NONE
						疲労	253	15 D	L,D	GRADE 2	AE	NONE
						食欲減退	260	CONT.	L,D	GRADE 1	AE	NONE
						下痢	260	464 D	L,D	GRADE 1	AE	NONE
						低カリウム血症	260	8 D	NOT RELATED	GRADE 3	AE	NONE
						白血球数減少	260	8 D	L	GRADE 3	AE	DELAYED
						疲労	267	276 D	L,D	GRADE 1	AE	NONE
						血小板減少症	267	15 D	L	GRADE 3	AE	NONE
						好中球減少症	281	15 D	L	GRADE 3	AE	NONE
						好中球減少症	295	57 D	L	GRADE 2	AE	NONE
						好中球減少症	351	43 D	L	GRADE 3	AE	NONE
						血小板減少症	365	15 D	L	GRADE 3	AE	NONE
						鼻出血	372	8 D	L	GRADE 1	AE	NONE
						歯肉出血	372	8 D	L	GRADE 1	AE	NONE
						嘔吐	382	1 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	393	43 D	L	GRADE 2	AE	NONE
						血小板減少症	393	71 D	L	GRADE 2	AE	NONE
						上気道感染	403	18 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						好中球減少症	435	71 D	L	GRADE 3	AE	NONE
						血小板減少症	463	14 D	L	GRADE 1	AE	NONE
						血小板減少症	477	99 D	L	GRADE 2	AE	NONE
						貧血	491	29 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	505	127 D	L	GRADE 2	AE	NONE
						疲労	513	49 D	L,D	GRADE 3	AE	DELAYED
						血小板減少症	575	15 D	L	GRADE 3	AE	NONE
						血小板減少症	589	CONT.	L	GRADE 1	AE	NONE
						好中球減少症	645	99 D	L	GRADE 2	AE	NONE
						低カリウム血症	701	29 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	724	2 D	D	GRADE 3	AE	NONE
						咳嗽	765	7 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	841	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	925	29 D	L	GRADE 2	AE	NONE
						疲労	925	29 D	E,L,D	GRADE 3	AE	DELAYED
						疲労	953	CONT.	E,L,D	GRADE 1	AE	NONE
						関節痛	1142	CONT.	NOT RELATED	GRADE 1	AE	NONE
						転倒	1182	1 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1185	21 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	1281	CONT.	E,L,D	GRADE 2	AE	DELAYED
						敗血症	1297	16 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
10 mg/kg	2502	WHITE	10 mg/kg	Male	6[redacted]	悪心	4	18 D	L	GRADE 1	AE	NONE
						リンパ球減少症	7	15 D	L	GRADE 4	AE	NONE
						悪寒	14	1 D	E	GRADE 2	AE	INTERRUPTED
						血小板減少症	14	21 D	L	GRADE 1	AE	NONE
						悪寒	21	1 D	E	GRADE 2	AE	INTERRUPTED
						白血球減少症	21	35 D	L	GRADE 4	AE	NONE
						好中球減少症	21	14 D	L	GRADE 3	AE	NONE
						斑状皮疹	21	14 D	L	GRADE 1	AE	NONE
						細菌性上気道感染	21	14 D	L	GRADE 2	AE	NONE
						末梢性浮腫	27	8 D	D	GRADE 1	AE	NONE
						リンパ球減少症	41	15 D	L	GRADE 4	AE	NONE
						好中球減少症	41	15 D	L	GRADE 3	AE	NONE
						上気道感染	41	29 D	NOT RELATED	GRADE 2	AE	NONE
						血小板減少症	55	CONT.	L	GRADE 3	AE	NONE
						免疫グロブリン減少	56	CONT.	NOT RELATED	GRADE 2	AE	NONE
						白血球減少症	69	15 D	L	GRADE 3	AE	NONE
						好中球減少症	69	15 D	L	GRADE 3	AE	NONE
						発疹	83	8 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						上気道感染	83	15 D	NOT RELATED	GRADE 1	AE	NONE
						憩室穿孔	92	8 D	D	GRADE 4	SAE	INTERRUPTED
						血中リン減少	93	5 D	NOT RELATED	GRADE 3	AE	NONE
						ヘモグロビン血症	93	6 D	L	GRADE 3	AE	NONE
						好中球減少症	96	5 D	L	GRADE 3	AE	NONE
						血中カリウム減少	97	2 D	NOT RELATED	GRADE 1	AE	NONE
						処置による疼痛	98	CONT.	NOT RELATED	GRADE 1	AE	NONE
						疲労	100	CONT.	L,D	GRADE 2	AE	NONE
						白血球減少症	125	CONT.	L	GRADE 3	AE	NONE
						真菌感染	132	36 D	D	GRADE 2	AE	NONE
						関節痛	139	CONT.	E,L,D	GRADE 2	AE	NONE
						好中球減少症	139	CONT.	L	GRADE 3	AE	NONE
						末梢性浮腫	167	CONT.	D	GRADE 1	AE	NONE
						便秘	185	1 D	NOT RELATED	GRADE 3	AE	NONE
10 mg/kg	2509	WHITE	10 mg/kg	Male	[redacted]	糖尿病	2	294 D	D	GRADE 2	AE	NONE
						浮動性めまい	15	1 D	NOT RELATED	GRADE 1	AE	NONE
						低血圧	15	1 D	NOT RELATED	GRADE 1	AE	NONE
						失神	15	1 D	NOT RELATED	GRADE 2	AE	NONE
						労作性呼吸困難	22	8 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	50	373 D	NOT RELATED	GRADE 1	AE	NONE
						インフルエンザ	54	32 D	NOT RELATED	GRADE 1	AE	NONE
						心雑音	57	29 D	NOT RELATED	GRADE 1	AE	NONE
						労作性呼吸困難	57	CONT.	NOT RELATED	GRADE 1	AE	NONE
						炎症	85	61 D	NOT RELATED	GRADE 1	AE	NONE
						深部静脈血栓症	105	CONT.	L,D	GRADE 3	AE	NONE
						挫傷	113	29 D	D	GRADE 1	AE	NONE
						斑状出血	113	29 D	D	GRADE 1	AE	NONE
						浮腫	113	29 D	D	GRADE 1	AE	NONE
						背部痛	169	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道咳症候群	281	CONT.	NOT RELATED	GRADE 1	AE	NONE
						耳漏	309	36 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	358	15 D	NOT RELATED	GRADE 1	AE	NONE
						浮動性めまい	454	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	454	7 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	480	40 D	NOT RELATED	GRADE 1	AE	NONE
						副鼻腔分泌過多	491	29 D	NOT RELATED	GRADE 1	AE	NONE
						湿性咳嗽	491	29 D	NOT RELATED	GRADE 1	AE	NONE
						筋力低下	511	37 D	D	GRADE 3	AE	NONE
						転倒	533	1 D	D	GRADE 2	AE	NONE
						上腹部痛	627	5 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	627	5 D	L	GRADE 1	AE	NONE
						胃腸音異常	627	33 D	L	GRADE 1	AE	NONE
						末梢性ニューロパチー	659	CONT.	L	GRADE 1	AE	NONE
						悪心	743	CONT.	L	GRADE 1	AE	NONE
						排尿困難	846	CONT.	NOT RELATED	GRADE 1	AE	NONE
						発熱性好中球減少症	871	16 D	L	GRADE 3	SAE	DECREASED, INTERRUPTED
						咳嗽	958	7 D	NOT RELATED	GRADE 1	AE	NONE
						鼻出血	974	CONT.	NOT RELATED	GRADE 1	AE	NONE
						ラ音	988	29 D	NOT RELATED	GRADE 1	AE	NONE
						鼻咽頭炎	995	50 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	1044	29 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚有棘細胞癌	1044	29 D	NOT RELATED	GRADE 1	AE	NONE
						口内炎	1055	18 D	NOT RELATED	GRADE 1	AE	NONE
						浮腫	1128	29 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	1156	CONT.	L	GRADE 1	AE	NONE
						皮膚剥脱	1184	29 D	L	GRADE 1	AE	NONE
						腹部不快感	1211	58 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	1240	29 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚剥脱	1240	CONT.	NOT RELATED	GRADE 2	AE	NONE
						ウイルス性胃腸炎	1242	31 D	NOT RELATED	GRADE 2	AE	NONE
						悪性黒色腫	1256	41 D	L	GRADE 3	SAE	NONE
						扁平上皮癌	1256	CONT.	L	GRADE 3	SAE	NONE
						ウイルス性胃腸炎	1293	2 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	1319	13 D	L	GRADE 1	AE	NONE
						下痢	1380	CONT.	NOT RELATED	GRADE 1	AE	NONE
10 mg/kg	2512	WHITE	10 mg/kg	Female	6[redacted]	不眠症	1	57 D	D	GRADE 2	AE	NONE
						末梢性ニューロパチー	1	CONT.	NOT RELATED	GRADE 2	AE	NONE
						振戦	1	57 D	D	GRADE 1	AE	NONE
						頭痛	45	6 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	45	6 D	L	GRADE 1	AE	NONE
						口の錯感覚	45	6 D	NOT RELATED	GRADE 1	AE	NONE
						寝汗	81	5 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	81	5 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	81	12 D	NOT RELATED	GRADE 2	AE	NONE
						蜂巣炎	96	14 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	110	2 D	NOT RELATED	GRADE 2	SAE	NONE
						ウイルス性鼻炎	141	29 D	NOT RELATED	GRADE 1	AE	NONE
						紅斑性皮疹	166	31 D	NOT RELATED	GRADE 1	AE	NONE
						帯状疱疹	169	28 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						心房細動	215	59 D	NOT RELATED	GRADE 2	AE	NONE
						尿路感染	215	59 D	NOT RELATED	GRADE 1	AE	NONE
						関節腫脹	225	29 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	237	11 D	L	GRADE 3	SAE	INTERRUPTED
						血小板減少症	237	52 D	L	GRADE 3	AE	DELAYED
						嘔吐	246	15 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	253	8 D	L	GRADE 3	AE	NONE
						副鼻腔炎	305	12 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	335	10 D	L	GRADE 2	AE	NONE
						局所腫脹	366	7 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	366	7 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	396	5 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	396	5 D	NOT RELATED	GRADE 1	AE	NONE
						インフルエンザ	640	41 D	NOT RELATED	GRADE 2	AE	NONE
						局所腫脹	708	56 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	736	15 D	L	GRADE 2	AE	NONE
						挫傷	759	20 D	NOT RELATED	GRADE 1	AE	NONE
						頭痛	761	18 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	763	16 D	NOT RELATED	GRADE 1	AE	NONE
						ラ音	763	30 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	945	16 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	947	CONT.	NOT RELATED	GRADE 3	AE	NONE
						咳嗽	960	15 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	960	CONT.	L	GRADE 1	AE	NONE
						血小板数減少	1030	CONT.	NOT RELATED	GRADE 3	AE	NONE
						発熱	1033	10 D	NOT RELATED	GRADE 1	AE	NONE
						骨髄異形成症候群	1058	CONT.	L	GRADE 4	SAE	PERMANENTLY DISCONTINUED
						呼吸困難	1071	CONT.	NOT RELATED	GRADE 1	AE	NONE
						内出血発生の増加傾向	1071	CONT.	NOT RELATED	GRADE 2	AE	NONE
10 mg/kg	2513	WHITE	10 mg/kg	Male	6[redacted]	便秘	1	29 D	E,L	GRADE 2	AE	NONE
						疲労	1	113 D	E,L	GRADE 2	AE	NONE
						高血圧	1	CONT.	D	GRADE 3	AE	NONE
						筋痙縮	8	29 D	E,L,D	GRADE 2	AE	NONE
						口腔咽頭痛	8	16 D	NOT RELATED	GRADE 1	AE	NONE
						ざ瘡	23	7 D	D	GRADE 1	AE	NONE
						味覚消失	27	CONT.	E,L,D	GRADE 2	AE	NONE
						筋痙縮	36	8 D	E,L	GRADE 3	AE	INTERRUPTED
						低体温	50	1 D	NOT RELATED	GRADE 2	AE	NONE
						洞性徐脈	50	CONT.	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						体重減少	55	17 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	141	57 D	NOT RELATED	GRADE 2	AE	NONE
						静脈穿刺不良	211	16 D	NOT RELATED	GRADE 1	AE	NONE
						嚥下障害	235	48 D	NOT RELATED	GRADE 2	AE	DELAYED
						呼吸困難	235	4 D	NOT RELATED	GRADE 3	AE	DELAYED
						疲労	235	19 D	NOT RELATED	GRADE 3	AE	DELAYED
						帯状疱疹	235	19 D	NOT RELATED	GRADE 1	AE	NONE
						インフルエンザ	235	4 D	L	GRADE 3	SAE	DELAYED
						発熱	235	4 D	NOT RELATED	GRADE 1	AE	DELAYED
						大葉性肺炎	237	31 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	267	43 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	313	CONT.	NOT RELATED	GRADE 1	AE	NONE
						副鼻腔うっ血	435	15 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	491	CONT.	L	GRADE 1	AE	NONE
						脳血管発作	511	2 D	L	GRADE 3	SAE	DELAYED
						上気道感染	580	10 D	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	645	CONT.	NOT RELATED	GRADE 2	AE	NONE
						クロストリジウム・ディフィシレ大腸炎	673	5 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
10 mg/kg	2601	WHITE	10 mg/kg	Female	[redacted]	食欲減退	1	CONT.	L	GRADE 1	AE	NONE
						味覚異常	1	CONT.	D	GRADE 1	AE	NONE
						疲労	8	CONT.	L	GRADE 2	AE	NONE
						血小板減少症	8	44 D	L	GRADE 1	AE	NONE
						便秘	16	169 D	L	GRADE 1	AE	NONE
						下痢	16	129 D	D	GRADE 1	AE	NONE
						鼻出血	26	4 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	29	9 D	L	GRADE 1	AE	NONE
						悪寒	44	29 D	D	GRADE 1	AE	NONE
						発熱	44	29 D	D	GRADE 1	AE	NONE
						悪心	52	CONT.	D	GRADE 1	AE	NONE
						寝汗	52	21 D	D	GRADE 1	AE	NONE
						腹部膨満	57	80 D	D	GRADE 1	AE	NONE
						腹痛	57	80 D	D	GRADE 1	AE	NONE
						貧血	57	37 D	NOT RELATED	GRADE 1	AE	NONE
						低カルシウム血症	57	16 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	57	2 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	81	4 D	L	GRADE 1	AE	NONE
						注射部位内出血	82	7 D	NOT RELATED	GRADE 1	AE	NONE
						深部静脈血栓症	83	CONT.	L	GRADE 2	AE	NONE
						咳嗽	85	15 D	D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						労作性呼吸困難	85	CONT.	D	GRADE 1	AE	NONE
						好中球減少症	85	1 D	L	GRADE 2	AE	NONE
						国際標準比増加	86	2 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	86	211 D	L	GRADE 1	AE	NONE
						国際標準比増加	88	CONT.	NOT RELATED	GRADE 3	AE	NONE
						血小板減少症	98	1039 D	L	GRADE 1	AE	NONE
						腹痛	137	5 D	D	GRADE 2	AE	NONE
						腹部膨満	142	245 D	D	GRADE 1	AE	NONE
						下痢	170	413 D	D	GRADE 1	AE	NONE
						好中球減少症	309	15 D	L	GRADE 2	AE	NONE
						下痢	324	3 D	L	GRADE 2	AE	NONE
						好中球減少症	337	CONT.	L	GRADE 2	AE	NONE
						筋骨格痛	354	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腹部膨満	387	8 D	D	GRADE 2	AE	NONE
						疲労	388	7 D	D	GRADE 2	AE	NONE
						インフルエンザ	401	4 D	NOT RELATED	GRADE 1	AE	NONE
						白内障	471	1 D	D		AE	NONE
						インフルエンザ	573	45 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	583	5 D	L	GRADE 2	AE	NONE
						筋痙縮	615	CONT.	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	655	47 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	773	27 D	L	GRADE 1	AE	NONE
						肺炎	773	8 D	NOT RELATED	GRADE 1	SAE	NONE
						クロストリジウム・ディフィシレ感染	790	25 D	NOT RELATED	GRADE 3	AE	NONE
						下痢	815	CONT.	L	GRADE 1	AE	NONE
						鼻咽頭炎	837	61 D	NOT RELATED	GRADE 1	AE	NONE
						失神	858	1 D	NOT RELATED	GRADE 3	AE	NONE
						低マグネシウム血症	869	16 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	910	44 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	910	44 D	NOT RELATED	GRADE 1	AE	NONE
						変形性関節症	912	CONT.	NOT RELATED	GRADE 1	AE	NONE
						霧視	917	CONT.	NOT RELATED	GRADE 1	AE	NONE
						子宮平滑筋腫	944	10 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	955	4 D	L	GRADE 2	AE	NONE
						関節脱臼	1116	1 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	1136	64 D	NOT RELATED	GRADE 3	AE	NONE
						血小板減少症	1136	64 D	NOT RELATED	GRADE 2	AE	NONE
						肺炎	1142	10 D	L,D	GRADE 2	AE	DELAYED
						貧血	1144	13 D	NOT RELATED	GRADE 3	AE	DELAYED
						血小板減少症	1199	14 D	NOT RELATED	GRADE 3	AE	NONE
						貧血	1212	7 D	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
10 mg/kg	2702	WHITE	10 mg/kg	Female	[redacted]	悪寒	1	1 D	E,L,D	GRADE 1	AE	NONE
						呼吸困難	1	1 D	E,L,D	GRADE 1	AE	NONE
						潮紅	1	1 D	E,D	GRADE 1	AE	NONE
						悪心	2	1 D	E	GRADE 1	AE	NONE
						貧血	8	22 D	L	GRADE 2	AE	NONE
						浮動性めまい	9	1 D	E,L,D	GRADE 1	AE	NONE
						関節痛	18	3 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	18	CONT.	L	GRADE 1	AE	NONE
						悪心	26	2 D	E	GRADE 1	AE	NONE
						悪寒	38	1 D	E,L,D	GRADE 1	AE	NONE
						潮紅	57	1 D	E,D	GRADE 1	AE	NONE
						発疹	62	CONT.	E,L,D	GRADE 1	AE	NONE
						筋痙縮	96	10 D	L	GRADE 1	AE	NONE
						紅斑	98	9 D	E,D	GRADE 1	AE	NONE
						筋痙縮	120	1 D	L	GRADE 1	AE	NONE
						上気道感染	213	12 D	L,D	GRADE 2	AE	INTERRUPTED
						肺炎	224	21 D	L,D	GRADE 2	AE	DELAYED
						低カルシウム血症	245	8 D	NOT RELATED	GRADE 1	AE	NONE
						間質性肺疾患	245	8 D	E	GRADE 2	AE	PERMANENTLY DISCONTINUED
						肺炎	245	8 D	L,D	GRADE 3	SAE	DELAYED
						敗血症	245	8 D	L,D	GRADE 3	SAE	DELAYED
						不安	247	1 D	NOT RELATED	GRADE 1	AE	NONE
						低リン酸血症	247	4 D	NOT RELATED	GRADE 2	AE	NONE
						不眠症	247	6 D	NOT RELATED	GRADE 1	AE	NONE
10 mg/kg	2801	WHITE	10 mg/kg	Female	[redacted]	貧血	14	1 D	NOT RELATED	GRADE 2	AE	NONE
						消化不良	19	CONT.	E,L,D	GRADE 1	AE	NONE
						発熱	19	1 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	33	18 D	D	GRADE 2	AE	NONE
						末梢性感覚ニューロパチー	94	CONT.	NOT RELATED	GRADE 1	AE	NONE
						脊椎痛	146	12 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						アレルギー性そう痒症	147	3 D	NOT RELATED	GRADE 2	AE	NONE
						便秘	148	CONT.	NOT RELATED	GRADE 2	AE	NONE
						口腔感染	156	16 D	NOT RELATED	GRADE 2	AE	NONE
10 mg/kg	2804	WHITE	10 mg/kg	Female	[redacted]	貧血	14	CONT.	NOT RELATED	GRADE 3	AE	NONE
						血小板減少症	15	CONT.	L	GRADE 4	AE	NONE
						口の錯感覚	18	47 D	NOT RELATED	GRADE 1	AE	NONE
						発熱性好中球減少症	49	2 D	L	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						好中球減少症	50	4 D	L	GRADE 4	SAE	INTERRUPTED
						上気道感染	50	7 D	L	GRADE 3	AE	NONE
						好中球減少症	53	CONT.	L	GRADE 3	AE	NONE
						疲労	105	344 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	107	7 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	127	15 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	154	11 D	NOT RELATED	GRADE 2	AE	NONE
						高ビリルビン血症	196	CONT.	NOT RELATED	GRADE 2	AE	NONE
						気管支炎	325	11 D	NOT RELATED	GRADE 2	AE	NONE
						インフルエンザ	382	3 D	NOT RELATED	GRADE 2	AE	NONE
						失神	382	1 D	NOT RELATED	GRADE 1	AE	NONE
						毛髪障害	401	CONT.	NOT RELATED	GRADE 1	AE	NONE
						発声障害	402	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	403	CONT.	D	GRADE 2	AE	NONE
						疲労	403	CONT.	D	GRADE 2	AE	DECREASED
						頭痛	404	CONT.	D	GRADE 3	AE	NONE
						多汗症	418	CONT.	D	GRADE 1	AE	NONE
						膀胱炎	438	7 D	D	GRADE 2	AE	NONE
						内出血発生の増加傾向	448	CONT.	D	GRADE 1	AE	NONE
10 mg/kg	2902	WHITE	10 mg/kg	Male	5[redacted]	便秘	35	23 D	L	GRADE 1	AE	NONE
						無力症	50	122 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	50	CONT.	L	GRADE 1	AE	NONE
						便秘	57	9 D	L	GRADE 2	AE	NONE
						便秘	66	2 D	L	GRADE 2	SAE	NONE
						全身性炎症反応症候群	66	2 D	NOT RELATED	GRADE 2	AE	NONE
						腎仙痛	92	2 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	195	10 D	NOT RELATED	GRADE 1	AE	NONE
						頭痛	221	2 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	276	11 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	276	11 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	302	7 D	NOT RELATED	GRADE 1	AE	NONE
						下腹部痛	332	2 D	NOT RELATED	GRADE 1	AE	NONE
						上腹部痛	337	47 D	D	GRADE 1	AE	NONE
						便秘	396	4 D	NOT RELATED	GRADE 1	AE	NONE
						うつ病	457	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腎仙痛	457	2 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	561	15 D	NOT RELATED	GRADE 1	AE	NONE
						腎仙痛	599	3 D	NOT RELATED	GRADE 3	SAE	NONE
						限局性感染	613	2 D	NOT RELATED	GRADE 2	SAE	NONE
						咽頭炎	666	22 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						背部痛	695	CONT.	NOT RELATED	GRADE 2	AE	NONE
						無力症	730	CONT.	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	743	CONT.	NOT RELATED	GRADE 2	AE	NONE
						肩回旋筋腱板症候群	811	184 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	913	10 D	NOT RELATED	GRADE 2	AE	NONE
						鼻咽頭炎	918	22 D	NOT RELATED	GRADE 1	AE	NONE
						視力低下	995	CONT.	D	GRADE 1	AE	NONE
						味覚異常	1009	2 D	E,D	GRADE 1	AE	NONE
						味覚異常	1023	2 D	E,D	GRADE 1	AE	NONE
						インフルエンザ	1026	9 D	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	1051	CONT.	L	GRADE 3	AE	NONE
						肺障害	1056	8 D	D	GRADE 3	SAE	NONE
10 mg/kg	3302	WHITE	10 mg/kg	Male	4[redacted]	疲労	1	CONT.	L	GRADE 2	AE	NONE
						熱性感染症	1	2 D	D	GRADE 2	AE	NONE
						味覚異常	2	CONT.	L,D	GRADE 1	AE	NONE
						皮膚亀裂	2	CONT.	L,D	GRADE 1	AE	NONE
						腹部膨満	3	213 D	L,D	GRADE 1	AE	NONE
						筋肉痛	9	3 D	NOT RELATED	GRADE 3	AE	NONE
						口内炎	10	16 D	L,D	GRADE 1	AE	NONE
						寝汗	32	CONT.	E,L,D	GRADE 2	AE	NONE
						発疹	32	62 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	64	1 D	D	GRADE 1	AE	NONE
						胃腸炎	69	5 D	NOT RELATED	GRADE 1	AE	NONE
						筋肉痛	93	3 D	NOT RELATED	GRADE 2	AE	NONE
						筋肉痛	121	3 D	NOT RELATED	GRADE 2	AE	NONE
						胃腸炎	172	8 D	E,L,D	GRADE 2	AE	NONE
						口腔咽頭痛	180	5 D	E,L,D	GRADE 1	AE	NONE
						気管支炎	186	7 D	E,L,D	GRADE 2	AE	NONE
						靱帯捻挫	219	87 D	NOT RELATED	GRADE 2	AE	NONE
						鼻咽頭炎	262	17 D	E,L,D	GRADE 2	AE	NONE
						爪真菌症	336	CONT.	D	GRADE 1	AE	NONE
						鼻漏	336	CONT.	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	346	4 D	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	357	5 D	L,D	GRADE 1	AE	NONE
						下痢	358	3 D	E,L,D	GRADE 1	AE	NONE
						回転性めまい	367	CONT.	L,D	GRADE 1	AE	NONE
						口腔咽頭痛	373	8 D	L,D	GRADE 1	AE	NONE
						全身健康状態低下	396	CONT.	L,D	GRADE 2	AE	NONE
						末梢性感覚ニューロパチー	397	CONT.	L	GRADE 1	AE	NONE
						上気道うっ血	397	CONT.	L,D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						精神障害	424	CONT.	L,D	GRADE 1	AE	NONE
						口内炎	459	CONT.	L,D	GRADE 1	AE	NONE
						記憶障害	489	CONT.	L,D	GRADE 1	AE	NONE
						便秘	498	43 D	L	GRADE 1	AE	NONE
						排尿困難	513	CONT.	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	526	8 D	E,L,D	GRADE 1	AE	NONE
						下痢	541	5 D	L,D	GRADE 1	AE	NONE
						口腔咽頭痛	568	7 D	L,D	GRADE 1	AE	NONE
						鉄欠乏性貧血	592	CONT.	NOT RELATED	GRADE 1	AE	NONE
						胃腸炎	602	3 D	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	672	17 D	L,D	GRADE 1	AE	NONE
						体重減少	733	CONT.	NOT RELATED	GRADE 1	AE	NONE
						不眠症	738	CONT.	NOT RELATED	GRADE 2	AE	NONE
						食欲減退	742	CONT.	NOT RELATED	GRADE 2	AE	NONE
						悪心	745	CONT.	NOT RELATED	GRADE 2	AE	NONE
						頭痛	756	CONT.	NOT RELATED	GRADE 1	AE	NONE
						プロトロンビン時間延長	763	31 D	NOT RELATED	GRADE 1	AE	NONE
						急性腎不全	766	CONT.	NOT RELATED	GRADE 3	SAE	NONE
10 mg/kg	3307	WHITE	10 mg/kg	Male	6[redacted]	発声障害	1	895 D	D	GRADE 1	AE	NONE
						労作性呼吸困難	10	65 D	L,D	GRADE 1	AE	NONE
						疲労	10	CONT.	L,D	GRADE 2	AE	NONE
						回転性めまい	10	65 D	L,D	GRADE 1	AE	NONE
						味覚異常	14	472 D	L,D	GRADE 1	AE	NONE
						リンパ球減少症	115	15 D	E,L	GRADE 4	AE	NONE
						脱毛症	134	CONT.	L,D	GRADE 1	AE	NONE
						悪心	150	168 D	L,D	GRADE 1	AE	NONE
						労作性呼吸困難	165	91 D	L,D	GRADE 1	AE	NONE
						乳房圧痛	171	29 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ節症	199	28 D	E,L,D	GRADE 1	AE	NONE
						鼻咽頭炎	205	51 D	E,L,D	GRADE 1	AE	NONE
						下痢	255	641 D	D	GRADE 1	AE	NONE
						潮紅	255	641 D	D	GRADE 2	AE	NONE
						睡眠障害	255	641 D	D	GRADE 2	AE	NONE
						鼻咽頭炎	280	20 D	L,D	GRADE 1	AE	NONE
						悪心	287	639 D	L,D	GRADE 2	AE	NONE
						鼻炎	387	15 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	395	29 D	D	GRADE 1	AE	NONE
						膣炎	395	29 D	L,D	GRADE 1	AE	NONE
						鼻咽頭炎	471	29 D	E,L,D	GRADE 1	AE	NONE
						味覚異常	485	441 D	L,D	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						鼻咽頭炎	492	8 D	L,D	GRADE 1	AE	NONE
						寝汗	493	160 D	D	GRADE 1	AE	NONE
						リンパ節症	509	3 D	E,L,D	GRADE 1	AE	NONE
						帯状疱疹	595	8 D	E,L,D	GRADE 1	AE	NONE
						帯状疱疹	602	10 D	E,L,D	GRADE 3	SAE	INTERRUPTED
						発疹	611	36 D	E,L,D	GRADE 2	AE	NONE
						皮膚色素過剰	646	57 D	NOT RELATED	GRADE 1	AE	NONE
						膵炎	702	169 D	L,D	GRADE 1	AE	NONE
						心音異常	730	141 D	NOT RELATED	GRADE 1	AE	NONE
						寝汗	745	92 D	E,L,D	GRADE 1	AE	NONE
						インフルエンザ様疾患	754	15 D	NOT RELATED	GRADE 1	AE	NONE
						放射線嚥下障害	926	31 D	NOT RELATED	GRADE 1	AE	NONE
10 mg/kg	3308	WHITE	10 mg/kg	Female	6[redacted]	口内乾燥	35	62 D	E,L,D	GRADE 1	AE	NONE
						潮紅	35	212 D	L,D	GRADE 1	AE	NONE
						筋痙縮	35	365 D	L,D	GRADE 1	AE	NONE
						抑うつ気分	66	76 D	D	GRADE 1	AE	NONE
						H1N1 インフルエンザ	66	10 D	NOT RELATED	GRADE 4	SAE	INTERRUPTED
						外陰部腟カンジダ症	98	2 D	E,L,D	GRADE 2	AE	NONE
						上気道閉塞	100	49 D	L,D	GRADE 2	AE	NONE
						粘液便	125	15 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	125	275 D	D	GRADE 1	AE	NONE
						下痢	141	4 D	L	GRADE 1	AE	NONE
						気管支炎	185	16 D	E,L,D	GRADE 2	AE	NONE
						気管支炎	213	19 D	E,L,D	GRADE 2	AE	NONE
						肺うっ血	240	17 D	L,D	GRADE 2	AE	NONE
						肺うっ血	271	13 D	L,D	GRADE 1	AE	NONE
						変色便	278	61 D	L,D	GRADE 1	AE	NONE
						鼻炎	294	3 D	E,L,D	GRADE 1	AE	NONE
						鉄欠乏性貧血	309	CONT.	NOT RELATED	GRADE 1	AE	NONE
						口腔ヘルペス	309	10 D	NOT RELATED	GRADE 1	AE	NONE
						肺うっ血	309	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼓腸	317	83 D	NOT RELATED	GRADE 1	AE	NONE
						労作性呼吸困難	339	CONT.	NOT RELATED	GRADE 1	AE	NONE
						感覚鈍麻	339	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	345	4 D	NOT RELATED	GRADE 1	AE	NONE
						回転性めまい	358	15 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	379	14 D	D	GRADE 1	AE	NONE
						四肢痛	400	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼻咽頭炎	414	17 D	E,L,D	GRADE 2	AE	NONE
						歯の障害	426	1 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
10 mg/kg	4003	WHITE	10 mg/kg	Male	5[redacted]	頭痛	1	8 D	NOT RELATED	GRADE 1	AE	NONE
						眼充血	1	8 D	NOT RELATED	GRADE 1	AE	NONE
						眼そう痒症	4	5 D	NOT RELATED	GRADE 1	AE	NONE
						浮腫	7	2 D	NOT RELATED	GRADE 1	AE	NONE
						全身性皮疹	12	3 D	L	GRADE 1	AE	INTERRUPTED
						発疹	13	18 D	L	GRADE 3	SAE	DELAYED
						筋痙縮	56	2 D	NOT RELATED	GRADE 1	AE	NONE
						頭痛	112	3 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	114	CONT.	L	GRADE 1	AE	NONE
						斑状丘疹状皮疹	127	15 D	L	GRADE 1	AE	NONE
						上気道感染	190	8 D	D	GRADE 1	AE	NONE
						易刺激性	225	7 D	D	GRADE 1	AE	NONE
						上気道感染	232	8 D	D	GRADE 2	AE	NONE
						喉頭炎	262	7 D	D	GRADE 1	AE	NONE
						鼻咽頭炎	262	7 D	NOT RELATED	GRADE 1	AE	NONE
10 mg/kg	4005	WHITE	10 mg/kg	Male	5[redacted]	胸部不快感	1	7 D	D	GRADE 1	AE	NONE
						ざ瘡様皮膚炎	1	CONT.	L	GRADE 1	AE	NONE
						便秘	7	CONT.	E,L	GRADE 1	AE	NONE
						疲労	7	CONT.	E,L,D	GRADE 1	AE	NONE
						末梢性ニューロパチー	7	CONT.	L,D	GRADE 1	AE	NONE
						そう痒症	7	CONT.	L	GRADE 1	AE	NONE
						攻撃性	14	3 D	NOT RELATED	GRADE 1	AE	NONE
						白内障	14	498 D	D	GRADE 1	AE	NONE
						白内障	14	407 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	14	CONT.	E,L,D	GRADE 1	AE	NONE
						口の錯感覚	14	CONT.	E,D	GRADE 1	AE	NONE
						精神運動亢進	14	3 D	D	GRADE 1	AE	NONE
						皮膚乾燥	21	CONT.	L,D	GRADE 1	AE	NONE
						不眠症	21	CONT.	D	GRADE 1	AE	NONE
						斑状丘疹状皮疹	21	8 D	NOT RELATED	GRADE 1	AE	NONE
						左室機能不全	22	CONT.	E,L	GRADE 1	AE	NONE
						下痢	28	2 D	E,L,D	GRADE 1	AE	NONE
						発声障害	35	3 D	D	GRADE 1	AE	NONE
						偶発的過量投与	41	2 D	L	GRADE 1	AE	NONE
						筋痙縮	41	2 D	L	GRADE 1	AE	NONE
						消化不良	42	29 D	NOT RELATED	GRADE 1	AE	NONE
						羞明	42	15 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	56	9 D	NOT RELATED	GRADE 1	AE	NONE
						心電図 QT 延長	57	CONT.	E,L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						呼吸困難	105	29 D	E,L,D	GRADE 1	AE	NONE
						筋痙縮	105	29 D	L	GRADE 1	AE	NONE
						浮腫	105	57 D	L,D	GRADE 1	AE	NONE
						発疹	105	15 D	NOT RELATED	GRADE 1	AE	DELAYED
						喘鳴	105	29 D	NOT RELATED	GRADE 1	AE	DELAYED
						薬物過敏症	119	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	131	3 D	L	GRADE 1	AE	NONE
						背部痛	132	2 D	NOT RELATED	GRADE 1	AE	NONE
						羞明	133	8 D	E,L,D	GRADE 1	AE	NONE
						霧視	133	15 D	E,L,D	GRADE 1	AE	NONE
						下痢	160	2 D	L	GRADE 2	AE	NONE
						末梢性ニューロパチー	161	64 D	L	GRADE 1	AE	NONE
						斑状丘疹状皮疹	161	CONT.	L,D	GRADE 1	AE	NONE
						蜂巣炎	175	22 D	D	GRADE 2	AE	DELAYED
						表在性血栓性静脈炎	177	6 D	D	GRADE 2	AE	DELAYED
						蜂巣炎	182	42 D	D	GRADE 2	AE	NONE
						上気道感染	182	11 D	D	GRADE 1	AE	NONE
						背部痛	196	8 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	196	8 D	L	GRADE 1	AE	NONE
						錯感覚	196	CONT.	L	GRADE 1	AE	NONE
						直腸しぶり	210	14 D	L,D	GRADE 1	AE	NONE
						末梢性ニューロパチー	224	14 D	L	GRADE 2	AE	NONE
						振戦	224	CONT.	L,D	GRADE 1	AE	NONE
						局所腫脹	237	8 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	237	15 D	E,L,D	GRADE 1	AE	NONE
						末梢性ニューロパチー	251	11 D	E,L	GRADE 2	AE	NONE
						霧視	251	CONT.	L,D	GRADE 1	AE	NONE
						静脈炎	265	8 D	NOT RELATED	GRADE 2	AE	DELAYED
						蜂巣炎	272	25 D	NOT RELATED	GRADE 3	SAE	DELAYED
						表在性静脈炎	272	25 D	NOT RELATED	GRADE 3	SAE	DELAYED
						上気道感染	313	58 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	350	9 D	D	GRADE 3	SAE	INTERRUPTED
						肺炎	350	9 D	D	GRADE 3	SAE	INTERRUPTED
						上腹部痛	412	2 D	E,L,D	GRADE 1	AE	DELAYED
						不安	455	2 D	NOT RELATED	GRADE 2	AE	NONE
						非心臓性胸痛	455	2 D	NOT RELATED	GRADE 2	AE	NONE
						口腔カンジダ症	468	15 D	D	GRADE 1	AE	NONE
						下痢	513	26 D	L,D	GRADE 2	AE	NONE
						脂肪腫	513	CONT.	NOT RELATED	GRADE 1	AE	NONE
						丘疹	513	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	538	CONT.	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						浮動性めまい	594	3 D	NOT RELATED	GRADE 1	AE	NONE
						静脈炎	594	13 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	622	CONT.	NOT RELATED	GRADE 1	AE	NONE
						胸部不快感	622	2 D	NOT RELATED	GRADE 1	AE	NONE
						うつ病	622	8 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	622	CONT.	NOT RELATED	GRADE 1	AE	NONE
						味覚減退	622	29 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	622	CONT.	L	GRADE 1	AE	NONE
						血中クレアチニン増加	636	CONT.	NOT RELATED	GRADE 2	AE	NONE
						血中マグネシウム減少	636	CONT.	NOT RELATED	GRADE 1	AE	NONE
						労作性呼吸困難	636	CONT.	NOT RELATED	GRADE 1	AE	NONE
						低血圧	636	23 D	NOT RELATED	GRADE 1	AE	NONE
						倦怠感	636	8 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	636	3 D	L	GRADE 1	AE	NONE
						筋骨格痛	636	3 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						発疹	649	4 D	D	GRADE 1	AE	NONE
						熱感	650	11 D	L	GRADE 1	AE	NONE
						皮膚真菌感染	664	5 D	D	GRADE 1	AE	NONE
						季節性アレルギー	664	6 D	NOT RELATED	GRADE 1	AE	NONE
						霧視	664	8 D	D	GRADE 1	AE	NONE
						体重減少	664	30 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	678	1 D	NOT RELATED	GRADE 2	AE	NONE
						歯牙破折	678	31 D	NOT RELATED	GRADE 1	AE	NONE
						食欲減退	679	15 D	L	GRADE 1	AE	NONE
						倦怠感	679	15 D	NOT RELATED	GRADE 1	AE	NONE
						腎不全	679	CONT.	L	GRADE 2	AE	DELAYED
						胃食道逆流性疾患	707	CONT.	D	GRADE 1	AE	NONE
						筋骨格不快感	707	CONT.	NOT RELATED	GRADE 1	AE	NONE
						知覚過敏	748	CONT.	L	GRADE 1	AE	NONE
						末梢性浮腫	748	CONT.	D	GRADE 1	AE	NONE
						歯牙破折	762	CONT.	D	GRADE 1	AE	NONE
						脱毛症	776	CONT.	L,D	GRADE 1	AE	NONE
						下痢	776	43 D	L,D	GRADE 2	AE	NONE
						感覚鈍麻	818	CONT.	L	GRADE 1	AE	NONE
						筋肉痛	818	15 D	L	GRADE 1	AE	NONE
						四肢痛	818	15 D	L	GRADE 1	AE	NONE
						下痢	846	3 D	L	GRADE 1	AE	NONE
						浮動性めまい	846	3 D	NOT RELATED	GRADE 1	AE	NONE
						勃起不全	846	CONT.	E,L	GRADE 1	AE	NONE
						静脈炎	874	6 D	L,D	GRADE 2	AE	NONE
						心筋症	876	CONT.	D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						鼻閉	893	38 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	893	38 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	893	10 D	NOT RELATED	GRADE 1	AE	NONE
						右脚ブロック	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						駆出率減少	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						心電図 QRS 群延長	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						心電図 QT 延長	902	CONT.	NOT RELATED	GRADE 2	AE	DELAYED
						左室肥大	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						QRS 軸異常	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						心室性期外収縮	902	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						下痢	958	11 D	L	GRADE 2	AE	NONE
						静脈炎	958	CONT.	D	GRADE 2	AE	NONE
						鼻炎	958	CONT.	L	GRADE 1	AE	NONE
						歩行障害	986	CONT.	NOT RELATED	GRADE 1	AE	NONE
						歯肉炎	986	8 D	D	GRADE 2	AE	NONE
						倦怠感	986	CONT.	E,L,D	GRADE 1	AE	NONE
						無力症	1014	5 D	NOT RELATED	GRADE 3	AE	DELAYED
						無気肺	1014	CONT.	NOT RELATED	GRADE 1	AE	DELAYED
						呼吸困難	1014	4 D	NOT RELATED	GRADE 3	SAE	DELAYED
						低血圧	1014	5 D	L	GRADE 2	AE	NONE
						歯肉炎	1028	15 D	D	GRADE 2	AE	NONE
						感覚鈍麻	1042	CONT.	L,D	GRADE 1	AE	NONE
						末梢性浮腫	1042	CONT.	L,D	GRADE 2	AE	NONE
10 mg/kg	4009	WHITE	10 mg/kg	Male	4[redacted]	疲労	3	3 D	E	GRADE 2	AE	NONE
						悪寒	5	1 D	NOT RELATED	GRADE 1	AE	NONE
						耳感染	5	4 D	NOT RELATED	GRADE 2	AE	NONE
						口腔ヘルペス	7	16 D	D	GRADE 2	AE	NONE
						紅斑	8	1 D	D	GRADE 1	AE	NONE
						耳感染	13	10 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						疲労	29	8 D	E,L,D	GRADE 1	AE	NONE
						筋痙縮	29	8 D	E,L	GRADE 1	AE	NONE
						動悸	29	8 D	D	GRADE 1	AE	NONE
						末梢性浮腫	35	2 D	L,D	GRADE 1	AE	NONE
						呼吸困難	85	48 D	NOT RELATED	GRADE 1	AE	NONE
						感覚鈍麻	99	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋肉痛	99	16 D	NOT RELATED	GRADE 1	AE	NONE
						攻撃性	111	32 D	D	GRADE 2	AE	NONE
						筋肉痛	114	CONT.	L,D	GRADE 1	AE	NONE
						精神運動亢進	114	CONT.	D	GRADE 2	AE	NONE
						不眠症	142	2 D	D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						筋骨格痛	142	5 D	NOT RELATED	GRADE 1	AE	NONE
						サンバーン	142	5 D	NOT RELATED	GRADE 1	AE	NONE
						肉離れ	309	CONT.	NOT RELATED	GRADE 1	AE	NONE
						骨格損傷	309	CONT.	NOT RELATED	GRADE 1	AE	NONE
						耳感染	323	16 D	NOT RELATED	GRADE 2	AE	NONE
						背部痛	337	5 D	NOT RELATED	GRADE 3	SAE	NONE
						筋骨格不快感	364	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	1521	BLACK OF AFRICAN HERITAGE	20 mg/kg	Male	4[redacted]	高血糖	1	15 D	D	GRADE 2	AE	NONE
						好中球数増加	1	8 D	NOT RELATED		AE	NONE
						白血球数増加	1	8 D	NOT RELATED		AE	NONE
						血中重炭酸塩減少	15	8 D	NOT RELATED	GRADE 2	AE	NONE
						低アルブミン血症	15	8 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	22	22 D	D	GRADE 2	AE	NONE
						口腔咽頭痛	35	2 D	NOT RELATED	GRADE 1	AE	NONE
						ウイルス性上気道感染	35	2 D	NOT RELATED	GRADE 1	AE	NONE
						喀血	43	3 D	NOT RELATED	GRADE 3	AE	NONE
						低アルブミン血症	43	15 D	NOT RELATED	GRADE 1	AE	NONE
						メレナ	43	11 D	NOT RELATED	GRADE 3	AE	NONE
						悪心	43	1 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	43	1 D	NOT RELATED	GRADE 1	AE	NONE
						食道静脈瘤	50	2 D	D	GRADE 1	SAE	INTERRUPTED
						大腸ポリープ	51	CONT.	NOT RELATED	GRADE 2	AE	NONE
						口腔咽頭痛	53	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中重炭酸塩減少	57	15 D	D	GRADE 2	AE	NONE
						高血糖	57	15 D	D	GRADE 2	AE	NONE
						四肢痛	57	CONT.	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	71	15 D	E,L	GRADE 1	AE	NONE
						上気道感染	72	7 D	NOT RELATED	GRADE 1	AE	NONE
						眼痛	78	1 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	85	22 D	D	GRADE 2	AE	NONE
						低アルブミン血症	85	15 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	99	10 D	NOT RELATED	GRADE 1	AE	NONE
						神経痛	99	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼻漏	99	10 D	NOT RELATED	GRADE 1	AE	NONE
						気分動揺	113	15 D	D	GRADE 3	AE	NONE
						好中球数増加	113	29 D	L		AE	NONE
						白血球数増加	113	15 D	L		AE	NONE
						低アルブミン血症	127	15 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	141	CONT.	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						低アルブミン血症	155	29 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	1522	WHITE	20 mg/kg	Female	5[redacted]	貧血	1	120 D	L	GRADE 2	AE	NONE
						リンパ球減少症	1	8 D	E	GRADE 3	AE	NONE
						高血糖	8	8 D	D	GRADE 2	AE	NONE
						リンパ球減少症	8	8 D	E,L	GRADE 2	AE	NONE
						アラニンアミノトランスフェラーゼ増加	15	8 D	L	GRADE 1	AE	NONE
						リンパ球減少症	15	22 D	E,L	GRADE 3	AE	NONE
						擦過傷	18	12 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	22	CONT.	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	22	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	29	2 D	NOT RELATED	GRADE 3	AE	NONE
						上気道感染	29	10 D	D	GRADE 1	AE	DELAYED
						血中重炭酸塩減少	36	15 D	NOT RELATED	GRADE 2	AE	NONE
						呼吸困難	40	1 D	NOT RELATED	GRADE 3	AE	NONE
						上気道感染	40	16 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						呼吸困難	41	15 D	NOT RELATED	GRADE 2	AE	NONE
						血中重炭酸塩減少	50	8 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	50	43 D	D	GRADE 2	AE	NONE
						白血球減少症	50	8 D	E,L	GRADE 3	AE	NONE
						リンパ球減少症	50	218 D	E,L	GRADE 3	AE	NONE
						好中球減少症	50	8 D	E,L	GRADE 2	AE	NONE
						多汗症	54	4 D	NOT RELATED	GRADE 1	AE	NONE
						血中重炭酸塩減少	57	22 D	NOT RELATED	GRADE 2	AE	NONE
						低アルブミン血症	57	8 D	NOT RELATED	GRADE 1	AE	NONE
						低カルシウム血症	57	8 D	NOT RELATED	GRADE 1	AE	NONE
						低血圧	57	1 D	E	GRADE 1	AE	NONE
						総蛋白減少	57	8 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	64	15 D	E,L	GRADE 2	AE	NONE
						血中重炭酸塩減少	78	43 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	78	15 D	E,L	GRADE 3	AE	NONE
						好中球減少症	78	15 D	L	GRADE 2	AE	NONE
						血小板減少症	78	15 D	E,L	GRADE 1	AE	NONE
						血中乳酸脱水素酵素増加	92	15 D	NOT RELATED		AE	NONE
						白血球減少症	92	15 D	L	GRADE 1	AE	NONE
						高血糖	106	28 D	D	GRADE 2	AE	NONE
						白血球減少症	106	43 D	L	GRADE 2	AE	NONE
						好中球減少症	106	15 D	L	GRADE 1	AE	NONE
						血小板減少症	106	106 D	L	GRADE 1	AE	NONE
						ウイルス性上気道感染	112	9 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						嘔吐	113	1 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	115	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中重炭酸塩減少	120	14 D	NOT RELATED	GRADE 3	AE	NONE
						副鼻腔うっ血	123	61 D	NOT RELATED	GRADE 1	AE	NONE
						血中重炭酸塩減少	133	16 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	139	1 D	L,D	GRADE 1	AE	NONE
						発熱	145	3 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	146	38 D	NOT RELATED	GRADE 2	AE	NONE
						アラニンアミノトランスフェラーゼ増加	148	15 D	L	GRADE 2	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	148	15 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	148	15 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	148	50 D	D	GRADE 2	AE	NONE
						白血球減少症	148	15 D	L	GRADE 3	AE	NONE
						好中球減少症	148	15 D	L	GRADE 1	AE	NONE
						皮膚病変	151	48 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	162	36 D	L	GRADE 2	AE	NONE
						貧血	172	5 D	NOT RELATED	GRADE 3	AE	NONE
						血中クレアチニン増加	176	8 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						血中重炭酸塩減少	183	43 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	197	15 D	L	GRADE 2	AE	NONE
						高血糖	197	15 D	NOT RELATED	GRADE 3	AE	NONE
						白血球減少症	197	15 D	L	GRADE 1	AE	NONE
						血中乳酸脱水素酵素増加	211	15 D	NOT RELATED		AE	NONE
						低ナトリウム血症	211	15 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	211	29 D	L	GRADE 2	AE	NONE
						上気道感染	217	8 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	225	43 D	D	GRADE 2	AE	NONE
						血小板減少症	225	29 D	L	GRADE 1	AE	NONE
						糸球体濾過率減少	239	36 D	NOT RELATED	GRADE 2	AE	DELAYED, INTERRUPTED
						呼吸困難	251	2 D	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	253	50 D	L	GRADE 1	AE	NONE
						貧血	253	15 D	L	GRADE 2	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	253	50 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	253	169 D	NOT RELATED	GRADE 2	AE	NONE
						血中クレアチニン増加	253	8 D	NOT RELATED	GRADE 3	AE	INTERRUPTED
						白血球減少症	253	15 D	L	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						血小板減少症	253	15 D	L	GRADE 2	AE	NONE
						嘔吐	253	1 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	254	2 D	NOT RELATED	GRADE 2	AE	NONE
						口腔カンジダ症	260	3 D	D	GRADE 2	AE	NONE
						低リン酸血症	262	6 D	D	GRADE 2	AE	NONE
						低アルブミン血症	267	22 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	267	CONT.	L	GRADE 2	AE	NONE
						好中球減少症	267	22 D	L	GRADE 1	AE	NONE
						血小板減少症	267	22 D	L	GRADE 3	AE	NONE
						発熱	268	5 D	NOT RELATED	GRADE 1	SAE	INTERRUPTED
						血中クレアチニン増加	287	99 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	288	71 D	L	GRADE 2	AE	NONE
						高血糖	288	15 D	D	GRADE 2	AE	NONE
						リンパ球減少症	288	57 D	L	GRADE 2	AE	NONE
						血小板減少症	288	15 D	L	GRADE 1	AE	NONE
						湿性咳嗽	298	5 D	NOT RELATED	GRADE 1	AE	NONE
						鼻漏	298	5 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	302	29 D	L	GRADE 1	AE	NONE
						上気道感染	308	9 D	NOT RELATED	GRADE 2	AE	NONE
						骨痛	329	29 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	330	29 D	D	GRADE 2	AE	NONE
						白血球増加症	330	15 D	L		AE	NONE
						鼻閉	332	6 D	NOT RELATED	GRADE 1	AE	NONE
						湿性咳嗽	332	6 D	NOT RELATED	GRADE 1	AE	NONE
						鼻漏	332	6 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	344	96 D	E,L	GRADE 3	AE	NONE
						筋痙縮	344	43 D	D	GRADE 1	AE	NONE
						疼痛	344	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	352	4 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	361	30 D	E	GRADE 1	AE	NONE
						副鼻腔炎	361	30 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	399	3 D	NOT RELATED	GRADE 2	AE	NONE
						筋痙縮	428	15 D	L,D	GRADE 1	AE	NONE
						リンパ球減少症	440	59 D	L	GRADE 2	AE	NONE
						節足動物咬傷アレルギー	442	29 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	464	33 D	L,D	GRADE 1	AE	NONE
						血中クレアチニン増加	470	85 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	470	15 D	D	GRADE 2	AE	NONE
						好中球減少症	470	15 D	L	GRADE 2	AE	NONE
						末梢性浮腫	470	29 D	D	GRADE 1	AE	NONE
						血小板減少症	470	15 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						アラニンアミノトランスフェラーゼ増加	484	29 D	L	GRADE 1	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	484	15 D	L	GRADE 1	AE	NONE
						高血糖	484	15 D	D	GRADE 1	AE	NONE
						血中重炭酸塩減少	498	42 D	NOT RELATED	GRADE 2	AE	NONE
						血中乳酸脱水素酵素増加	498	43 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	498	15 D	D	GRADE 2	AE	NONE
						リンパ球減少症	498	29 D	NOT RELATED	GRADE 2	AE	NONE
						悪心	498	CONT.	E	GRADE 1	AE	NONE
						血中尿素増加	512	17 D	NOT RELATED	GRADE 1	AE	NONE
						発疹	512	15 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	526	29 D	L	GRADE 1	AE	NONE
						リンパ球減少症	526	29 D	L	GRADE 2	AE	NONE
						好中球減少症	526	29 D	L	GRADE 1	AE	NONE
						歯牙破折	526	106 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	534	1 D	E	GRADE 1	AE	NONE
						上気道感染	534	CONT.	NOT RELATED	GRADE 2	AE	NONE
						脊柱損傷	554	2 D	NOT RELATED	GRADE 2	AE	NONE
						ほてり	582	CONT.	NOT RELATED	GRADE 1	AE	NONE
						歯牙破折	632	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	666	15 D	NOT RELATED	GRADE 2	AE	NONE
						肺塞栓症	667	28 D	L	GRADE 3	AE	NONE
						全身性炎症反応症候群	668	27 D	NOT RELATED	GRADE 3	AE	NONE
						急性呼吸不全	676	16 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						脱水	678	17 D	NOT RELATED	GRADE 1	AE	NONE
						レジオネラ菌性肺炎	678	17 D	NOT RELATED	GRADE 3	AE	NONE
						活性化部分トロンボプラスチン時間延長	693	16 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	694	CONT.	NOT RELATED	GRADE 2	AE	NONE
						血中ブドウ糖減少	694	28 D	NOT RELATED	GRADE 2	AE	NONE
						国際標準比増加	694	14 D	NOT RELATED	GRADE 3	AE	NONE
						膣出血	707	17 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	708	15 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	722	112 D	NOT RELATED	GRADE 2	AE	NONE
						プロトロンビン時間延長	722	42 D	NOT RELATED	GRADE 1	AE	NONE
						潮紅	723	1 D	D	GRADE 1	AE	NONE
						上気道感染	745	6 D	NOT RELATED	GRADE 1	AE	NONE
						血中尿素増加	749	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	750	CONT.	L,D	GRADE 1	AE	NONE
						皮膚病変	764	CONT.	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	788	30 D	NOT RELATED	GRADE 1	AE	NONE
						プロトロンビン時間延長	792	43 D	NOT RELATED	GRADE 1	AE	NONE
						膿疱性皮疹	806	29 D	NOT RELATED	GRADE 2	AE	NONE
						末梢性浮腫	820	15 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	834	29 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	838	9 D	E	GRADE 3	SAE	NONE
						呼吸困難	848	15 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	862	42 D	NOT RELATED	GRADE 2	AE	NONE
						プロトロンビン時間延長	862	CONT.	NOT RELATED	GRADE 1	AE	NONE
						肺炎	890	14 D	NOT RELATED	GRADE 1	AE	NONE
						国際標準比増加	904	CONT.	NOT RELATED	GRADE 1	AE	NONE
						背部痛	911	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	1526	WHITE	20 mg/kg	Female	8[redacted]	高血糖	1	CONT.	NOT RELATED	GRADE 1	AE	NONE
						肺炎	2	7 D	NOT RELATED	GRADE 2	SAE	NONE
20 mg/kg	2103	BLACK OF AFRICAN HERITAGE	20 mg/kg	Female	4[redacted]	硬膜外腔炎症	11	12 D	NOT RELATED	GRADE 3	AE	NONE
						放射線胃腸炎	21	4 D	NOT RELATED	GRADE 2	SAE	NONE
						体重減少	22	134 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	23	21 D	NOT RELATED	GRADE 1	AE	NONE
						放射線胃腸炎	25	12 D	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	29	7 D	NOT RELATED	GRADE 3	AE	NONE
						貧血	50	36 D	L	GRADE 2	AE	NONE
						好中球減少症	57	7 D	L	GRADE 3	AE	NONE
						鼻漏	71	15 D	NOT RELATED	GRADE 1	AE	NONE
						鼻漏	226	29 D	NOT RELATED	GRADE 1	AE	NONE
						不安	254	98 D	D	GRADE 2	AE	NONE
						不眠症	254	98 D	D	GRADE 2	AE	NONE
						末梢性感覚ニューロパチー	337	CONT.	L	GRADE 1	AE	NONE
						骨粗鬆症	347	74 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	393	29 D	NOT RELATED	GRADE 1	AE	NONE
						骨粗鬆症	421	CONT.	NOT RELATED	GRADE 2	AE	NONE
						歯肉炎	449	15 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	460	18 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	520	34 D	NOT RELATED	GRADE 2	AE	NONE
						骨痛	520	CONT.	NOT RELATED	GRADE 2	AE	NONE
						上肢骨折	536	CONT.	NOT RELATED	GRADE 3	AE	NONE
						無力症	554	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2106	WHITE	20 mg/kg	Male	4[redacted]	筋痙縮	2	28 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						鼻咽頭炎	9	7 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	15	22 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	23	285 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	24	5 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	36	15 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	41	2 D	L	GRADE 2	AE	NONE
						骨痛	51	421 D	NOT RELATED	GRADE 1	AE	NONE
						ビタミンD欠乏	57	75 D	NOT RELATED	GRADE 1	AE	NONE
						喉頭炎	94	6 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	101	8 D	NOT RELATED	GRADE 2	AE	NONE
						口内炎	101	8 D	NOT RELATED	GRADE 1	AE	NONE
						咬傷感染	121	7 D	NOT RELATED	GRADE 2	AE	NONE
						高カルシウム尿症	129	253 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	157	307 D	L	GRADE 1	AE	NONE
						気管支炎	191	5 D	NOT RELATED	GRADE 2	AE	NONE
						インフルエンザ	299	5 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	325	43 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	325	2 D	NOT RELATED	GRADE 2	AE	NONE
						口腔咽頭痛	326	28 D	NOT RELATED	GRADE 2	AE	NONE
						高カルシウム血症	367	15 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	463	21 D	NOT RELATED	GRADE 2	AE	NONE
						骨痛	472	12 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	484	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	484	CONT.	NOT RELATED	GRADE 1	AE	NONE
						肺感染	507	8 D	NOT RELATED	GRADE 3	SAE	NONE
						好中球減少症	507	8 D	NOT RELATED	GRADE 4	AE	NONE
20 mg/kg	2107	WHITE	20 mg/kg	Male	6[redacted]	筋痙縮	2	22 D	L	GRADE 2	AE	NONE
						酒さ	2	29 D	D	GRADE 1	AE	NONE
						発熱	5	2 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	9	21 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	9	7 D	NOT RELATED	GRADE 2	AE	NONE
						食欲減退	16	35 D	NOT RELATED	GRADE 2	AE	NONE
						体重減少	16	14 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	30	21 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	30	CONT.	NOT RELATED	GRADE 2	AE	NONE
						振戦	30	2 D	NOT RELATED	GRADE 1	AE	NONE
						体重減少	30	85 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	51	7 D	L	GRADE 2	AE	NONE
						食欲減退	51	8 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	58	14 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						痛風	71	16 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	72	14 D	L	GRADE 2	AE	NONE
						無力症	86	43 D	L	GRADE 1	AE	NONE
						寝汗	157	217 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	166	19 D	L	GRADE 1	AE	NONE
						腹痛	197	2 D	NOT RELATED	GRADE 2	AE	NONE
						胆嚢炎	198	4 D	NOT RELATED	GRADE 3	SAE	DELAYED
						下痢	200	2 D	NOT RELATED	GRADE 1	AE	NONE
						良性前立腺肥大症	202	17 D	NOT RELATED	GRADE 2	AE	NONE
						良性前立腺肥大症	219	7 D	NOT RELATED	GRADE 3	SAE	DELAYED
						膀胱移行上皮癌	222	141 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						無力症	283	28 D	L	GRADE 1	AE	NONE
						肺感染	304	7 D	NOT RELATED	GRADE 2	AE	NONE
20 mg/kg	2108	WHITE	20 mg/kg	Male	8[redacted]	歩行障害	3	5 D	NOT RELATED	GRADE 2	AE	NONE
						歩行障害	8	210 D	NOT RELATED	GRADE 1	AE	NONE
						一過性脳虚血発作	8	2 D	NOT RELATED	GRADE 3	SAE	DELAYED
						便秘	22	183 D	NOT RELATED	GRADE 1	AE	NONE
						食欲減退	29	50 D	NOT RELATED	GRADE 1	AE	NONE
						味覚異常	36	15 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	44	286 D	NOT RELATED	GRADE 1	AE	NONE
						体重減少	50	637 D	NOT RELATED	GRADE 1	AE	NONE
						口腔カンジダ症	57	22 D	D	GRADE 1	AE	NONE
						末梢性ニューロパチー	92	70 D	NOT RELATED	GRADE 2	AE	NONE
						リンパ節症	141	22 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	148	114 D	L	GRADE 1	AE	NONE
						背部痛	148	84 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	162	CONT.	NOT RELATED	GRADE 1	AE	NONE
						歩行障害	218	CONT.	D	GRADE 2	AE	NONE
						食欲減退	219	70 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	232	CONT.	NOT RELATED	GRADE 2	AE	NONE
						無力症	274	43 D	L	GRADE 2	AE	NONE
						白内障	280	1 D	NOT RELATED	GRADE 3	AE	NONE
						白内障	322	1 D	NOT RELATED	GRADE 3	AE	NONE
						骨痛	330	CONT.	NOT RELATED	GRADE 2	AE	NONE
						回転性めまい	388	1 D	NOT RELATED	GRADE 2	AE	NONE
						回転性めまい	402	2 D	NOT RELATED	GRADE 2	AE	NONE
						便秘	610	CONT.	NOT RELATED	GRADE 1	AE	NONE
						無力症	652	49 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	679	9 D	NOT RELATED	GRADE 2	AE	DELAYED

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	684	18 D	NOT RELATED	GRADE 1	AE	NONE
						体重減少	687	CONT.	NOT RELATED	GRADE 2	AE	NONE
						無力症	701	14 D	NOT RELATED	GRADE 2	AE	NONE
						無力症	715	196 D	NOT RELATED	GRADE 1	AE	NONE
						食欲減退	890	CONT.	NOT RELATED	GRADE 1	AE	NONE
						無力症	911	CONT.	NOT RELATED	GRADE 2	AE	NONE
						錯乱状態	927	18 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2201	WHITE	20 mg/kg	Male	[redacted]	高血圧	1	1 D	E,D	GRADE 1	AE	NONE
						骨痛	8	CONT.	NOT RELATED	GRADE 1	AE	NONE
						毛包炎	15	8 D	D	GRADE 1	AE	NONE
						無力症	22	204 D	L	GRADE 1	AE	NONE
						紅斑	22	8 D	E,L,D	GRADE 1	AE	NONE
						貧血	29	7 D	E	GRADE 1	AE	NONE
						血中クレアチニン増加	29	22 D	E,L,D	GRADE 1	AE	NONE
						発熱	35	1 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	36	35 D	E	GRADE 2	AE	NONE
						複視	50	8 D	NOT RELATED	GRADE 1	AE	NONE
						消化管運動障害	50	8 D	NOT RELATED	GRADE 1	AE	NONE
						呼吸困難	57	15 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	57	29 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	71	56 D	E	GRADE 1	AE	NONE
						消化管運動障害	99	317 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	141	42 D	E	GRADE 1	AE	NONE
						貧血	183	56 D	E	GRADE 2	AE	NONE
						骨痛	211	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	239	14 D	E	GRADE 1	AE	NONE
						中心静脈カテーテル留置	239	1 D	NOT RELATED	GRADE 1	AE	INTERRUPTED
						貧血	253	27 D	L	GRADE 2	AE	NONE
						気管支炎	265	17 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	280	43 D	L	GRADE 1	AE	NONE
						アフタ性口内炎	332	20 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	365	93 D	L	GRADE 2	AE	NONE
						気管支炎	376	27 D	NOT RELATED	GRADE 1	AE	NONE
						体重減少	378	CONT.	NOT RELATED	GRADE 2	AE	NONE
						無力症	393	CONT.	L	GRADE 2	AE	NONE
						肺障害	403	7 D	D	GRADE 3	SAE	DELAYED
						うつ病	410	CONT.	NOT RELATED	GRADE 2	AE	NONE
						下痢	416	20 D	L	GRADE 3	AE	NONE
						アスペルギルス感染	430	5 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						アスペルギルス感染	435	18 D	NOT RELATED	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						胸水	435	CONT.	NOT RELATED	GRADE 2	AE	NONE
						便秘	436	12 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	447	CONT.	L	GRADE 3	AE	NONE
						低カリウム血症	447	1 D	NOT RELATED	GRADE 3	AE	NONE
						低カリウム血症	448	1 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	458	2 D	L	GRADE 3	AE	NONE
						肺障害	458	15 D	NOT RELATED	GRADE 2	SAE	NONE
						貧血	460	CONT.	L	GRADE 2	AE	NONE
20 mg/kg	2203	WHITE	20 mg/kg	Male	6[redacted]	悪心	1	CONT.	E	GRADE 1	AE	NONE
						嘔吐	6	2 D	L	GRADE 1	AE	NONE
						無力症	8	15 D	L	GRADE 1	AE	NONE
						背部痛	22	8 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	43	CONT.	L	GRADE 2	AE	NONE
						尿路感染	43	22 D	NOT RELATED	GRADE 2	AE	NONE
						局所腫脹	57	29 D	NOT RELATED	GRADE 1	AE	NONE
						腱痛	57	15 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	73	5 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	84	16 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	86	5 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	113	15 D	NOT RELATED	GRADE 1	AE	NONE
						排尿困難	113	15 D	NOT RELATED	GRADE 1	AE	NONE
						筋骨格系胸痛	148	44 D	NOT RELATED	GRADE 3	AE	NONE
						吐血	160	5 D	D	GRADE 3	SAE	NONE
						背部痛	169	CONT.	NOT RELATED	GRADE 3	AE	NONE
						肺障害	177	4 D	NOT RELATED	GRADE 2	AE	NONE
						肺障害	181	4 D	NOT RELATED	GRADE 3	SAE	NONE
20 mg/kg	2205	WHITE	20 mg/kg	Male	7[redacted]	糖尿病	2	28 D	D	GRADE 3	AE	NONE
						糖尿病	29	CONT.	D	GRADE 2	AE	NONE
						便秘	30	91 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	60	61 D	NOT RELATED	GRADE 1	AE	NONE
						鼻咽頭炎	79	21 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	99	56 D	L	GRADE 2	AE	NONE
						うつ病	113	197 D	D	GRADE 1	AE	NONE
						下痢	133	23 D	L	GRADE 3	AE	NONE
						無力症	141	15 D	L	GRADE 2	AE	NONE
						深部静脈血栓症	181	12 D	L,D	GRADE 2	SAE	DELAYED
						低カルシウム血症	181	5 D	NOT RELATED	GRADE 3	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						低リン酸血症	181	5 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	182	11 D	NOT RELATED	GRADE 1	AE	NONE
						腹痛	183	10 D	NOT RELATED	GRADE 1	AE	NONE
						ビタミンD欠乏	183	31 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	185	1 D	NOT RELATED	GRADE 1	AE	NONE
						低マグネシウム血症	185	1 D	NOT RELATED	GRADE 4	AE	NONE
						低カルシウム血症	186	4 D	NOT RELATED	GRADE 2	AE	NONE
						低マグネシウム血症	190	10 D	NOT RELATED	GRADE 1	AE	NONE
						易刺激性	211	29 D	D	GRADE 3	AE	NONE
						低カリウム血症	213	12 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	239	13 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	407	14 D	L	GRADE 2	AE	NONE
						貧血	421	553 D	L	GRADE 1	AE	NONE
						気管支炎	430	7 D	NOT RELATED	GRADE 1	AE	NONE
						肺感染	602	6 D	NOT RELATED	GRADE 2	AE	DELAYED
						咳嗽	644	8 D	NOT RELATED	GRADE 2	AE	NONE
						発熱	644	8 D	NOT RELATED	GRADE 1	AE	NONE
						白内障	686	1 D	NOT RELATED	GRADE 3	AE	NONE
						下痢	856	6 D	NOT RELATED	GRADE 1	AE	NONE
						肺障害	867	6 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	974	14 D	L	GRADE 2	AE	NONE
						貧血	988	163 D	L	GRADE 1	AE	NONE
						背部痛	1002	14 D	NOT RELATED	GRADE 1	AE	NONE
						胃腸炎	1007	3 D	NOT RELATED	GRADE 1	AE	NONE
						腎クレアチニン・クリアランス減少	1086	CONT.	L	GRADE 2	AE	NONE
						不眠症	1140	11 D	NOT RELATED	GRADE 3	AE	NONE
						貧血	1151	7 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	1158	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2307	WHITE	20 mg/kg	Female	[redacted]	頻脈	1	2 D	E,L,D	GRADE 2	AE	NONE
						頭痛	2	1 D	E,L,D	GRADE 1	AE	NONE
						咽喉刺激感	22	99 D	E,L,D	GRADE 1	AE	NONE
						霧視	22	99 D	E,L,D	GRADE 1	AE	NONE
						頭痛	28	1 D	NOT RELATED	GRADE 2	AE	NONE
						膀胱痙縮	29	9 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	29	57 D	E,L,D	GRADE 2	AE	NONE
						浮動性めまい	29	92 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	29	107 D	E,L,D	GRADE 1	AE	NONE
						尿失禁	29	9 D	NOT RELATED	GRADE 1	AE	NONE
						記憶障害	71	78 D	E,L,D	GRADE 1	AE	NONE
						不眠症	80	41 D	E,L,D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						便秘	85	22 D	E,L,D	GRADE 1	AE	NONE
						心房細動	112	4 D	L,D	GRADE 2	SAE	DELAYED
						呼吸困難	120	49 D	E,L,D	GRADE 1	AE	NONE
						記憶障害	148	31 D	E,L,D	GRADE 3	AE	NONE
						痙攣	171	1 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	171	CONT.	L,D	GRADE 1	AE	NONE
						下痢	173	63 D	E,L,D	GRADE 2	AE	NONE
						背部痛	178	CONT.	NOT RELATED	GRADE 1	AE	NONE
						聴力低下	178	230 D	NOT RELATED	GRADE 1	AE	NONE
						記憶障害	178	143 D	L,D	GRADE 2	AE	NONE
						体重増加	178	230 D	D	GRADE 1	AE	NONE
						寝汗	192	44 D	D	GRADE 1	AE	NONE
						痙攣	202	1 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	320	27 D	L,D	GRADE 1	AE	NONE
						関節痛	374	CONT.	NOT RELATED	GRADE 1	AE	NONE
						痛風	386	3 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2308	BLACK OF AFRICAN HERITAGE	20 mg/kg	Female	5[redacted]	呼吸困難	15	15 D	NOT RELATED	GRADE 1	AE	NONE
						歯痛	15	15 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	29	8 D	E,L,D	GRADE 3	AE	NONE
						耳不快感	36	22 D	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	36	15 D	E,L,D	GRADE 1	AE	NONE
						好中球減少症	50	8 D	E,L,D	GRADE 3	AE	NONE
						好中球減少症	57	CONT.	E,L,D	GRADE 2	AE	NONE
						貧血	85	CONT.	E,L,D	GRADE 2	AE	NONE
						疲労	99	CONT.	L	GRADE 1	AE	NONE
						せつ	183	CONT.	E	GRADE 1	AE	NONE
						せつ	183	15 D	NOT RELATED	GRADE 1	AE	NONE
						発熱性好中球減少症	255	4 D	NOT RELATED	GRADE 3	SAE	NONE
20 mg/kg	2310	BLACK OF AFRICAN HERITAGE	20 mg/kg	Female	7[redacted]	感覚鈍麻	15	29 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	15	29 D	NOT RELATED	GRADE 1	AE	NONE
						低血糖症	22	1 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	29	113 D	E,L,D	GRADE 1	AE	NONE
						四肢痛	65	2 D	NOT RELATED	GRADE 1	AE	NONE
						血腫	85	47 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	141	53 D	E,L,D	GRADE 2	AE	NONE
						疲労	141	22 D	E,L,D	GRADE 1	AE	NONE
						深部静脈血栓症	169	CONT.	E,L,D	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	183	CONT.	L	GRADE 1	AE	NONE
						貧血	197	CONT.	E,L,D	GRADE 1	AE	NONE
						高血糖	253	15 D	NOT RELATED	GRADE 2	AE	NONE
						便秘	365	CONT.	L	GRADE 1	AE	NONE
						疲労	421	CONT.	L	GRADE 3	AE	NONE
						上気道感染	428	8 D	NOT RELATED	GRADE 2	AE	NONE
						高血糖	505	CONT.	D	GRADE 3	AE	NONE
						下痢	533	CONT.	E,L	GRADE 1	AE	NONE
						関節痛	642	18 D	NOT RELATED	GRADE 3	SAE	DELAYED
20 mg/kg	2313	WHITE	20 mg/kg	Female	[redacted]	疲労	5	25 D	E,L,D	GRADE 1	AE	NONE
						発疹	6	4 D	E,L,D	GRADE 1	AE	NONE
						悪心	8	15 D	E,L,D	GRADE 1	AE	NONE
						好中球減少症	22	15 D	E,L,D	GRADE 3	AE	DELAYED
						疲労	29	8 D	E,L,D	GRADE 2	AE	NONE
						味覚消失	36	42 D	E,L,D	GRADE 1	AE	NONE
						貧血	36	36 D	E,L,D	GRADE 2	AE	NONE
						疲労	36	87 D	E,L,D	GRADE 1	AE	NONE
						白血球減少症	36	78 D	E,L,D	GRADE 2	AE	NONE
						好中球減少症	36	8 D	E,L,D	GRADE 2	AE	NONE
						好中球減少症	43	8 D	E,L,D	GRADE 1	AE	NONE
						好中球減少症	57	15 D	E,L,D	GRADE 3	AE	NONE
						関節痛	58	CONT.	E,L,D	GRADE 2	AE	NONE
						貧血	77	7 D	E,L,D	GRADE 2	AE	NONE
						好中球減少症	77	16 D	E,L,D	GRADE 2	AE	NONE
						咳嗽	79	27 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	81	9 D	L,D	GRADE 3	SAE	INTERRUPTED
						低酸素症	83	1 D	NOT RELATED	GRADE 3	AE	NONE
						末梢性浮腫	92	53 D	NOT RELATED	GRADE 2	AE	NONE
						好中球減少症	99	50 D	E,L,D	GRADE 2	AE	NONE
						貧血	105	CONT.	E,L,D	GRADE 2	AE	NONE
						疲労	123	68 D	L	GRADE 2	AE	NONE
						好中球減少症	148	29 D	E,L,D	GRADE 3	AE	NONE
						好中球減少症	176	28 D	E,L,D	GRADE 1	AE	NONE
						疲労	190	281 D	L	GRADE 1	AE	NONE
						丘疹性皮疹	357	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	387	28 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	387	31 D	NOT RELATED	GRADE 1	AE	NONE
						味覚異常	510	120 D	E,L,D	GRADE 1	AE	NONE
						鼓腸	630	92 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	708	29 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
20 mg/kg	2406	WHITE	20 mg/kg	Female	5[redacted]	高カリウム血症	1	8 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	2	CONT.	E,L	GRADE 1	AE	NONE
						高ビリルビン血症	8	7 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	12	1 D	E,L,D	GRADE 1	AE	NONE
						関節痛	16	2 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	17	2 D	E,L,D	GRADE 1	AE	NONE
						関節痛	22	8 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	61	25 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	71	15 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	96	32 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	98	9 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	127	CONT.	E,L	GRADE 1	AE	NONE
						低カリウム血症	127	29 D	NOT RELATED	GRADE 1	AE	NONE
						消化不良	169	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	197	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	219	4 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	219	4 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	226	14 D	NOT RELATED	GRADE 1	AE	NONE
						眼刺激	233	CONT.	NOT RELATED	GRADE 1	AE	NONE
						関節痛	253	CONT.	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	264	4 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	288	22 D	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	295	15 D	NOT RELATED	GRADE 2	AE	NONE
						アレルギー性鼻炎	309	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	329	9 D	NOT RELATED	GRADE 1	AE	NONE
						口内炎	358	50 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	360	2 D	NOT RELATED	GRADE 1	AE	NONE
						筋骨格痛	381	CONT.	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	410	26 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	410	2 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	411	25 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	446	1 D	NOT RELATED	GRADE 1	AE	NONE
						肺炎	470	36 D	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	477	16 D	NOT RELATED	GRADE 1	AE	NONE
						低カリウム血症	505	15 D	NOT RELATED	GRADE 1	AE	NONE
						不安	561	CONT.	D	GRADE 1	AE	NONE
						上気道感染	587	17 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	596	6 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	617	29 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						尿路感染	621	5 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	654	20 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	668	146 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	668	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼻閉	696	CONT.	NOT RELATED	GRADE 1	AE	NONE
						鼻漏	696	118 D	D	GRADE 1	AE	NONE
						上気道感染	696	14 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	743	15 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	766	6 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	785	15 D	NOT RELATED	GRADE 2	AE	NONE
						尿路感染	796	4 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	798	16 D	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	838	19 D	NOT RELATED	GRADE 1	AE	NONE
						尿路感染	923	6 D	L,D	GRADE 3	SAE	DELAYED
						うっ血性心不全	925	4 D	NOT RELATED	GRADE 2	AE	DELAYED
						肺炎	925	4 D	NOT RELATED	GRADE 2	AE	DELAYED
						尿路感染	950	53 D	NOT RELATED	GRADE 3	AE	NONE
						筋肉痛	1002	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1003	14 D	NOT RELATED	GRADE 2	AE	NONE
						尿路感染	1041	4 D	NOT RELATED	GRADE 2	AE	NONE
						血圧上昇	1115	28 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1121	8 D	NOT RELATED	GRADE 2	AE	NONE
						便秘	1139	2 D	NOT RELATED	GRADE 1	AE	NONE
						ウイルス性上気道感染	1338	8 D	L,D	GRADE 2	AE	DELAYED
						白血球減少症	1362	CONT.	L	GRADE 2	AE	NONE
						リンパ球減少症	1376	CONT.	L	GRADE 2	AE	NONE
						咳嗽	1387	24 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	1421	21 D	L	GRADE 1	AE	NONE
						上気道感染	1421	40 D	D	GRADE 1	AE	NONE
						下痢	1441	10 D	L	GRADE 2	AE	NONE
						貧血	1450	CONT.	NOT RELATED	GRADE 2	AE	NONE
						下痢	1451	CONT.	L	GRADE 1	AE	NONE
						上気道感染	1460	33 D	NOT RELATED	GRADE 2	AE	NONE
						歯牙破折	1487	CONT.	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	1506	8 D	NOT RELATED	GRADE 3	AE	DELAYED
						好中球減少症	1513	29 D	NOT RELATED	GRADE 1	AE	NONE
						疼痛	1513	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1522	CONT.	NOT RELATED	GRADE 1	AE	NONE
						好中球減少症	1541	15 D	NOT RELATED	GRADE 3	AE	DELAYED

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
20 mg/kg	2409	BLACK OF AFRICAN HERITAGE	20 mg/kg	Female	4[redacted]	便秘	2	21 D	E,L	GRADE 1	AE	NONE
						疲労	2	21 D	E,L,D	GRADE 1	AE	NONE
						悪心	2	28 D	E,L	GRADE 1	AE	NONE
						浮動性めまい	8	8 D	NOT RELATED	GRADE 1	AE	NONE
						頭痛	8	22 D	E,L,D	GRADE 1	AE	NONE
						低カリウム血症	8	1 D	NOT RELATED	GRADE 1	AE	NONE
						そう痒症	18	2 D	E	GRADE 1	AE	NONE
						蕁麻疹	18	2 D	E	GRADE 1	AE	NONE
						アナフィラキシー反応	22	8 D	E	GRADE 4	SAE	PERMANENTLY DISCONTINUED
						貧血	23	CONT.	L	GRADE 2	AE	NONE
20 mg/kg	2413	BLACK OF AFRICAN HERITAGE	20 mg/kg	Male	6[redacted]	腹痛	1	2 D	NOT RELATED	GRADE 1	AE	NONE
						発声障害	1	15 D	D	GRADE 1	AE	NONE
						疲労	1	44 D	E,L	GRADE 1	AE	NONE
						寝汗	1	22 D	D	GRADE 1	AE	NONE
						発熱	3	1 D	NOT RELATED	GRADE 1	AE	NONE
						気分動揺	8	CONT.	D	GRADE 1	AE	NONE
						下痢	21	5 D	L	GRADE 1	AE	NONE
						便秘	25	12 D	L	GRADE 1	AE	NONE
						下痢	36	36 D	L	GRADE 1	AE	NONE
						疲労	44	14 D	L,D	GRADE 2	AE	NONE
						上気道感染	44	28 D	NOT RELATED	GRADE 1	AE	NONE
						浮動性めまい	54	CONT.	NOT RELATED	GRADE 1	AE	NONE
						疲労	57	3 D	E,L,D	GRADE 1	AE	NONE
						疲労	59	41 D	D	GRADE 2	AE	NONE
						筋痙縮	91	CONT.	NOT RELATED	GRADE 1	AE	NONE
						疲労	99	CONT.	D	GRADE 1	AE	NONE
						低カリウム血症	113	15 D	NOT RELATED	GRADE 1	AE	NONE
						硝子体浮遊物	113	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	118	24 D	NOT RELATED	GRADE 3	AE	NONE
						低リン酸血症	120	CONT.	NOT RELATED	GRADE 3	AE	NONE
						貧血	127	29 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	197	14 D	NOT RELATED	GRADE 1	AE	NONE
						上気道咳症候群	246	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腹部膨満	266	CONT.	NOT RELATED	GRADE 1	AE	NONE
						便秘	266	CONT.	L	GRADE 1	AE	NONE
						下痢	266	CONT.	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						関節痛	286	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	286	CONT.	E,L	GRADE 1	AE	NONE
						非心臓性胸痛	309	1 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	351	43 D	NOT RELATED	GRADE 1	AE	NONE
						呼吸困難	351	14 D	NOT RELATED	GRADE 1	AE	NONE
						鼻閉	351	43 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	364	72 D	L	GRADE 2	AE	NONE
						浮動性めまい	413	9 D	L	GRADE 2	AE	NONE
						胸部不快感	491	1 D	NOT RELATED	GRADE 1	AE	INTERRUPTED
						多汗症	491	1 D	NOT RELATED	GRADE 1	AE	INTERRUPTED
						上腹部痛	547	16 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	561	CONT.	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	592	33 D	NOT RELATED	GRADE 1	AE	NONE
						口腔咽頭痛	592	33 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	610	15 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	637	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	675	6 D	NOT RELATED	GRADE 1	AE	NONE
						側腹部痛	675	48 D	NOT RELATED	GRADE 1	AE	NONE
						眼充血	709	56 D	NOT RELATED	GRADE 1	AE	NONE
						胃食道逆流性疾患	785	CONT.	NOT RELATED	GRADE 1	AE	NONE
						上腹部痛	791	114 D	NOT RELATED	GRADE 1	AE	NONE
						側腹部痛	791	114 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	925	CONT.	D	GRADE 1	AE	NONE
						腹痛	960	71 D	L	GRADE 2	AE	DELAYED
						腹痛	1030	CONT.	L	GRADE 1	AE	NONE
						ほてり	1108	1 D	D	GRADE 1	AE	NONE
						肺炎	1119	8 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						咳嗽	1142	15 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2505	WHITE	20 mg/kg	Male	4[redacted]	疲労	1	CONT.	L	GRADE 2	AE	NONE
						悪心	15	277 D	L	GRADE 1	AE	NONE
						疼痛	29	197 D	L	GRADE 1	AE	NONE
						食欲減退	85	85 D	L	GRADE 1	AE	NONE
						末梢性ニューロパチー	127	CONT.	L	GRADE 1	AE	NONE
						頭痛	141	197 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	169	57 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	172	54 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	197	1317 D	D	GRADE 1	AE	NONE
						末梢性浮腫	281	29 D	D	GRADE 1	AE	NONE
						口腔カンジダ症	393	29 D	D	GRADE 1	AE	NONE
						末梢性浮腫	421	281 D	D	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						体重増加	421	14 D	D	GRADE 1	AE	NONE
						肺塞栓症	438	12 D	L,D	GRADE 4	SAE	NONE
						肺梗塞	438	12 D	L,D	GRADE 3	AE	NONE
						深部静脈血栓症	441	37 D	L	GRADE 3	SAE	NONE
						上気道感染	476	58 D	NOT RELATED	GRADE 1	AE	NONE
						感染性結膜炎	504	33 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	533	29 D	NOT RELATED	GRADE 1	AE	NONE
						副鼻腔分泌過多	533	29 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	561	29 D	L	GRADE 2	AE	NONE
						嵌入爪	561	29 D	NOT RELATED	GRADE 1	AE	NONE
						嵌入爪	715	15 D	NOT RELATED	GRADE 1	AE	NONE
						気分変化	841	CONT.	D	GRADE 1	AE	NONE
						下痢	1037	29 D	NOT RELATED	GRADE 1	AE	NONE
						錯感覚	1037	23 D	L	GRADE 1	AE	NONE
						瘢痕ヘルニア	1115	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋肉痛	1121	25 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	1149	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	1176	31 D	L	GRADE 1	AE	NONE
						末梢性ニューロパチー	1289	CONT.	L	GRADE 1	AE	NONE
						口腔カンジダ症	1289	7 D	D	GRADE 1	AE	NONE
						末梢性浮腫	1327	50 D	NOT RELATED	GRADE 1	AE	NONE
						血中トリグリセリド増加	1358	CONT.	D	GRADE 1	AE	NONE
						鼓腸	1449	CONT.	D	GRADE 1	AE	NONE
						斑状丘疹状皮疹	1511	30 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	1513	29 D	D	GRADE 2	AE	NONE
						腹部ヘルニア	1569	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2506	BLACK OF AFRICAN HERITAGE	20 mg/kg	Male	4[redacted]	高血糖	1	28 D	D	GRADE 2	AE	NONE
						下痢	12	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	28	16 D	L	GRADE 1	AE	NONE
						多汗症	35	2 D	D	GRADE 2	AE	NONE
						疲労	43	CONT.	L,D	GRADE 2	AE	NONE
						インフルエンザ様疾患	43	5 D	L	GRADE 3	AE	NONE
						血小板減少症	43	8 D	L	GRADE 4	AE	NONE
						腹痛	68	7 D	L	GRADE 1	AE	NONE
						血中カリウム減少	74	3 D	NOT RELATED	GRADE 1	AE	NONE
						食欲減退	74	CONT.	NOT RELATED	GRADE 1	AE	NONE
						低血圧	74	6 D	NOT RELATED	GRADE 2	AE	NONE
						悪心	74	15 D	L	GRADE 1	AE	NONE
						疼痛	74	2 D	NOT RELATED	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						動悸	74	6 D	NOT RELATED	GRADE 1	AE	NONE
						敗血症	74	6 D	NOT RELATED	GRADE 3	SAE	NONE
						胃食道逆流性疾患	75	5 D	D	GRADE 1	AE	NONE
						血中ブドウ糖増加	76	4 D	D	GRADE 1	AE	NONE
						血中マグネシウム減少	76	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中リン減少	76	1 D	NOT RELATED	GRADE 1	AE	NONE
						血中ブドウ糖増加	84	5 D	D	GRADE 1	AE	NONE
						悪心	102	CONT.	L	GRADE 1	AE	NONE
20 mg/kg	2507	WHITE	20 mg/kg	Male	5[redacted]	胸痛	4	13 D	NOT RELATED	GRADE 3	SAE	NONE
						筋痙縮	4	13 D	NOT RELATED	GRADE 2	AE	NONE
						便秘	7	10 D	NOT RELATED	GRADE 2	AE	NONE
						尿量減少	10	13 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	12	3 D	NOT RELATED	GRADE 2	AE	NONE
						嗜眠	12	5 D	NOT RELATED	GRADE 3	AE	NONE
						嘔吐	12	2 D	NOT RELATED	GRADE 2	AE	NONE
						上気道性喘鳴	15	1 D	E,D	GRADE 3	SAE	NONE
						蕁麻疹	15	1 D	E	GRADE 2	AE	NONE
						胸痛	16	52 D	NOT RELATED	GRADE 2	AE	NONE
						疲労	22	CONT.	NOT RELATED	GRADE 2	AE	NONE
						上気道性喘鳴	22	1 D	E	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						蕁麻疹	22	1 D	E	GRADE 2	AE	PERMANENTLY DISCONTINUED
						血中クロール減少	35	12 D	NOT RELATED	GRADE 2	AE	NONE
						形質細胞腫	67	CONT.	NOT RELATED	GRADE 1	AE	NONE
						ストレス	78	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2511	WHITE	20 mg/kg	Female	5[redacted]	上腹部痛	8	8 D	L	GRADE 1	AE	NONE
						医薬品副作用	8	1 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	57	307 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	70	CONT.	NOT RELATED	GRADE 1	AE	NONE
						肺炎	77	16 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	223	96 D	NOT RELATED	GRADE 1	AE	NONE
						紅斑	223	65 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	223	681 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	223	65 D	NOT RELATED	GRADE 1	AE	NONE
						四肢痛	223	65 D	NOT RELATED	GRADE 2	AE	NONE
						肺炎	300	3 D	NOT RELATED	GRADE 3	SAE	DELAYED
						副鼻腔分泌過多	363	12 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	374	754 D	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						ウイルス性消化管感染	527	39 D	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	527	39 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	582	CONT.	L	GRADE 1	AE	NONE
						関節痛	618	35 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	623	16 D	NOT RELATED	GRADE 1	AE	NONE
						腹痛	668	286 D	NOT RELATED	GRADE 1	AE	NONE
						アレルギー性皮膚炎	680	60 D	NOT RELATED	GRADE 1	AE	NONE
						薬物過敏症	680	CONT.	NOT RELATED	GRADE 1	AE	NONE
						転倒	680	29 D	NOT RELATED	GRADE 1	AE	NONE
						胃食道逆流性疾患	820	42 D	NOT RELATED	GRADE 1	AE	NONE
						乳房腫瘤	902	CONT.	NOT RELATED	GRADE 2	AE	NONE
						不眠症	903	CONT.	D	GRADE 2	AE	NONE
						回転性めまい	984	31 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	1036	1 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	1053	1 D	NOT RELATED	GRADE 1	AE	NONE
						悪心	1095	2 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1110	18 D	NOT RELATED	GRADE 2	AE	NONE
						浮動性めまい	1124	1 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	1127	CONT.	L	GRADE 2	AE	NONE
						鼻閉	1155	41 D	NOT RELATED	GRADE 1	AE	NONE
						節足動物咬傷	1183	44 D	NOT RELATED	GRADE 1	AE	NONE
						情動障害	1183	29 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	1258	38 D	NOT RELATED	GRADE 1	AE	NONE
						上気道感染	1258	38 D	NOT RELATED	GRADE 2	AE	NONE
						外傷後頚部症候群	1319	61 D	NOT RELATED	GRADE 1	AE	NONE
						RIGHT KNEE INJURY - X-RAY SHOWED ARTHRITIS AND POSSIBLE BONE SPUR	1349	CONT.	NOT RELATED	GRADE 2	AE	NONE
						上気道感染	1365	14 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						咳嗽	1379	CONT.	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2705	WHITE	20 mg/kg	Male	5[redacted]	低リン酸血症	8	16 D	NOT RELATED	GRADE 2	AE	NONE
						筋痙縮	8	CONT.	L	GRADE 1	AE	NONE
						寝汗	8	1 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	16	8 D	NOT RELATED	GRADE 1	AE	NONE
						アラニンアミノトランスフェラーゼ増加	17	2 D	NOT RELATED	GRADE 3	AE	NONE
						アスパラギン酸アミノトランスフェラーゼ増加	17	2 D	NOT RELATED	GRADE 2	AE	NONE
						発熱性好中球減少症	17	3 D	E,L	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						低カルシウム血症	17	4 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						低血圧	17	3 D	NOT RELATED	GRADE 1	AE	NONE
						白血球減少症	17	5 D	E	GRADE 3	AE	PERMANENTLY DISCONTINUED
						好中球減少症	17	7 D	E,L	GRADE 4	SAE	PERMANENTLY DISCONTINUED
						失神寸前の状態	17	3 D	NOT RELATED	GRADE 1	AE	NONE
						血小板減少症	17	12 D	E,L	GRADE 4	AE	DELAYED
						アラニンアミノトランスフェラーゼ増加	18	2 D	NOT RELATED	GRADE 2	AE	NONE
						貧血	18	6 D	E,L	GRADE 2	AE	DELAYED
						アスパラギン酸アミノトランスフェラーゼ増加	18	2 D	NOT RELATED	GRADE 1	AE	NONE
						斑状丘疹状皮疹	18	25 D	E,L	GRADE 1	AE	PERMANENTLY DISCONTINUED
						アラニンアミノトランスフェラーゼ増加	19	10 D	NOT RELATED	GRADE 1	AE	NONE
						血中重炭酸塩減少	19	4 D	NOT RELATED	GRADE 1	AE	NONE
						低カルシウム血症	20	9 D	NOT RELATED	GRADE 2	AE	NONE
						白血球減少症	21	22 D	E	GRADE 1	AE	NONE
						悪心	21	3 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	2802	WHITE	20 mg/kg	Female	5[redacted]	不眠症	1	CONT.	NOT RELATED	GRADE 2	AE	NONE
						低カリウム血症	7	CONT.	NOT RELATED	GRADE 1	AE	NONE
						貧血	8	36 D	L	GRADE 3	AE	NONE
						下痢	10	CONT.	E,L,D	GRADE 1	AE	NONE
						悪心	10	7 D	E,L,D	GRADE 2	AE	NONE
						食欲減退	16	CONT.	E,L	GRADE 3	AE	NONE
						悪心	16	7 D	E,L	GRADE 3	AE	DELAYED
						鼻出血	19	3 D	NOT RELATED	GRADE 1	AE	NONE
						胃腸出血	19	3 D	NOT RELATED	GRADE 3	AE	NONE
						血尿	19	3 D	NOT RELATED	GRADE 1	AE	NONE
						血小板減少症	19	CONT.	L	GRADE 3	AE	NONE
						便秘	22	CONT.	NOT RELATED	GRADE 2	AE	NONE
						悪心	22	7 D	E,L	GRADE 3	SAE	DELAYED
						脱水	23	4 D	E,L,D	GRADE 3	AE	NONE
						発熱性好中球減少症	24	5 D	E,L,D	GRADE 2	AE	NONE
						悪心	28	9 D	E,L	GRADE 2	AE	NONE
						貧血	43	8 D	L	GRADE 2	AE	NONE
						好中球減少症	49	CONT.	L	GRADE 4	AE	NONE
						貧血	50	15 D	L	GRADE 3	AE	NONE
						貧血	64	21 D	L	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						貧血	91	CONT.	L	GRADE 4	AE	NONE
20 mg/kg	2901	WHITE	20 mg/kg	Male	[redacted]	呼吸困難	8	CONT.	NOT RELATED	GRADE 2	AE	NONE
						リンパ球減少症	8	267 D	L	GRADE 4	AE	NONE
						嘔吐	25	42 D	NOT RELATED	GRADE 2	AE	NONE
						気管支炎	59	11 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	67	3 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	67	3 D	L	GRADE 3	SAE	NONE
						下痢	70	2 D	NOT RELATED	GRADE 1	AE	NONE
						耳痛	72	13 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	72	13 D	NOT RELATED	GRADE 1	AE	NONE
						不眠症	98	58 D	D	GRADE 1	AE	NONE
						気管支炎	101	6 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	127	15 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	141	134 D	D	GRADE 3	AE	NONE
						下痢	142	28 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	197	57 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性感覚ニューロパチー	197	15 D	NOT RELATED	GRADE 1	AE	NONE
						気管支肺炎	265	11 D	NOT RELATED	GRADE 1	AE	NONE
						汎血球減少症	316	43 D	L	GRADE 3	AE	NONE
						腱鞘炎	344	CONT.	NOT RELATED	GRADE 1	AE	NONE
						血腫	358	15 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	372	CONT.	L	GRADE 3	AE	NONE
						血小板減少症	385	16 D	L	GRADE 3	AE	NONE
						好中球減少症	389	CONT.	L	GRADE 3	AE	NONE
						貧血	414	15 D	L	GRADE 3	AE	NONE
						血小板減少症	414	13 D	L	GRADE 4	AE	NONE
						骨髄異形成症候群	442	CONT.	L	GRADE 3	SAE	PERMANENTLY DISCONTINUED
20 mg/kg	2904	WHITE	20 mg/kg	Male	[redacted]	筋痙縮	1	22 D	NOT RELATED	GRADE 1	AE	NONE
						しゃっくり	8	1 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	15	44 D	NOT RELATED	GRADE 3	AE	NONE
						気管支炎	15	6 D	NOT RELATED	GRADE 2	SAE	NONE
						基底細胞癌	51	1 D	NOT RELATED	GRADE 3	AE	NONE
						一過性全健忘	54	2 D	L	GRADE 1	SAE	NONE
						動悸	113	14 D	NOT RELATED	GRADE 1	AE	NONE
						痛風	159	11 D	NOT RELATED	GRADE 1	AE	NONE
						心房細動	185	CONT.	L	GRADE 1	AE	NONE
						前立腺癌	198	CONT.	L	GRADE 4	SAE	PERMANENTLY DISCONTINUED

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						前立腺炎	207	6 D	NOT RELATED	GRADE 2	SAE	NONE
20 mg/kg	2905	WHITE	20 mg/kg	Male	[redacted]	背部痛	14	43 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	14	16 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	14	30 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	14	30 D	NOT RELATED	GRADE 1	AE	NONE
						胃食道逆流性疾患	29	8 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	34	3 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	36	8 D	NOT RELATED	GRADE 1	AE	NONE
						振戦	36	8 D	NOT RELATED	GRADE 1	AE	NONE
						静脈炎	41	39 D	L	GRADE 3	SAE	NONE
						骨痛	56	CONT.	NOT RELATED	GRADE 2	AE	NONE
						末梢性感覚ニューロパチー	71	CONT.	NOT RELATED	GRADE 1	AE	NONE
						振戦	71	15 D	NOT RELATED	GRADE 1	AE	NONE
						胃食道逆流性疾患	99	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	99	CONT.	L	GRADE 1	AE	NONE
						気管支炎	166	7 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	169	CONT.	NOT RELATED	GRADE 2	AE	NONE
						気管支炎	201	6 D	NOT RELATED	GRADE 1	AE	NONE
						気管支炎	215	7 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	316	CONT.	L	GRADE 1	AE	NONE
						リンパ球減少症	323	CONT.	E,L	GRADE 4	SAE	NONE
						気管支炎	331	8 D	NOT RELATED	GRADE 1	AE	NONE
						鼻出血	331	8 D	NOT RELATED	GRADE 1	AE	NONE
						鼻出血	407	2 D	NOT RELATED	GRADE 1	AE	NONE
						気管支肺炎	527	CONT.	NOT RELATED	GRADE 2	AE	NONE
						高カルシウム血症	527	5 D	NOT RELATED	GRADE 3	SAE	NONE
20 mg/kg	3204	WHITE	20 mg/kg	Female	[redacted]	体重減少	1	29 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	2	1 D	NOT RELATED	GRADE 1	AE	NONE
						無力症	3	1 D	NOT RELATED	GRADE 1	AE	NONE
						口腔ヘルペス	5	11 D	L,D	GRADE 1	AE	NONE
						リンパ節症	6	9 D	NOT RELATED	GRADE 1	AE	NONE
						口腔内潰瘍形成	6	9 D	D	GRADE 1	AE	NONE
						発疹	12	4 D	NOT RELATED	GRADE 1	AE	NONE
						食欲減退	14	CONT.	NOT RELATED	GRADE 1	AE	NONE
						悪心	20	2 D	E,L	GRADE 1	AE	NONE
						疼痛	20	6 D	NOT RELATED	GRADE 1	AE	NONE
						胸膜炎	20	6 D	NOT RELATED	GRADE 2	AE	NONE
						肺塞栓症	25	5 D	L,D	GRADE 2	SAE	NONE
						寝汗	42	2 D	D	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						寝汗	49	2 D	D	GRADE 1	AE	NONE
						リンパ節症	62	16 D	NOT RELATED	GRADE 1	AE	NONE
						口腔内潰瘍形成	62	16 D	D	GRADE 1	AE	NONE
						口腔真菌感染	66	12 D	L,D	GRADE 2	AE	NONE
						背部痛	72	5 D	NOT RELATED	GRADE 1	AE	NONE
						筋骨格系胸痛	77	1 D	NOT RELATED	GRADE 1	AE	NONE
20 mg/kg	3303	WHITE	20 mg/kg	Male	5[redacted]	便秘	1	CONT.	E,L,D	GRADE 2	AE	NONE
						寝汗	1	CONT.	D	GRADE 2	AE	NONE
						味覚異常	2	CONT.	E,L,D	GRADE 1	AE	NONE
						鼻出血	3	1 D	NOT RELATED	GRADE 3	AE	NONE
						呼吸困難	13	3 D	NOT RELATED	GRADE 2	AE	NONE
						筋痙縮	21	23 D	NOT RELATED	GRADE 2	AE	NONE
						末梢性感覚ニューロパチー	22	CONT.	L	GRADE 2	AE	NONE
						振戦	23	7 D	E,L,D	GRADE 1	AE	NONE
						高血糖	29	CONT.	D	GRADE 3	AE	NONE
						上気道感染	44	17 D	L,D	GRADE 2	AE	INTERRUPTED
						皮膚カンジダ	53	CONT.	L,D	GRADE 2	AE	NONE
						上気道感染	66	11 D	L,D	GRADE 2	AE	NONE
						血小板減少症	71	15 D	L	GRADE 2	AE	NONE
						痔核	84	CONT.	NOT RELATED	GRADE 2	AE	NONE
						内臓リーシュマニア症	88	10 D	E,L,D	GRADE 2	AE	NONE
						顎骨壊死	93	CONT.	NOT RELATED	GRADE 3	AE	NONE
						貧血	97	CONT.	E,L,D	GRADE 3	AE	NONE
						血小板減少症	97	2 D	E,L,D	GRADE 3	AE	NONE
						内臓リーシュマニア症	97	43 D	E,L,D	GRADE 3	SAE	PERMANENTLY DISCONTINUED
						白血球減少症	98	CONT.	E,L,D	GRADE 4	AE	NONE
						肝障害	98	CONT.	E,L,D	GRADE 1	AE	NONE
						胸水	98	CONT.	E,L,D	GRADE 1	AE	NONE
						珪肺症	98	CONT.	NOT RELATED	GRADE 1	AE	NONE
						脾腫	98	CONT.	E,L,D	GRADE 1	AE	NONE
						血小板減少症	98	CONT.	E,L,D	GRADE 4	AE	NONE
						伝染性紅斑	100	CONT.	E,L,D	GRADE 3	AE	NONE
						口腔カンジダ症	101	CONT.	E,L,D	GRADE 2	AE	NONE
						良性前立腺肥大症	133	CONT.	NOT RELATED	GRADE 1	AE	NONE
						低ナトリウム血症	134	2 D	L,D	GRADE 3	AE	NONE
						内臓リーシュマニア症	139	CONT.	E,L,D	GRADE 2	AE	NONE
20 mg/kg	3306	WHITE	20 mg/kg	Male	7[redacted]	便秘	4	215 D	NOT RELATED	GRADE 1	AE	NONE
						全身性皮疹	4	5 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						筋痙縮	17	1 D	NOT RELATED	GRADE 2	AE	NONE
						全身性皮疹	33	5 D	NOT RELATED	GRADE 2	AE	NONE
						良性前立腺肥大症	35	CONT.	NOT RELATED	GRADE 1	AE	NONE
						疲労	35	CONT.	L	GRADE 2	AE	NONE
						筋力低下	127	CONT.	L,D	GRADE 1	AE	NONE
						気管支炎	146	73 D	E,L,D	GRADE 2	AE	NONE
						鼻乾燥	157	90 D	L,D	GRADE 1	AE	NONE
						労作性呼吸困難	188	125 D	L,D	GRADE 1	AE	NONE
						四肢痛	219	120 D	NOT RELATED	GRADE 1	AE	NONE
						背部痛	247	262 D	NOT RELATED	GRADE 1	AE	NONE
						全身健康状態低下	278	CONT.	L,D	GRADE 2	AE	NONE
						下痢	327	4 D	L,D	GRADE 2	AE	NONE
						不眠症	339	122 D	L	GRADE 2	AE	NONE
						神経過敏	339	45 D	NOT RELATED	GRADE 1	AE	NONE
						傾眠	339	45 D	NOT RELATED	GRADE 1	AE	NONE
						視力障害	339	45 D	NOT RELATED	GRADE 1	AE	NONE
						体重増加	339	CONT.	D	GRADE 1	AE	NONE
						心房粗動	394	3 D	L,D	GRADE 3	AE	INTERRUPTED
						寝汗	400	CONT.	L,D	GRADE 2	AE	NONE
						心房細動	452	2 D	D	GRADE 2	SAE	NONE
						下痢	490	3 D	L,D	GRADE 2	AE	NONE
						下痢	494	38 D	L,D	GRADE 1	AE	NONE
						回転性めまい	501	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腹痛	508	CONT.	NOT RELATED	GRADE 2	AE	NONE
						背部痛	508	CONT.	NOT RELATED	GRADE 2	AE	NONE
						労作性呼吸困難	508	CONT.	L	GRADE 1	AE	NONE
						扁平上皮癌	528	1 D	NOT RELATED	GRADE 3	SAE	NONE
						鼻咽頭炎	542	22 D	L,D	GRADE 2	AE	NONE
						循環虚脱	557	27 D	L,D	GRADE 2	AE	NONE
						胸痛	577	2 D	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	620	22 D	NOT RELATED	GRADE 2	AE	NONE
						鼻咽頭炎	620	CONT.	L,D	GRADE 1	AE	NONE
20 mg/kg	3401	WHITE	20 mg/kg	Male	5[redacted]	血中クレアチニン増加	1	7 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	1	8 D	D	GRADE 2	AE	NONE
						貧血	8	2 D	L	GRADE 2	AE	NONE
						背部痛	8	7 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	8	1 D	NOT RELATED	GRADE 2	AE	NONE
						血中クレアチニン増加	8	8 D	NOT RELATED	GRADE 3	AE	NONE
						血中尿素増加	8	51 D	NOT RELATED	GRADE 1	AE	NONE
						C－反応性蛋白増加	8	55 D	E,L,D	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	8	41 D	L	GRADE 1	AE	NONE
						高血糖	8	2 D	D	GRADE 1	AE	NONE
						高血圧	8	1 D	D	GRADE 2	AE	NONE
						聴力低下	8	CONT.	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	8	8 D	D	GRADE 2	AE	NONE
						腎不全	8	54 D	NOT RELATED	GRADE 3	SAE	NONE
						血小板減少症	8	15 D	L	GRADE 1	AE	NONE
						貧血	9	2 D	NOT RELATED	GRADE 3	AE	NONE
						白血球減少症	9	2 D	L	GRADE 1	AE	NONE
						貧血	10	26 D	NOT RELATED	GRADE 2	AE	NONE
						白血球減少症	10	13 D	L	GRADE 2	AE	NONE
						アラニンアミノトランスフェラーゼ増加	12	11 D	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチンホスホキナーゼ増加	14	9 D	NOT RELATED	GRADE 1	AE	NONE
						骨痛	14	29 D	NOT RELATED	GRADE 2	AE	NONE
						悪心	14	CONT.	L	GRADE 1	AE	NONE
						四肢痛	14	CONT.	NOT RELATED	GRADE 1	AE	NONE
						血中クレアチニン増加	15	35 D	NOT RELATED	GRADE 2	AE	NONE
						味覚異常	15	7 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	15	8 D	D	GRADE 1	AE	NONE
						リンパ球減少症	15	21 D	D	GRADE 3	AE	NONE
						頻脈	15	8 D	E,L,D	GRADE 1	AE	NONE
						振戦	15	8 D	NOT RELATED	GRADE 1	AE	NONE
						味覚異常	22	5 D	NOT RELATED	GRADE 2	AE	NONE
						労作性呼吸困難	22	35 D	NOT RELATED	GRADE 2	AE	NONE
						高血圧	22	1 D	D	GRADE 1	AE	NONE
						高血圧	22	1 D	E,D	GRADE 2	AE	NONE
						白血球減少症	22	14 D	L	GRADE 1	AE	NONE
						血中重炭酸塩減少	24	14 D	NOT RELATED	GRADE 1	AE	NONE
						貧血	35	15 D	NOT RELATED	GRADE 3	AE	NONE
						血中アルブミン増加	35	17 D	NOT RELATED	GRADE 1	AE	NONE
						高血糖	35	28 D	D	GRADE 1	AE	NONE
						リンパ球減少症	35	8 D	L,D	GRADE 2	AE	NONE
						味覚異常	36	CONT.	NOT RELATED	GRADE 2	AE	NONE
						高血圧	42	1 D	E,D	GRADE 2	AE	NONE
						高尿酸血症	42	21 D	NOT RELATED	GRADE 1	AE	NONE
						リンパ球減少症	42	8 D	D	GRADE 3	AE	NONE
						下痢	44	CONT.	E,L,D	GRADE 1	AE	NONE
						貧血	49	CONT.	NOT RELATED	GRADE 2	AE	NONE
						血中クレアチニン増加	49	14 D	NOT RELATED	GRADE 3	AE	NONE
						疲労	49	13 D	E,L	GRADE 2	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						γ－グルタミルトランスフェラーゼ増加	49	CONT.	L	GRADE 2	AE	NONE
						高リン酸塩血症	49	CONT.	NOT RELATED	GRADE 1	AE	NONE
						筋痙縮	49	CONT.	NOT RELATED	GRADE 2	AE	NONE
						筋骨格痛	49	CONT.	E	GRADE 1	AE	NONE
						嘔吐	54	1 D	NOT RELATED	GRADE 1	AE	NONE
						高カリウム血症	56	3 D	NOT RELATED	GRADE 2	AE	NONE
						低アルブミン血症	56	7 D	NOT RELATED	GRADE 1	AE	NONE
						気道感染	56	CONT.	E,L,D	GRADE 1	AE	NONE
						血中尿素増加	58	CONT.	NOT RELATED	GRADE 2	AE	NONE
						無力症	62	CONT.	NOT RELATED	GRADE 3	AE	NONE
						血中重炭酸塩減少	62	CONT.	NOT RELATED	GRADE 2	AE	NONE
						血中クレアチニン増加	62	CONT.	NOT RELATED	GRADE 4	AE	NONE
						C－反応性蛋白増加	62	CONT.	E,L,D	GRADE 4	AE	NONE
						疲労	62	CONT.	NOT RELATED	GRADE 3	AE	NONE
						高カルシウム血症	62	CONT.	NOT RELATED	GRADE 1	AE	NONE
						高尿酸血症	62	CONT.	E,L,D	GRADE 3	AE	NONE
						低アルブミン血症	62	CONT.	NOT RELATED	GRADE 2	AE	NONE
						腎不全	62	CONT.	NOT RELATED	GRADE 4	SAE	NONE
20 mg/kg	4002	WHITE	20 mg/kg	Male	[redacted]	下痢	1	1 D	NOT RELATED	GRADE 1	AE	NONE
						しゃっくり	8	26 D	D	GRADE 1	AE	NONE
						四肢痛	8	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	35	1 D	NOT RELATED	GRADE 1	AE	NONE
						記憶障害	36	15 D	NOT RELATED	GRADE 1	AE	NONE
						発疹	49	2 D	NOT RELATED	GRADE 1	AE	NONE
						悪寒	77	2 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	77	18 D	NOT RELATED	GRADE 1	AE	NONE
						発熱	77	2 D	NOT RELATED	GRADE 2	AE	NONE
						下痢	94	49 D	NOT RELATED	GRADE 1	AE	NONE
						発疹	114	7 D	NOT RELATED	GRADE 1	AE	NONE
						便秘	142	6 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	165	22 D	NOT RELATED	GRADE 1	AE	NONE
						鼻炎	167	6 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	170	17 D	NOT RELATED	GRADE 2	AE	NONE
						紅斑	170	17 D	E	GRADE 2	AE	NONE
						疲労	170	17 D	E,L,D	GRADE 2	AE	NONE
						色素沈着障害	170	17 D	E	GRADE 2	AE	NONE
						皮膚亀裂	226	14 D	E,L,D	GRADE 1	AE	NONE
						霧視	226	14 D	L,D	GRADE 1	AE	NONE
						下痢	253	CONT.	L	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						皮膚乾燥	253	16 D	L,D	GRADE 2	AE	NONE
						末梢性浮腫	253	16 D	L,D	GRADE 1	AE	NONE
						皮膚乾燥	268	57 D	L,D	GRADE 1	AE	NONE
						健忘	350	CONT.	D	GRADE 1	AE	NONE
						斑状出血	422	81 D	D	GRADE 1	AE	NONE
						筋骨格硬直	422	CONT.	L,D	GRADE 1	AE	NONE
						創傷	422	85 D	NOT RELATED	GRADE 1	AE	NONE
						引っかき傷	436	14 D	NOT RELATED	GRADE 1	AE	NONE
						非心臓性胸痛	492	29 D	NOT RELATED	GRADE 1	AE	NONE
						関節痛	604	50 D	NOT RELATED	GRADE 1	AE	NONE
						創合併症	611	36 D	D	GRADE 2	AE	INTERRUPTED
						悪寒	624	19 D	NOT RELATED	GRADE 1	AE	NONE
						錯乱状態	624	37 D	NOT RELATED	GRADE 2	AE	NONE
						食欲減退	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						疲労	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						倦怠感	624	22 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	627	20 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						貧血	632	43 D	NOT RELATED	GRADE 1	AE	NONE
						瞳孔不同	632	CONT.	NOT RELATED	GRADE 1	AE	NONE
						腎不全	632	15 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚乾燥	639	CONT.	NOT RELATED	GRADE 1	AE	NONE
						擦過傷	639	4 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	639	8 D	NOT RELATED	GRADE 1	AE	NONE
						皮膚剥脱	639	CONT.	NOT RELATED	GRADE 2	AE	NONE
						筋骨格痛	646	CONT.	NOT RELATED	GRADE 1	AE	NONE
						錯乱状態	660	40 D	NOT RELATED	GRADE 3	SAE	NONE
						腎不全	699	1 D	NOT RELATED	GRADE 5	SAE	NONE
20 mg/kg	4007	WHITE	20 mg/kg	Female	6[redacted]	頭痛	1	3 D	D	GRADE 1	AE	NONE
						悪心	2	21 D	E	GRADE 1	AE	NONE
						落ち着きのなさ	2	2 D	D	GRADE 1	AE	NONE
						食欲減退	8	22 D	L	GRADE 1	AE	NONE
						疲労	8	2 D	E,L	GRADE 2	AE	NONE
						記憶障害	8	8 D	D	GRADE 1	AE	NONE
						不安	15	15 D	D	GRADE 1	AE	NONE
						無力症	15	2 D	E,L,D	GRADE 1	AE	NONE
						うつ病	15	15 D	D	GRADE 1	AE	NONE
						便秘	16	8 D	D	GRADE 1	AE	NONE
						上腹部痛	18	3 D	NOT RELATED	GRADE 1	AE	NONE
						浮動性めまい	18	1 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	19	5 D	NOT RELATED	GRADE 1	AE	NONE

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						末梢性浮腫	22	8 D	NOT RELATED	GRADE 2	AE	NONE
						上腹部痛	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	37	2 D	NOT RELATED	GRADE 2	AE	NONE
						悪心	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						嘔吐	37	2 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性浮腫	40	18 D	NOT RELATED	GRADE 2	AE	NONE
						体重増加	50	8 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	57	85 D	E,L,D	GRADE 3	AE	NONE
						咳嗽	60	CONT.	NOT RELATED	GRADE 1	AE	NONE
						水疱	71	71 D	NOT RELATED	GRADE 2	AE	NONE
						痂皮	71	CONT.	NOT RELATED	GRADE 2	AE	NONE
						四肢痛	85	15 D	NOT RELATED	GRADE 1	AE	NONE
						灼熱感	99	1 D	E,L	GRADE 1	AE	NONE
						筋痙縮	99	43 D	E,L	GRADE 1	AE	NONE
						血中ブドウ糖増加	111	CONT.	L,D	GRADE 3	AE	NONE
						多汗症	127	28 D	L,D	GRADE 1	AE	NONE
						発疹	127	8 D	NOT RELATED	GRADE 1	AE	NONE
						下痢	133	30 D	D	GRADE 1	AE	NONE
						麦粒腫	139	3 D	L,D	GRADE 1	AE	NONE
						末梢性浮腫	141	29 D	E,L,D	GRADE 1	AE	NONE
						末梢性ニューロパチー	155	197 D	L	GRADE 1	AE	NONE
						皮膚変色	168	2 D	NOT RELATED	GRADE 1	AE	NONE
						局所腫脹	169	CONT.	L,D	GRADE 2	AE	NONE
						霧視	218	8 D	D	GRADE 1	AE	NONE
						頭痛	251	3 D	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	253	8 D	D	GRADE 2	AE	NONE
						上気道感染	253	8 D	NOT RELATED	GRADE 2	AE	NONE
						うつ病	393	CONT.	NOT RELATED	GRADE 1	AE	NONE
						疲労	393	CONT.	E,L,D	GRADE 1	AE	NONE
						四肢痛	393	CONT.	NOT RELATED	GRADE 1	AE	NONE
						背部痛	418	6 D	NOT RELATED	GRADE 3	AE	DELAYED
						感覚鈍麻	435	CONT.	NOT RELATED	GRADE 1	AE	NONE
						蜂巣炎	469	8 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
						肺炎	469	8 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						多臓器不全	471	6 D	NOT RELATED	GRADE 4	SAE	INTERRUPTED
						敗血症	471	6 D	NOT RELATED	GRADE 4	SAE	INTERRUPTED
						多臓器不全	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
						肺炎	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						敗血症	476	1 D	NOT RELATED	GRADE 5	SAE	PERMANENTLY DISCONTINUED
20 mg/kg	4008	WHITE	20 mg/kg	Female	[redacted]	疲労	2	133 D	E,L	GRADE 2	AE	NONE
						高血糖	22	CONT.	NOT RELATED	GRADE 3	AE	NONE
						四肢痛	64	CONT.	NOT RELATED	GRADE 1	AE	NONE
						医療機器機能不良	78	16 D	NOT RELATED	GRADE 3	AE	NONE
						下痢	92	6 D	L	GRADE 1	AE	NONE
						四肢痛	120	CONT.	L	GRADE 2	AE	NONE
						疲労	134	CONT.	E,L	GRADE 1	AE	NONE
						歩行障害	134	CONT.	NOT RELATED	GRADE 1	AE	NONE
						感覚鈍麻	134	CONT.	NOT RELATED	GRADE 1	AE	NONE
						水疱	163	29 D	L,D	GRADE 1	AE	NONE
						紅斑	163	3 D	D	GRADE 1	AE	NONE
						上気道感染	190	7 D	NOT RELATED	GRADE 2	AE	INTERRUPTED
						四肢痛	344	CONT.	NOT RELATED	GRADE 2	AE	NONE
						肺臓炎	498	61 D	NOT RELATED	GRADE 2	SAE	NONE
						関節痛	506	49 D	NOT RELATED	GRADE 1	AE	NONE
						錯乱状態	509	11 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						髄膜炎	509	11 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						発熱	509	8 D	NOT RELATED	GRADE 3	SAE	INTERRUPTED
						肺臓炎	528	CONT.	NOT RELATED	GRADE 2	AE	NONE
						挫傷	540	8 D	NOT RELATED	GRADE 1	AE	NONE
						斑状出血	540	8 D	NOT RELATED	GRADE 1	AE	NONE
						アナフィラキシー反応	547	1 D	NOT RELATED	GRADE 2	AE	NONE
						四肢痛	559	CONT.	L	GRADE 1	AE	NONE
						歩行障害	568	CONT.	L	GRADE 1	AE	NONE
						多汗症	568	CONT.	D	GRADE 1	AE	NONE
						末梢性浮腫	568	CONT.	L,D	GRADE 2	AE	NONE
						関節痛	596	CONT.	NOT RELATED	GRADE 1	AE	NONE
						下痢	610	CONT.	L	GRADE 1	AE	NONE
						筋痙縮	610	CONT.	E,L	GRADE 1	AE	NONE
						眼充血	610	15 D	NOT RELATED	GRADE 1	AE	NONE
						末梢性ニューロパチー	625	CONT.	L	GRADE 1	AE	NONE
						悪心	708	CONT.	E,D	GRADE 1	AE	NONE
						難聴	712	CONT.	NOT RELATED	GRADE 2	AE	NONE
						乳腺上皮内小葉癌	767	CONT.	NOT RELATED	GRADE 3	SAE	NONE
						皮膚腫脹	834	CONT.	NOT RELATED	GRADE 2	AE	NONE
						排尿困難	862	4 D	NOT RELATED	GRADE 1	AE	NONE
						咳嗽	904	20 D	NOT RELATED	GRADE 2	AE	DELAYED
						呼吸困難	904	8 D	NOT RELATED	GRADE 1	AE	DELAYED

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						鼻漏	904	20 D	NOT RELATED	GRADE 2	AE	DELAYED
						乳房石灰化	954	15 D	NOT RELATED	GRADE 2	AE	NONE
						咳嗽	1016	7 D	NOT RELATED	GRADE 1	AE	INTERRUPTED
						大葉性肺炎	1016	7 D	NOT RELATED	GRADE 3	AE	INTERRUPTED

APPENDIX 48　　重篤な有害事象を発現した被験者の一覧（007 試験、治験薬投与例）

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
NRF	1706-00102	WHITE	10 mg/kg	MALE	5[redacted]	便秘	25		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	25		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	25		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	30	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内乾燥	58	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	58	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						流涙増加	89	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	89	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼窩周囲浮腫	89	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	99	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼の異常感	102	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	115	30D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	115		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	144	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	158	3D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						インフルエンザ	172	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	215	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	215	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	215	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						背部痛	243	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	271	47D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	282	36D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						無力症	283	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	283	5D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸困難	283	7D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						多汗症	283	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						倦怠感	283	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	283	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頻脈	283	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						頻呼吸	283	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋肉痛	284	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱性好中球減少症	285	48.0H	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低酸素症	285	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腹部膨満	286	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						紅斑	286	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						点状出血	286	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性浮腫	288	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発疹	288	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						下痢	289	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疲労	380	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	404	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	404	19D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	412	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	426	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	436	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	450	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	450	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	506	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	534		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	534		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	548		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	562	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	562	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳痛	562	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	576	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						基底細胞癌	590		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						術後創感染	632	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						痂皮	646	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	648	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
NRF	1708-00151	WHITE	10 mg/kg	FEMALE	6[redacted]	クロストリジウム・ディフィシレ感染	3	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低マグネシウム血症	14	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低ナトリウム血症	14	48.0H	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						低リン酸血症	14	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						顎痛	14	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症	14	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	15	3D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低ナトリウム血症	15	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	16	46.9H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低ナトリウム血症	18		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	29	59M	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
NRF	1713-00030	WHITE	10 mg/kg	MALE	4[redacted]	高血糖	6	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	29	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						多汗症	29	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	30	28D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高血圧	36	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	41	3D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肺塞栓症	41	3D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	42	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血栓症	42	9D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	44	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	44	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	44	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	50	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	50	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	50	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	57		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	64	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	74	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	74	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						異型肺炎	93	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	93	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	93	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	99	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位漏出	99	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	120	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	131	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
SRI	1702-00128	WHITE	10 mg/kg	FEMALE	6[redacted]	疲労	2		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入部位内出血	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	22		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	22	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	43		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	43		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	60		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	60	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢不快感	78	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	80	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	80	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	81	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						蜂巣炎	85	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						紅斑	85	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	92	50D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性浮腫	92	162D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	92	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発疹	99	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						RS ウイルス肺炎	154	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	155	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高マグネシウム血症	157	23.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	197	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	197	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	274	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						足関節部骨折	301	37D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	337	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	380	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	380	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨盤痛	380	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	394	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	449		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	449		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢不快感	473		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	473		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
SRI	1705-00002	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	7[redacted]	高血糖	2		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	2	18D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低ナトリウム血症	9	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	17	20D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気管支炎	20	30D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	23	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						痛風性関節炎	32	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	44	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	49	4D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						顎痛	50	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	53	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	53		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痛風	54	37.7H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カリウム血症	55	30.6H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	58	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						痛風	58	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋肉痛	58	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	58		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腎不全	58	2D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						軟部組織感染	82		RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
SRI	1710-00201	ASIAN	10 mg/kg	FEMALE	[redacted]	不安	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	2	111D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	2	111D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	2	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	2	407D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						倦怠感	5	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	5	108D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	12	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	14		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						貧血	21		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	21	133D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	29	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胆嚢炎	39	7D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腹痛	49	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						挫傷	84	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	84	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	97	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	98	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	126	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	138		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	138		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	138	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
SRI	1713-00026	WHITE	10 mg/kg	MALE	6[redacted]	薬疹	2	9D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						疲労	3		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	16	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ナトリウム血症	22	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						失神	29	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	30	36.5H	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カリウム血症	37	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ナトリウム血症	37	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	38	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	39	371D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	58	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						汗疹	58	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	72	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ナトリウム血症	79	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	86	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	86	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	107	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中乳酸脱水素酵素増加	120		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	135	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	156	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	163	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	175	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
SRI	1713-00031	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	8[redacted]	高血糖	1	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	5	1.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	7		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	8	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	29	49D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚢胞	34		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	35		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	56	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	60		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	60	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	63	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	64		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	77		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	77	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	98	23D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						過敏症	104		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霧視	110	146D	RELATED	GRADE 1	AE	DOSE REDUCED	
						高血圧クリーゼ	112	9D	RELATED	GRADE 4	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						下痢	117	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	119		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	120	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	120		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血中カリウム減少	126	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	126	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中尿酸増加	140	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	141	79D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血中カリウム減少	161	95D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	161		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	178		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	178	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	295	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋痙縮	340		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	340	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	408		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
ESRD	1702-00126	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	嘔吐	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	43	72D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						好中球減少症	43	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	49	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						局所腫脹	59	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	71	9D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	99	15D	RELATED	GRADE 4	AE	DOSE REDUCED	
						下痢	115		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
ESRD	1705-00001	WHITE	10 mg/kg	FEMALE	4[redacted]	偶発的過量投与	2	2.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ球減少症	2	141D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	4		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	6		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	9	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	16	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	21	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	21	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	23	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ブドウ球菌性菌血症	23	11D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						甲状腺機能亢進症	27	32D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						悪心	36	48.0H	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						アラニンアミノトランスフェラーゼ増加	38	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	38	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格不快感	38	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	38	105D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚剥脱	80	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	85	16D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	86	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	87		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節痛	115	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	115	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	115	9.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						クッシング様症状	143	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	143	29D	RELATED	GRADE 2	AE	DOSE REDUCED	
						リンパ球減少症	157	180D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						皮膚剥脱	166	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	171	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	172	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	172	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格不快感	172	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	172		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	183	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	185	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	200	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	200	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	217	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						挫傷	227	35D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	254	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						背部痛	262	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						上気道感染	305	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
ESRD	1705-00003	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	3[redacted]	霧視	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	23		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						体位性めまい	30	38D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	30	38D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	30	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	37	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	44	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						リンパ球減少症	51	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	51	12D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高カルシウム血症	58	7D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	58		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	67		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱性好中球減少症	68	4D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
ESRD	1706-00108	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	5[redacted]	筋骨格系胸痛	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	2	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	3	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	3	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	8		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	8	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	16	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	16	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低マグネシウム血症	16	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高リン酸塩血症	22	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	29		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	70		RELATED	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/NOT RESOLVED
						局所腫脹	70	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						頚部痛	70	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低カリウム血症	71	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	81	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	127	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
ESRD	1708-00154	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	5[redacted]	貧血	1	78D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中尿素増加	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	1	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	8	32.7H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						高血糖	8	13.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高カリウム血症	8	32.7H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高カリウム血症	8	13.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低カルシウム血症	8	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	9	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	9	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	14	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	22	25D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						不眠症	22	50D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	25	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	36	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						注入に伴う反応	43	2.1H	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						白血球減少症	43	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	50	11D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高血糖	51	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	51	36.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	53	2D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	55	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	58	18.8H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						低カルシウム血症	59	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	61	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	71	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	71	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	71		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球増加症	71	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板増加症	71	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	76	46.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	78	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	78	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発疹	78	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						外陰腟不快感	78	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	79		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	85	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球増加症	85	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	90	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	90	15.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内炎	90	24D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重増加	91	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	92	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	92	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						変形性関節症	92		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	97	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	97	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						瘻孔	99		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	99	2.8H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	99	11.0H	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						高カリウム血症	99	10.9H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						低カルシウム血症	99	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低ナトリウム血症	99	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔内痛	99	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	106	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	113	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	113		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						靱帯捻挫	115	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						創傷	115	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	127	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						労作性呼吸困難	127		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低アルブミン血症	141	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	148	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道分泌増加	148	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	148	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	148	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	155	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚真菌感染	166	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	169	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	169		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	183	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						貧血	197	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	197		RELATED	GRADE 2	AE	DOSE REDUCED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						インフルエンザ	204	6D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺炎	204	6D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カリウム血症	205	9.5H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	211		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	211	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カリウム血症	211	8.8H	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						高カリウム血症	211	14.1H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カリウム血症	225	14D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						そう痒症	239		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	249	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	267	24.6H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						胸痛	275	6.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	281	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	295	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	309		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胸痛	337	38.5H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高カリウム血症	337	2.5H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED WITH SEQUELAE
						高カリウム血症	337	21.4H	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
ESRD	1710-00202	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	[redacted]	不安	12	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胸部不快感	12	43.5H	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						胸部不快感	12	43.5H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	12	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	49	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
ESRD	1714-00176	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	末梢性感覚ニューロパチー	2		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房細動	23	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	23	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心拡大	23		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻脈	23	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						四肢静脈血栓症	23		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉	27	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	29	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気分変化	30	1.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	58	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	71	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	127	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						処置後感染	127	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	156	33.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						臍径ヘルニア	180	70D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Renal Function Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
NOT ASSIGNED	1706-00103	BLACK OR AFRICAN AMERICAN	10 mg/kg	MALE	5[redacted]	巣径部痛			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED
						骨溶解			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/NOT RESOLVED

APPENDIX 49　　重篤な有害事象を発現した被験者の一覧（009 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-BD	1902-00167	WHITE	10 mg/kg	MALE	7[redacted]	錯乱状態	2	9.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯乱状態	30	9.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腕骨骨折	85	8D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						硬膜下血腫	85	8D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性ニューロパチー	148		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						歯肉潰瘍	299	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	1909-00023	WHITE	10 mg/kg	FEMALE	7[redacted]	動悸	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口渇	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口渇	14		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	15	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	34		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						耳痛	37	12.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	40	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	46	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	46		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	92		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嚥下障害	103	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	124		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	126		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	127	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血管痛	137	12.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	169	161D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カリウム血症	176	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹部膨満	251	81D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	251	81D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	252	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	254		RELATED	GRADE 2	AE	DOSE REDUCED	
						発熱	254		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	254	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	264		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	267	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣出血	307	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						イレウス	320	17D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腹部膨満	333	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	333	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	333	4D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪心	333	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						鼻出血	342		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	344		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						尿中クレアチニン減少	369		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿中蛋白陽性	369	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						手首関節骨折	486		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	491		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						カテーテル留置部位浮腫	491		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	533	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	537		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	561		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	575		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	610		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	645		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						胸痛	652		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	708	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯乱状態	724	33D	RELATED	GRADE 2	AE	DOSE REDUCED	
						意識レベルの低下	724	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	724	33D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						舌痛	724		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口渇	724		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	729	28D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	758		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	1909-00098	WHITE	10 mg/kg	FEMALE	8[redacted]	収縮期血圧上昇	1	33M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低カルシウム血症	4	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	11	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	14	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						失神	16	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						咳嗽	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						欲求不満	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紫斑	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	40	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	40	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						末梢性浮腫	40		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						低カリウム血症	45	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	1912-00160	WHITE	10 mg/kg	FEMALE	[redacted]	高血糖	4		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	15		RELATED	GRADE 1	AE	DOSE REDUCED	
						味覚異常	15		RELATED	GRADE 1	AE	DOSE REDUCED	
						食欲亢進	15		RELATED	GRADE 1	AE	DOSE REDUCED	
						不眠症	15		RELATED	GRADE 2	AE	DOSE REDUCED	
						精神状態変化	15		RELATED	GRADE 2	AE	DOSE REDUCED	
						発声障害	36		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚病変	50	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	57		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	64	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	64	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	85		RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						喉頭炎	88	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						皮膚病変	113		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼部腫脹	123	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						麦粒腫	123	47D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	219		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						上気道感染	219	65D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	247	37D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	250		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						関節痛	283		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腱痛	283		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	295	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						上気道感染	295	43D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格痛	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	393		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	401	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	409	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	423		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	423	97D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	431		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼瞼紅斑	450	28D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	450		RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						椎間板変性症	477		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						複視	485	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高血糖	519		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-BD	1919-00114	WHITE	10 mg/kg	MALE	[redacted]	悪心	2	427D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	9	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	16	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	19	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	19	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	24	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	26	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	31	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	40	264D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蕁麻疹	40		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	47	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	50	527D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	51	25D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						下肢静止不能症候群	62	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	76	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						激越	86		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	87	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼刺激	89	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						低ナトリウム血症	89	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	94	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	97	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						蜂巣炎	101		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						耳感染	101	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	107		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	107		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	108	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	118	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	149	163D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	171	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	178	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						限局性感染	218	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	218	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	227	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	261		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						限局性感染	261	51D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	283	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	283		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	290	78D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	291	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	297	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高カリウム血症	346	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	347	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	354		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	399	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪夢	399	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	403	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	425	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	451		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						癰	477	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痛風	477		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	477		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	500		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	502		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高カルシウム血症	507	67D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	514	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	558		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血尿	563		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	563		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	563		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	573		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪寒	573		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						発熱	573		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	573	8D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						心房細動	575		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						血中クレアチニン増加	576		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						腎不全	576		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	577		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
E-BD	1926-00031	BLACK OR AFRICAN AMERICAN	10 mg/kg	FEMALE	5[redacted]	呼吸困難	2	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	5	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	8	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ球減少症	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						重感	8	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	8	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	11	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	11	10D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼感染	20	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	32	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	50	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	68	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						結膜炎	71	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼感染	71	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	74	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	74	82D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	74	12D	RELATED	GRADE 1	AE	DOSE REDUCED	
						高血圧	85		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	91	9D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	99	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						熱感	106	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球減少症	106	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	116		RELATED	GRADE 2	AE	DOSE REDUCED	
						上気道感染	148	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	183		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高マグネシウム血症	188	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ナトリウム血症	188	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪心	188	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						嘔吐	188	14D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	191	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	211		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	1927-00176	WHITE	10 mg/kg	FEMALE	[redacted]	低カルシウム血症	8	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	15	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						下痢	20	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	22	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	22	108D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	25	5D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	29	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	29	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	32	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	32	40D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	36	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	40	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	40	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	60	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	64	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	79	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	96	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	97	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	97	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	97	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	113	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アラニンアミノトランスフェラーゼ増加	116	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	130	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	138	46D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	148	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	148	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	148	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	148	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	148	24.0H	NOT RELATED	GRADE	AE	DOSE NOT CHANGED	
						足部白癬	148	72D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	156	42D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	156	13D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	156	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						非心臓性胸痛	156	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	169	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	169	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	169	135D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	176	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	176	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	180	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	183	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	198	6D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	201	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	201	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	204	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アスパラギン酸アミノトランスフェラーゼ増加	204	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中アルカリホスファターゼ増加	204	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨痛	204	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	211	21D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	211	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	211		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内乾燥	218	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	218	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	219	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	223	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						うつ病	223	94D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	226	6D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アスパラギン酸アミノトランスフェラーゼ増加	226	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	232	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	235	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アラニンアミノトランスフェラーゼ増加	239	8D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスパラギン酸アミノトランスフェラーゼ増加	239	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	239	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	239	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	253	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	254	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嘔吐	255	6D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						アラニンアミノトランスフェラーゼ増加	260	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内乾燥	261	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	267	100D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	275	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						大腸炎	284	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						大腸炎	288	16D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						四肢痛	338		NOT RELATED	GRADE	AE	DOSE NOT CHANGED	
E-BD	1928-00025	WHITE	10 mg/kg	MALE	6[redacted]	しゃっくり	4	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						偶発的過量投与	26	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	26	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血中クレアチニン増加	26	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						失神	26	3D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						振戦	26		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創合併症	26	42D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重増加	86	43D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						腹部膨満	110	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	110	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸水	110		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						洞性徐脈	110	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	111	11D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						紅斑	113	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	114	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						季節性アレルギー	115	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心房粗動	121	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	254	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						紅斑	282		NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						蜂巣炎	344	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	1944-00185	NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	10 mg/kg	MALE	[redacted]	腹部膨満	15	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	22	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	44	211D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	50	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	50		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						夜間頻尿	50		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	64		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺水腫	64	191D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重増加	64	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	81	6D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						うっ血性心不全	81	6D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						食欲減退	94	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	106		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	1955-00067	WHITE	10 mg/kg	MALE	8[redacted]	末梢性ニューロパチー	1	5M	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷	4	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	15		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋力低下	15		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	22	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	23	2D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	29		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多発ニューロパチー	43		RELATED	GRADE 2	AE	DOSE REDUCED	
						蜂巣炎	192	6D	NOT RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						認知障害	260		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						冠動脈疾患	260	52D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性浮腫	358		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	358		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-BD	1989-00164	WHITE	10 mg/kg	MALE	6[redacted]	ヘモグロビン減少	7		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						敗血症性ショック	13	2D	RELATED	GRADE 4	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						低ナトリウム血症	28	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	29	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						活性化部分トロンボプラスチン時間延長	42	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	64	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肋骨骨折	64	120D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	74	2D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						乳酸アシドーシス	74	2D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	UNKNOWN
						リパーゼ増加	74		RELATED	GRADE 3	AE	DOSE REDUCED	
						高血糖	76		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	84	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	4901-00059	WHITE	10 mg/kg	FEMALE	5[redacted]	貧血	1	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	1	39D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	4	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	12.6H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	12	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						貧血	19	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔内出血	19	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						直腸出血	19	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	19	48.0H	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	22	3D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						鼻出血	25	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	25	3D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	28	4D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	32	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞性骨髄腫	32	39D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						血小板減少症	32		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						貧血	37	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	45		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	46	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎感染	46		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	47	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	58		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	4902-00052	WHITE	10 mg/kg	FEMALE	7[redacted]	無力症	36		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						感染	41	10D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						錯感覚	50		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	74	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	74	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	74	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	88	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	110	7D	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED WITH SEQUELAE
						感染	110	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴力低下	113	64D	RELATED	GRADE 2	AE	DOSE REDUCED	
						顔面浮腫	116	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	148		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	183	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						麦粒腫	351	22D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						インフルエンザ	459	9D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	4902-00099	WHITE	10 mg/kg	FEMALE	6[redacted]	高血糖	8	21D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	29		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	29	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	29	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	43	49D	RELATED	GRADE 2	AE	DOSE REDUCED	
						発熱	50	11D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	71	263D	RELATED	GRADE 1	AE	DOSE REDUCED	
						コントロール不良の糖尿病	112	7D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						頚部痛	344	35D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	4905-00032	WHITE	10 mg/kg	MALE	7[redacted]	骨痛	1	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	6	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支障害	18	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	18	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						体重減少	22	31D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	25	29D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	43	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	46	46D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	53		RELATED	GRADE 2	AE	DOSE REDUCED	
						体重減少	53		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						偶発的過量投与	64	10.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	64		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食道炎	68	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						偶発的過量投与	74	11.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	92		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	92	8D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-BD	4915-00041		10 mg/kg	FEMALE	7[redacted]	筋骨格痛	-18	12D	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						処置後出血	-6	48.0H	NOT APPLICABLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血腫	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	15	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	15	101D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						無力症	29		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	31	97D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						胸水	36	4D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						蟻走感	106		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	116	110D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脱毛症	122		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	148	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血腫	148	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	171	4.3H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	183	124D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血管痛	197	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	236	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						性器脱	268	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4915-00055	OTHER	10 mg/kg	FEMALE	[redacted]	嘔吐	2	190D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						食欲減退	8	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	12	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	12		RELATED	GRADE 2	AE	DOSE REDUCED	
						失神	12	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						喘鳴	12	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	15		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	18	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	19	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不安	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						浮動性めまい	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	58		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	58	4D	RELATED	GRADE 3	SAE	DOSE REDUCED	RECOVERED/ RESOLVED
						全身健康状態低下	58	131D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カルシウム血症	58	5D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	59	154D	RELATED	GRADE 1	AE	DOSE REDUCED	
						無力症	85	29D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋力低下	85	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						反射消失	92		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支閉塞	106	86D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	106	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	107	14D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						低カリウム血症	113	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	113	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	113	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重減少	113	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼瞼炎	148	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	148	44D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ヘルペスウイルス感染	148	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肺感染	148	44D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低音性連続性ラ音	148	44D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						アスペルギルス感染	162	30D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪性新生物進行	162		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						腎不全	162	30D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
E-BD	4915-00087	OTHER	10 mg/kg	MALE	[redacted]	無力症	8	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	8	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	10	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						慢性気管支炎	11	95D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋痙縮	21	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	28	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頚腕症候群	37	132D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	42	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頚部痛	42	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	42	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷	45	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	49	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	49	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	52	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発疹	52	12D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸困難	58	89D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						結膜炎	63	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	63	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	66	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						神経痛	70	225D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						気管支炎	83	5D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						筋骨格系胸痛	91	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面浮腫	115	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	115	96D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	115	82D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ミオパチー	126	57D	RELATED	GRADE 3	AE	DOSE REDUCED	
						錯感覚	126		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	126	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	128	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下痛	129	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	136	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	157	26D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠障害	157	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	168	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						そう痒症	168	57D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	182	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	182	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						結膜炎	196	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	196	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						創傷	210	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	224	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	238	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						反射消失	252	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	265	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	280	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	280	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	280	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	294	15D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						悪心	309	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	309		RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						血小板減少症	323		NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						背部痛	336	127D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						基底細胞癌	365	52D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						基底細胞癌	365	52D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						気管支炎	383	40D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	427	36D	NOT APPLICABLE	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	4915-00152	OTHER	10 mg/kg	MALE	6[redacted]	肝炎	3	19D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胆汁うっ滞	8	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肝細胞損傷	8	18D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	8	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胸痛	12	15D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	36	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						睡眠障害	36	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻脈	36	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	43	127D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼡径部痛	43	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	50		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻出血	114	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	131	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻閉塞	138	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	176	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	239	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	277	9D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						気管支閉塞	316	33D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	316	33D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	316		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	323		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	327	22D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	375	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支痙攣	403	24.0H	NOT APPLICABLE	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	403	32D	NOT APPLICABLE	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	4930-00018	WHITE	10 mg/kg	FEMALE	6[redacted]	血小板減少症	32	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						帯状疱疹	36	28D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板減少症	36	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						咳嗽	41	2D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	41	2D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						咳嗽	49	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						急性腎不全	130	9D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-BD	4930-00157	WHITE	10 mg/kg	FEMALE	7[redacted]	結節性紅斑	23	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	65	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						結節性紅斑	65		RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						背部痛	101	122D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リンパ管炎	114	25D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						膵炎	161	42.8H	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4933-00037	WHITE	10 mg/kg	MALE	6[redacted]	骨痛	9		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	11		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						片耳難聴	15	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	16		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ECOG パフォーマンスステータス悪化	26		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						便秘	30	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	49	14D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	52	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	52	7D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	52	23D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺炎	74	10D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						貧血	75	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	75	4D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板減少症	75		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症	96	10D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4933-00044	WHITE	10 mg/kg	MALE	5[redacted]	骨痛	3	12.8H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	3	12.8H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	5	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	5	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膀胱炎	5	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	8	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	14	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	16	11D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						激越	30	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	30	67D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹部膨満	34	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	34	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	39	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	44	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	51	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	65	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	65	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	72	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	80	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	80	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	80	6D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性感覚ニューロパチー	107	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						四肢痛	114	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	114		RELATED	GRADE 1	AE	DOSE REDUCED	
						便秘	118	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	128	32D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						咳嗽	132	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	132	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	135	4D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	144	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	207	17D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4934-00009	WHITE	10 mg/kg	MALE	6[redacted]	貧血	1	464D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板数減少	1	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	4	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	5	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発声障害	9	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	9	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	9	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球数減少	12	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	17	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	17	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	22	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	29	436D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	36	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	50	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	64	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						帯状疱疹	86	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板数減少	116	13D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	132	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	135	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	135	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻尿	137	27D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	137	48.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						血小板数減少	138	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	140	20D	NOT RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カリウム血症	140	20D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	140	20D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						低カルシウム血症	143	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯感覚	198	99D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	223	32D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	254		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						骨痛	267	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肋骨骨折	267	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	324	13D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4934-00016	WHITE	10 mg/kg	MALE	7[redacted]	貧血	4	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	11	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	22	48.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	25	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	32	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	39	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	43	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	46		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	71	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板数減少	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	92		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						多汗症	92		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低クロール血症	92	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低ナトリウム血症	92	48.0H	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						熱傷	92	4D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						不眠症	95	12D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						筋肉痛	95		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	106		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	106		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	127	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疼痛	127	11D	RELATED	GRADE 1	AE	DRUG WITHDRAWN	
E-BD	4934-00034	WHITE	10 mg/kg	FEMALE	6[redacted]	便秘	11	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	25	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	35	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	36	7D	RELATED	GRADE 2	AE	DOSE REDUCED	
						貧血	42	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						乳房腫瘤	43	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	43	24.0H	RELATED	GRADE 3	AE	DOSE REDUCED	
						錯感覚	43	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	46	4D	RELATED	GRADE 1	AE	DOSE REDUCED	
						錯感覚	46	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	50	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	50	3D	RELATED	GRADE 3	AE	DOSE REDUCED	
						四肢痛	50	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口内炎	50	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	53	101D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	53	11D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性ニューロパチー	53	116D	RELATED	GRADE 1	AE	DOSE REDUCED	
						高血糖	67	8D	RELATED	GRADE 3	AE	DOSE REDUCED	
						無力症	71	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						熱傷	71	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	88	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎痛	88	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	90	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	92	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	92	57D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肛門直腸不快感	111	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						熱傷	111	27D	NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						性器灼熱感	116	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	130	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						口内炎	132	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鉄欠乏性貧血	137	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	156	20D	RELATED	GRADE 1	AE	DOSE REDUCED	
						神経痛	169	29D	RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	176		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	176	7D	RELATED	GRADE 3	AE	DOSE REDUCED	
						高血糖	197	28D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性ニューロパチー	225	56D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	238	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						胃腸炎	238	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	281	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	295	14D	RELATED	GRADE 3	AE	DOSE REDUCED	
						背部痛	465	25D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						血小板数減少	484	24.0H	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
E-BD	4934-00084	WHITE	10 mg/kg	FEMALE	5[redacted]	好中球減少症	4	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	22	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	43	42D	RELATED	GRADE 3	AE	DOSE REDUCED	
						口内炎	43	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						麦粒腫	53	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	54		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	73	34D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道の炎症	85	43D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						発熱	89	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	148	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎	158	26D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						高血糖	365		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	505		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	512	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
E-BD	4934-00104	WHITE	10 mg/kg	MALE	[redacted]	貧血	1	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	1	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	1	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	1	92D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	11	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	22	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	25	68D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	43	50D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	43	50D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						炎症	43	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	43	50D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						発熱	43	20D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						歯膿瘍	43	24.0H	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						振戦	43	50D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						視力低下	43	50D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						円柱尿	85	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	102	16D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-BD	4942-00133	WHITE	10 mg/kg	MALE	7[redacted]	貧血	4	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	8	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	11	43D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	14	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	19	15D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						錯感覚	60	17D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	71	13D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						無力症	74	10D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						錯感覚	77	100D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	4943-00106	WHITE	10 mg/kg	MALE	6[redacted]	発熱	2	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	29	75D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	33	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	33	71D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						貧血	46	58D	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						疲労	46	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	50	54D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						間質性肺疾患	64	39D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	FATAL
						悪性新生物進行	103	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
E-BD	4946-00101	WHITE	10 mg/kg	FEMALE	6[redacted]	高尿酸血症	-8	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	1	13D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カルシウム血症	4	154D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨痛	8	63D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	21	137D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	21	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	32	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	39	32D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嘔吐	39	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						クッシング様症状	66	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						顔面浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						眼窩周囲浮腫	66	27D	RELATED	GRADE 2	AE	DOSE REDUCED	
						骨痛	71	87D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	96	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	96	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高クレアチニン血症	96	62D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	99	59D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						真菌性肺炎	102	56D	RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
E-BD	4947-00060	WHITE	10 mg/kg	MALE	6[redacted]	貧血	5	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	12	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	16	7D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						貧血	23	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	23	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	30	3D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板数減少	33	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	37	10D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						血小板数減少	51	4D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	53	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	53	7D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	74	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	75	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	79	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肝腫大	86	23D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	86	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	90	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	97	11D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板数減少	115	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	118	11D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						咳嗽	202	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	258	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
E-BD	4947-00131	WHITE	10 mg/kg	MALE	6[redacted]	表在性静脈炎	28	22D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						サイトメガロウイルス感染	84	16D	RELATED	GRADE 1	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						紅斑	133	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢静脈血栓症	133	44D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						サイトメガロウイルス感染	149	20D	RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
E-BD	4950-00091	WHITE	10 mg/kg	MALE	7[redacted]	貧血	1	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発声障害	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	14	52D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	14	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	27	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	27	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	34	37D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	38	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						サイトメガロウイルス性大腸炎	41	25D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						食欲減退	41	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	70		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
E-BD	4962-00086	WHITE	10 mg/kg	FEMALE	7[redacted]	下気道感染	7	58D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	22	260D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	32	18D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						便秘	34	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	35	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	35	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	50	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	68	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						坐骨神経痛	105	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						帯状疱疹	116	33D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	130		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	365	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下気道感染	456	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腎不全	565	22D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						貧血	566	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
E-BD	4963-00070	WHITE	10 mg/kg	MALE	6[redacted]	血中ブドウ糖増加	3	3D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						高血糖	27	24.0H	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						末梢性浮腫	39	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	43	5D	RELATED	GRADE 3	AE	DOSE REDUCED	
						皮膚潰瘍	56	29D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	70	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	72	173D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮膚剥脱	84	26D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						注射部位内出血	109	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						B型肝炎	158		NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
						血中トリグリセリド増加	244		NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
E-BD	4967-00166	WHITE	10 mg/kg	FEMALE	7[redacted]	血小板数減少	29	4D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						末梢性浮腫	107	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	142		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	158	11D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板数減少	169		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						食欲減退	199	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	264		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						器質化肺炎	302	12D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
BD	1927-00125	BLACK OR AFRICAN AMERICAN	0	FEMALE	[redacted]	振戦	7	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	11	12D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						筋肉痛	11	14D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	11	12D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	15	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	22	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	22	48.0H	RELATED	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板数減少	22	3D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	22	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎不全	23	90D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						副鼻腔うっ血	23	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	24	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	24	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉痛	25	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	26	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低カリウム血症	29	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	29	3D	NOT RELATED	GRADE 4	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	32	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	32	46D	RELATED	GRADE 3	AE	DOSE REDUCED	
						肺炎	38	35D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						呼吸音異常	72	41D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口唇乾燥	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	72	41D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						頻脈	72	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	112		NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	1927-00168	BLACK OR AFRICAN AMERICAN	0	MALE	7[redacted]	筋骨格系胸痛	4		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高尿酸血症	11	13D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						顎痛	11		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						聴力低下	19		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						第７脳神経麻痺	19		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪性新生物進行	23	44D	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	1955-00035	ASIAN	0	MALE	5[redacted]	便秘	2	401D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	2	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	22	381D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹部膨満	32	371D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	38	386D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体液貯留	38	61D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						多飲症	38	386D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低音性連続性ラ音	38	386D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						乾癬	52	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						帯状疱疹	59	414D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	64	381D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	74	411D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体液貯留	99		RELATED	GRADE 1	AE	DOSE REDUCED	
						錯乱状態	108	28D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	113	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	113	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						眼痛	136		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	147		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						リパーゼ増加	147		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						小腸閉塞	147	10D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						肺炎	195	12D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						乾癬	227		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	367	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						眼球浮腫	437		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	465	65D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋梗塞	474	2D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						狭心症	483	3D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						副鼻腔障害	548		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体重増加	548		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	605		NOT RELATED	GRADE 1	AE	DOSE REDUCED	
						肺炎	662	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	670	4D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						胃排出不全	696	3D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
BD	1972-00148	WHITE	0	MALE	7[redacted]	おくび	8	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	8	102D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	8	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	11	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	22	135D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	22	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	28	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気分変化	31	79D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						湿性咳嗽	33	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	37	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	40	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						呼吸困難	40	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	40	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	40	6D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道うっ血	40	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						喘鳴	40	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	46	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	50	57D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	56	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃食道逆流性疾患	71	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	77	25D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪寒	80	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	81		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	82	12D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						疲労	83		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ	83	5D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						発熱	83	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	97	94D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	102	116D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高ビリルビン血症	102	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	105	112D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	106		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	107	3D	RELATED	GRADE 2	AE	DOSE REDUCED	
						気分変化	110		RELATED	GRADE 1	AE	DOSE REDUCED	
						錯感覚	110	38D	RELATED	GRADE 1	AE	DOSE REDUCED	
						錯感覚	110		RELATED	GRADE 1	AE	DOSE REDUCED	
						基底細胞癌	117	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						扁平上皮癌	117	24.0H	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						高ビリルビン血症	124	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ビリルビン血症	145	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	157		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	217		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						視力障害	399		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	405	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
BD	1984-00078	BLACK OR AFRICAN AMERICAN	0	FEMALE	7[redacted]	筋痙縮	11	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	14	225D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						過小食	21	89D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	25		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	32		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	43		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃炎	47	7D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
						食道炎	47	7D	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						錯乱状態	51	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						着色尿	64	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	84	45D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	85	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	109		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	109		RELATED	GRADE 1	AE	DOSE REDUCED	
						乳房腫瘤	128		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	148		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮腫	172	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	228		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	228		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						腹痛	240		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						洞性頻脈	246		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						小腸閉塞	253	15D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
BD	1984-00110	BLACK OR AFRICAN AMERICAN	0	FEMALE	4[redacted]	血中クレアチニン増加	8	3D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						浮腫	8	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						変形性関節症	8		RELATED	GRADE 2	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						急性腎不全	8	4D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						子宮頚部上皮異形成	17		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						体液貯留	21		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	42	84D	RELATED	GRADE 1	AE	DOSE REDUCED	
						背部痛	63	63D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カリウム血症	109	33D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	126	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	126	8D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						下痢	129		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性ニューロパチー	224		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節炎	240		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上顎炎	249		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歩行障害	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	280		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格痛	308		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	340	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻咽頭炎	340	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						口腔咽頭痛	340	19D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						低マグネシウム血症	428		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	484		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	484		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
BD	4902-00072	WHITE	0	MALE	6[redacted]	起立性低血圧	1	105D	RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						血小板減少症	1	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						尿路感染	8		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	22	70D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	31	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	33	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						下痢	33	11D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						細菌性肺炎	74	15D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						血小板減少症	92	14D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
BD	4902-00135	OTHER	0	FEMALE	7[redacted]	無力症	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	67	239D	RELATED	GRADE 1	AE	DOSE REDUCED	
						筋骨格系胸痛	340	18D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						肺障害	342	16D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
BD	4905-00030	WHITE	0	MALE	6[redacted]	無力症	4	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						しゃっくり	4	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高クレアチニン血症	4	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋肉内出血	77	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	88	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	109	54D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	109		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	130	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	130	156D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	152	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	165	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	215	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	257	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	263	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	271	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	285	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨盤痛	291	58D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白内障	305	58D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						発熱	310	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						排尿困難	313	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	341	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	366	35D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顎痛	372	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	427		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	439	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚乾燥	505	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻炎	512	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	561	36D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						そう痒症	561	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻漏	568	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	596	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	653	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						憩室炎	660	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
BD	4905-00124	WHITE	0	FEMALE	6[redacted]	紅斑	3	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	8	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						粘膜の炎症	15	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	18	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						骨痛	24	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	28	4D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	34	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼乾燥	43		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	63	65D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	64	134D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	64	134D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	67	61D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						関節痛	74	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	74		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	74	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						顔面浮腫	78	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	85	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	91	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注射部位紅斑	95	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	113	8D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪心	114	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	114	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	116	12D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						麦粒腫	137	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						骨盤痛	145	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	146	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	151	398D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	155	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	157	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						尿路感染	188	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気管支炎	207	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	225	70D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	225	77D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋痙縮	253	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯感染	280	22D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						筋骨格系胸痛	309		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸痛	349		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	350	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼瞼炎	355	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	365	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ほてり	390	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	390	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	421	64D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	433	24D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鼻咽頭炎	441	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	441	16D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						視力低下	456		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯痛	506	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
BD	4905-00149	WHITE	0	FEMALE	[redacted]	関節痛	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						単ニューロパチー	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	1	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	4	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	21D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						インフルエンザ	20	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	22	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脂肪腫	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	29	27D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	29	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	32	4D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	36		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	50	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	55		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	59	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	64	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	68		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						変形性関節症	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						歩行障害	125	9D	NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						形質細胞性骨髄腫	167	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4905-00179	WHITE	0	FEMALE	8[redacted]	貧血	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						食欲減退	1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						労作性呼吸困難	1		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						細菌性腎盂腎炎	20	5D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						硬膜下血腫	36	19D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						肺炎	43		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
BD	4915-00082	OTHER	0	MALE	7[redacted]	無力症	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	29	10D	RELATED	GRADE 1	AE	DOSE REDUCED	
						心肺停止	38	54M	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4930-00090	WHITE	0	MALE	6[redacted]	帯状疱疹	-9	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	22	4D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	137	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	493		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	505		RELATED	GRADE 1	AE	DOSE REDUCED	
						血中マグネシウム減少	533		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	575		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢損傷	619		NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
BD	4933-00053	WHITE	0	MALE	7[redacted]	不眠症	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	12	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	23	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	34	14D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	50	40D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						口腔咽頭痛	53	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房粗動	57	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						疲労	64	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						甲状腺機能低下症	85	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	96	16D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						下痢	153	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	153	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	153	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
BD	4934-00003	WHITE	0	MALE	6[redacted]	貧血	1	84D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	1	2D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	1	16D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	1	2D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	4	18D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						白血球数減少	4	18D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	9	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	10	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						湿性咳嗽	13	12D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	13	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板数減少	17	20D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	22	21D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球数減少	22	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球数減少	24	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	29	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	37	6D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						肺炎	37	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						白血球数減少	39	24D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	43	69D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	43	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	53	11D	NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						血小板数減少	63	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						敗血症性ショック	63	15D	RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						貧血	85	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	85	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	92	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						貧血	95	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	95	28D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低カルシウム血症	106	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	109		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便通不規則	113	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	113	4D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						白血球数減少	113	4D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						好中球減少症	123	7D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	123	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球数減少	123	8D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						骨痛	127	11D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	130		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						白血球数減少	134		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	137		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	148	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯感覚	148	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
BD	4934-00076	WHITE	0	FEMALE	7[redacted]	非心臓性胸痛	17	15D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						肺高血圧症	17	15D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						発熱	17	15D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						肺炎	24	36D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						呼吸困難	40	80D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	40	80D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						末梢性浮腫	40	80D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						肺高血圧症	40	80D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
BD	4934-00103	WHITE	0	MALE	6[redacted]	高血圧	1	73D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						急性肺水腫	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						関節炎	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						悪心	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱	51	14D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						急性腎不全	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						敗血症	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						頻脈	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						嘔吐	51	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						悪性新生物進行	73	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4934-00112	WHITE	0	FEMALE	7[redacted]	貧血	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	1	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	1	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	1	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	8	49D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	11	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	11	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						傾眠	11	46D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						麻痺性イレウス	14	43D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板数減少	14	43D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						敗血症	56	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4935-00088	WHITE	0	MALE	5[redacted]	四肢痛	43	26.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						霰粒腫	59	34D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						そう痒症	85	4D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	116	5M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	116	95D	RELATED	GRADE 1	AE	DOSE REDUCED	
						霰粒腫	169	43D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						四肢痛	208	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						直腸出血	269	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	311	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺臓炎	333	48D	RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
BD	4935-00174	WHITE	0	FEMALE	6[redacted]	関節痛	22	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						喘鳴	22	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						リンパ浮腫	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	64	22D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	66	41D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	148	50D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						手首関節骨折	204	40D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						手首関節骨折	223	4D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						錯感覚	271	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	327		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ラ音	383	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						インフルエンザ様疾患	397	14D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
BD	4939-00123	WHITE	0	FEMALE	6[redacted]	形質細胞腫	17	31D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	UNKNOWN
						霧視	17	31D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	UNKNOWN
BD	4942-00075	WHITE	0	MALE	5[redacted]	白血球減少症	1	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						好中球減少症	1	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						そう痒症	2	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	2	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						白血球減少症	8	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	11	11D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	26	46.5H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	29	2D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	32	10D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	43	2D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	46	6D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血圧	53	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	53	10D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						血小板減少症	64	3D	RELATED	GRADE 2	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	78	36D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						肺炎	88	9D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						形質細胞性骨髄腫	109	6D	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4944-00130	WHITE	0	MALE	8[redacted]	血小板減少症	11	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板数減少	15	5D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						好中球減少症	28	6D	RELATED	GRADE 3	AE	DOSE REDUCED	
						血小板数減少	29	22D	RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	39	198D	NOT RELATED	GRADE 2	AE	DOSE REDUCED	
						血小板数減少	60	12D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						血小板数減少	85	6D	RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						下痢	88	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低血圧	89	99D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	90	98D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						好中球減少症	102	3D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	126	62D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血胸	144	24.0H	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						肋骨骨折	144	5D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						好中球減少症	160	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
BD	4946-00049	WHITE	0	MALE	7[redacted]	上腹部痛	7	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						倦怠感	7	22D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						傾眠	7	5D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	22	3D	RELATED	GRADE 3	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						末梢性感覚ニューロパチー	22		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	22	7D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	26	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						嘔吐	26	7D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	29	147D	NOT APPLICABLE	GRADE 1	AE	DOSE NOT CHANGED	
						倦怠感	29	148D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血小板減少症	29	116D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						大腿骨骨折	40	72D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
BD	4947-00068	WHITE	0	FEMALE	[redacted]	筋骨格痛	1	267D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						全身性皮疹	23	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板数減少	32	11D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	43	173D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	64	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	64	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	85	53D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	132	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	138	7D	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	145	10D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						眼痛	154	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	171	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						脊椎痛	172	96D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	201	14D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						高カルシウム血症	215	27D	NOT RELATED	GRADE 4	AE	DRUG WITHDRAWN	
						腎不全	215	23D	NOT RELATED	GRADE 2	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						敗血症性ショック	267	24.0H	NOT RELATED	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
BD	4947-00081	WHITE	0	FEMALE	7[redacted]	振戦	22	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	25	68D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						浮動性めまい	59	7D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						下痢	71	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上腹部痛	74	39D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	78		RELATED	GRADE 3	AE	DOSE REDUCED	
						下痢	112	42D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	143	219D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	175		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	175	100D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						四肢痛	204	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						視力低下	204	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	288	74D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
BD	4947-00163	WHITE	0	FEMALE	6[redacted]	胸骨骨折	7	11D	NOT RELATED	GRADE 4	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						血小板減少症	29	4D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	33	24D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	33	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	33	16D	RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						痔核	46	23D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肛門周囲痛	88	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	99		RELATED	GRADE 3	AE	DRUG WITHDRAWN	
BD	4950-00043	WHITE	0	MALE	7[redacted]	骨痛	1	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	4	29D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						真菌性肺炎	14	19D	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	38	34D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						錯感覚	71	24.0H	NOT RELATED	GRADE 3	AE	DRUG WITHDRAWN	
						起立性低血圧	73	7D	RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
BD	4962-00042	WHITE	0	FEMALE	8[redacted]	悪心	4	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	4	5D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	14	6D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						嘔吐	14	31.3H	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						心肺停止	19	24.0H	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	FATAL
						胃腸出血	19	24.0H	NOT RELATED	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
BD	4963-00024	WHITE	0	MALE	6[redacted]	そう痒症	1	21D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						体重減少	1	106D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	49	206D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						低ナトリウム血症	81	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						気道感染	81	14D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						失神	98	5D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						無力症	116	49D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低血圧	116	49D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気道感染	139	75D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	140	81D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性感覚ニューロパチー	140	172D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	196	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						食欲減退	205	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	214	11D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						深部静脈血栓症	221	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪液質	226	373D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						下痢	255		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	262	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
NOT TREATED	1984-00147	WHITE		FEMALE	5[redacted]	貧血			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						脳損傷		4D	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						肺炎			NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
NOT TREATED	4903-00065	WHITE		MALE	6[redacted]	消化器癌		15D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
NOT TREATED	4945-00155	WHITE		MALE	6[redacted]	心停止		22M	NOT APPLICABLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
						心不全			NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						肺炎		9D	NOT APPLICABLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						発熱		5D	NOT APPLICABLE	GRADE 1	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

APPENDIX 50　　重篤な有害事象を発現した被験者の一覧（1702 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
P1 ELOTUZUMAB 2.5 MG/KG	0016-01601	WHITE	2.5 mg/kg	FEMALE	6[redacted]	悪寒	1	12.8H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	1	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	1	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						感覚鈍麻	3		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腫瘤	3		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不安	4		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔うっ血	22	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	29	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	37	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						排尿困難	66	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	119	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	119	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	122		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						咳嗽	122	35D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	122		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	122	9D	NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	122		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						うつ病	136		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上腹部痛	148	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	148	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋肉痛	151	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	165		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	176	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	184		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	191	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	191	38D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻咽頭炎	194	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						鼻咽頭炎	218	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						湿性咳嗽	232	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 5 MG/KG	0016-01602	WHITE	5 mg/kg	FEMALE	5[redacted]	疲労	5	50D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						うつ病	12		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	12		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	12		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	22	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	26	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中マグネシウム減少	29	57D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顔面浮腫	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	54	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE DELAYED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋力低下	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	54		RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE DELAYED
						敗血症	56	13D	RELATED	GRADE 3	SAE	E:DOSE DELAYED, DRUG WITHDRAWN B:DOSE DELAYED, DRUG WITHDRAWN D:DOSE DELAYED, DRUG WITHDRAWN
						嘔吐	69		NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中マグネシウム減少	85		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0011-01101	WHITE	20 mg/kg	MALE	7[redacted]	肺炎	-12	8D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性心筋梗塞	1	3D	NOT RELATED	GRADE 3	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						胸痛	1		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血管穿刺部位血腫	10		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性心筋梗塞	23	5D	NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0013-01307	BLACK OR AFRICAN AMERICAN	20 mg/kg	MALE	6[redacted]	尺骨骨折	42		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						単純ヘルペス	45	29D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						末梢性感覚ニューロパチー	63	8D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	67	22D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						過小食	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						多飲症	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						多尿	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						関節硬直	70		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	70	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中ビリルビン増加	77	7D	NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	77		RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	81	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高カルシウム血症	81	8D	NOT RELATED	GRADE 4	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	81	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性腎不全	81	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腎尿細管性アシドーシス	81	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						肺炎	83		NOT RELATED	GRADE 2	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	83	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0014-01403	WHITE	20 mg/kg	FEMALE	6[redacted]	頭痛	1	30M	RELATED	GRADE 2	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						喘鳴	1	22D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋攣縮	21	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	22	23D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気管支炎	22	23D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	22	23D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口内炎	22	23D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	32	4M	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	32	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	44		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頚部痛	44		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						脱水	53	3D	NOT RELATED	GRADE 2	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						靭帯捻挫	53		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						靭帯捻挫	53		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0015-01506	WHITE	20 mg/kg	MALE	4[redacted]	冷汗	4	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	4		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	4	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	4		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	4		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	5	3D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	11	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カルシウム血症	11	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						神経痛	11	54D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	20	34D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	20		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						発熱	20	48.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻漏	20	13D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						γ－グルタミルトランスフェラーゼ増加	22	21D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	22	21D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	22	21D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	30	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						そう痒性皮疹	42	12D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	43		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胸痛	53	48.0H	RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顔面浮腫	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カルシウム血症	53	18D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						局所腫脹	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	53	18D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						浮動性めまい	54	16D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	54	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中重炭酸塩減少	64	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						紅斑	64	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						局所腫脹	64	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪寒	66	4D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胃腸炎	66	4D	RELATED	GRADE 3	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						蕁麻疹	66		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	81		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0015-01509	BLACK OR AFRICAN AMERICAN	20 mg/kg	FEMALE	6[redacted]	神経痛	-13	77D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	6	24D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	11	74D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	11	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	15	98D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	15		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	22	52D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	22	10D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	32	32D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	32	42D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	32	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	50	4D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球形態異常	53	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						カテーテル留置部位疼痛	56	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						カテーテル留置部位紅斑	64	21D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	74	14D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	84	24.3H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	85	32D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						高血糖	85	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	88	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	95	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	95	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	95	21D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	95	11D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中乳酸脱水素酵素増加	106	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	106	10D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	106	21D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	106	162D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						骨痛	109	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	113	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						高血糖	116	15D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中トロンボプラスチン増加	127	151D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						白血球減少症	127	141D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	127	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	134	134D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	134	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						好中球減少症	134	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DRUG INTERRUPTED D:DOSE NOT CHANGED
						副鼻腔うっ血	134	15D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	136		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋骨格系胸痛	144	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	148	51D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	155	24.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	169	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	176	36D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	176	24D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	190	120D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						低カリウム血症	199	13D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						アフタ性口内炎	232		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	235	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中アルブミン減少	253	15D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	253	7D	NOT RELATED	GRADE 3	SAE	E:DOSE DELAYED B:DOSE DELAYED D:DOSE NOT CHANGED
						血中リン増加	267	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	274	36D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	277	33D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肉離れ	277	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	288	21D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	288	11D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	298	46D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	298	12D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	309	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						好中球減少症	309	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	316	87D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔炎	316	14D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	343	9D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	351	52D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低ナトリウム血症	351	52D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	351	32D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	351	32D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顎骨壊死	351		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	382	12D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	382	12D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	382	18D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	387	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	399	4D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
P1 ELOTUZUMAB 20 MG/KG	0018-01803	WHITE	20 mg/kg	MALE	4[redacted]	体重減少	1		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	5		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	5	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発疹	7	16D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	11		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	43	4D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						流涙増加	46		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	53	40D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胃食道逆流性疾患	63		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	71	32D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	85		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	120		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	126	12D	NOT RELATED	GRADE 2	SAE	E:DOSE DELAYED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発疹	144	33D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						腹痛	193	29D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						霧視	197		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	212	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼡径部痛	220	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	240	52D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	296	28D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	323		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	358	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低血圧	365	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	401		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	403	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	407	32D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	431	20D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						インフルエンザ	431	5D	NOT RELATED	GRADE 3	SAE	E:DOSE DELAYED B:DOSE DELAYED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						低カリウム血症	442	4D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	449		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	545	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口唇潰瘍	577	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	631	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	633	6D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						結膜炎	634	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	634	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	662	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気管支炎	749	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	771	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	783	10D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						背部痛	813		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0019-01901	WHITE	20 mg/kg	MALE	[redacted]	貧血	-10	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						貧血	1	28D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪寒	1	11.1H	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	1	11.1H	NOT RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	1	11.1H	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	1	4.1H	NOT RELATED	GRADE 2	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻呼吸	1	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口唇水疱	2	26D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	2	48.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	6	31D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	8	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	8	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	8	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	9	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	9	28D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						労作性呼吸困難	9	11D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						非心臓性胸痛	9	5D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻呼吸	10	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	11	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						イレウス	11	3D	RELATED	GRADE 1	SAE	E:DOSE DELAYED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	11	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	29	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	36	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	36	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	36	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	36	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	37	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻出血	38	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	40	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						好中球数減少	40	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	40	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	45	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻閉	45	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	48	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	54	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	57	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	57		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						放屁	58	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	58	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	58	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						霧視	59		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	61	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						末梢性感覚ニューロパチー	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	69	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	69		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻閉	69	13D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	69	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球数減少	71		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球数減少	71		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	72		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	72	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	72		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	82	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	90		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	90		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性感覚ニューロパチー	90		RELATED	GRADE 2	AE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						活動性低下	103	16D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気道うっ血	111		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						活動性低下	118		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0019-01902	WHITE	20 mg/kg	MALE	5[redacted]	多汗症	1	30M	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						湿性咳嗽	1	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口腔咽頭痛	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気道うっ血	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔炎に伴う頭痛	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	7	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	8	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						消化不良	10		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						季節性アレルギー	10	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	11	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	22	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						頭痛	22	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	25		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	32		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						帯状疱疹	32	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	32	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						神経痛	32	26D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性浮腫	32	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						そう痒症	32	29D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	32	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						しゃっくり	34	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						眼乾燥	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						四肢痛	46		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	64	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	67	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						激越	77	5D	NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						アンモニア増加	77	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	77	11D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	77	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						尿失禁	77	11D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						代謝性脳症	78	10D	NOT RELATED	GRADE 4	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						末梢性浮腫	78	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						自殺念慮	78		NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						トロポニンＩ増加	78	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	79	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	80	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	81	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	82	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋力低下	85	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						ほてり	88		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						四肢痛	99		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

APPENDIX 51　投与サイクル別のINFUSION REACTIONの発現割合（004 試験及び統合E-LD群、治験薬投与例）

System Organ Class (%) Preferred Term (%)	CA204-004 E-Ld N = 318			Pooled E-Ld E-Ld N = 451		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 1: 451						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 1	28 (6.2)	4 (0.9)	0	32 (7.1)	4 (0.9)	0
一般・全身障害および投与部位の状態	14 (3.1)	1 (0.2)	0	17 (3.8)	1 (0.2)	0
発熱	10 (2.2)	0	0	13 (2.9)	0	0
悪寒	3 (0.7)	0	0	4 (0.9)	0	0
無力症	1 (0.2)	0	0	1 (0.2)	0	0
胸部不快感	1 (0.2)	0	0	1 (0.2)	0	0
胸痛	1 (0.2)	1 (0.2)	0	1 (0.2)	1 (0.2)	0
冷感	1 (0.2)	0	0	1 (0.2)	0	0
血管障害	4 (0.9)	1 (0.2)	0	6 (1.3)	1 (0.2)	0
潮紅	1 (0.2)	0	0	2 (0.4)	0	0
高血圧	2 (0.4)	1 (0.2)	0	2 (0.4)	1 (0.2)	0
ほてり	0	0	0	1 (0.2)	0	0
低血圧	1 (0.2)	0	0	1 (0.2)	0	0
神経系障害	4 (0.9)	0	0	4 (0.9)	0	0
浮動性めまい	1 (0.2)	0	0	1 (0.2)	0	0
味覚異常	1 (0.2)	0	0	1 (0.2)	0	0
頭痛	1 (0.2)	0	0	1 (0.2)	0	0
振戦	1 (0.2)	0	0	1 (0.2)	0	0
傷害、中毒および処置合併症	3 (0.7)	0	0	3 (0.7)	0	0
注入に伴う反応	3 (0.7)	0	0	3 (0.7)	0	0

System Organ Class (%) Preferred Term (%)	CA204-004 E-Ld N = 318			Pooled E-Ld E-Ld N = 451		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
皮膚および皮下組織障害	3 (0.7)	0	0	3 (0.7)	0	0
多汗症	1 (0.2)	0	0	1 (0.2)	0	0
そう痒症	1 (0.2)	0	0	1 (0.2)	0	0
顔面腫脹	1 (0.2)	0	0	1 (0.2)	0	0
胃腸障害	2 (0.4)	1 (0.2)	0	2 (0.4)	1 (0.2)	0
下痢	1 (0.2)	1 (0.2)	0	1 (0.2)	1 (0.2)	0
消化不良	1 (0.2)	0	0	1 (0.2)	0	0
免疫系障害	2 (0.4)	0	0	2 (0.4)	0	0
過敏症	2 (0.4)	0	0	2 (0.4)	0	0
呼吸器、胸郭および縦隔障害	2 (0.4)	0	0	2 (0.4)	0	0
咳嗽	1 (0.2)	0	0	1 (0.2)	0	0
呼吸困難	1 (0.2)	0	0	1 (0.2)	0	0
心臓障害	1 (0.2)	1 (0.2)	0	1 (0.2)	1 (0.2)	0
うっ血性心不全	1 (0.2)	1 (0.2)	0	1 (0.2)	1 (0.2)	0
眼障害	1 (0.2)	0	0	1 (0.2)	0	0
霧視	1 (0.2)	0	0	1 (0.2)	0	0
筋骨格系および結合組織障害	1 (0.2)	0	0	1 (0.2)	0	0
筋肉痛	1 (0.2)	0	0	1 (0.2)	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 2: 440						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 2	7 (1.6)	0	0	11 (2.5)	0	0
皮膚および皮下組織障害	3 (0.7)	0	0	4 (0.9)	0	0
発疹	1 (0.2)	0	0	2 (0.5)	0	0

System Organ Class (%) Preferred Term (%)	CA204-004 E-Ld N = 318			Pooled E-Ld E-Ld N = 451		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
紅斑	1 (0.2)	0	0	1 (0.2)	0	0
蕁麻疹	1 (0.2)	0	0	1 (0.2)	0	0
傷害、中毒および処置合併症	1 (0.2)	0	0	3 (0.7)	0	0
注入に伴う反応	1 (0.2)	0	0	3 (0.7)	0	0
血管障害	3 (0.7)	0	0	3 (0.7)	0	0
潮紅	1 (0.2)	0	0	1 (0.2)	0	0
高血圧	1 (0.2)	0	0	1 (0.2)	0	0
低血圧	1 (0.2)	0	0	1 (0.2)	0	0
眼障害	1 (0.2)	0	0	2 (0.5)	0	0
眼球浮腫	1 (0.2)	0	0	1 (0.2)	0	0
眼窩周囲浮腫	0	0	0	1 (0.2)	0	0
胃腸障害	1 (0.2)	0	0	2 (0.5)	0	0
腹痛	0	0	0	1 (0.2)	0	0
消化不良	1 (0.2)	0	0	1 (0.2)	0	0
悪心	0	0	0	1 (0.2)	0	0
一般・全身障害および投与部位の状態	1 (0.2)	0	0	2 (0.5)	0	0
悪寒	0	0	0	1 (0.2)	0	0
顔面浮腫	1 (0.2)	0	0	1 (0.2)	0	0
心臓障害	1 (0.2)	0	0	1 (0.2)	0	0
徐脈	1 (0.2)	0	0	1 (0.2)	0	0
免疫系障害	1 (0.2)	0	0	1 (0.2)	0	0
過敏症	1 (0.2)	0	0	1 (0.2)	0	0

System Organ Class (%) Preferred Term (%)	CA204-004 E-Ld N = 318			Pooled E-Ld E-Ld N = 451		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
筋骨格系および結合組織障害	0	0	0	1 (0.2)	0	0
背部痛	0	0	0	1 (0.2)	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 3: 429						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 3	0	0	0	1 (0.2)	1 (0.2)	0
一般・全身障害および投与部位の状態	0	0	0	1 (0.2)	0	0
疼痛	0	0	0	1 (0.2)	0	0
皮膚および皮下組織障害	0	0	0	1 (0.2)	1 (0.2)	0
発疹	0	0	0	1 (0.2)	1 (0.2)	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 4: 411						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 4	2 (0.5)	0	0	2 (0.5)	0	0
血管障害	2 (0.5)	0	0	2 (0.5)	0	0
高血圧	1 (0.2)	0	0	1 (0.2)	0	0
低血圧	1 (0.2)	0	0	1 (0.2)	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 5: 395						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 5	1 (0.3)	0	0	1 (0.3)	0	0
血管障害	1 (0.3)	0	0	1 (0.3)	0	0
高血圧	1 (0.3)	0	0	1 (0.3)	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 6: 383						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 6	0	0	0	0	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 7: 362						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 7	2 (0.6)	0	0	2 (0.6)	0	0

System Organ Class (%) Preferred Term (%)	CA204-004 E-Ld N = 318			Pooled E-Ld E-Ld N = 451		
	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
一般・全身障害および投与部位の状態	1 (0.3)	0	0	1 (0.3)	0	0
悪寒	1 (0.3)	0	0	1 (0.3)	0	0
血管障害	1 (0.3)	0	0	1 (0.3)	0	0
高血圧	1 (0.3)	0	0	1 (0.3)	0	0
TOTAL NUMBER OF SUBJECTS WHO REACHED CYCLE 8: 344						
TOTAL SUBJECTS WITH AN EVENT IN CYCLE 8	0	0	0	0	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
AE or SAE reported as infusion reaction and that start on the day or the date after the Elotuzumab infusion.
Infusion reaction based on investigator assessment per CRF for studies CA204-004, CA204-007 and the phase 2 of HuLuc63-1703,
and based on the preferred term of 'infusion related reaction' for study CA204-005 and the phase 1 of HuLuc63-1703.
Percentage is based on total number of subjects who reached the cycle.
Sorting is done by cycle and then by decreasing order based on the 'any grade' column of the pooled E-Ld arm.
Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ae-inf-cycle-tx.sas 13FEB2015:00:51:43

APPENDIX 52　投与期間を考慮した二次発がんの発現数（004 試験及び統合E-LD群、治験薬投与例）

	CA204-004				Phase 1/2 Pooled E-Ld		Pooled E-Ld	
	E-Ld N = 318 P-Y = 621.89		Ld N = 317 P-Y = 572.78		E-Ld N = 133 P-Y = 221.87		E-Ld N = 451 P-Y = 843.76	
Preferred Term	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)
TOTAL EVENTS	26	4.2	18	3.1	16	7.2	42	5.0
皮膚有棘細胞癌	8	1.3	2	0.3	1	0.5	9	1.1
基底細胞癌	3	0.5	3	0.5	2	0.9	5	0.6
骨髄異形成症候群	3	0.5	5	0.9	2	0.9	5	0.6
肺の悪性新生物	3	0.5	1	0.2	0	0.0	3	0.4
扁平上皮癌	1	0.2	1	0.2	2	0.9	3	0.4
膀胱癌	1	0.2	0	0.0	0	0.0	1	0.1
膀胱移行上皮癌	0	0.0	0	0.0	1	0.5	1	0.1
乳癌	1	0.2	0	0.0	0	0.0	1	0.1
慢性リンパ性白血病	1	0.2	0	0.0	0	0.0	1	0.1
赤白血病	1	0.2	0	0.0	0	0.0	1	0.1
消化器新生物	1	0.2	0	0.0	0	0.0	1	0.1
脂肪腫	0	0.0	0	0.0	1	0.5	1	0.1
乳腺上皮内小葉癌	0	0.0	0	0.0	1	0.5	1	0.1
肺腺癌	1	0.2	0	0.0	0	0.0	1	0.1
悪性黒色腫	0	0.0	0	0.0	1	0.5	1	0.1
原発巣不明の悪性新生物	1	0.2	1	0.2	0	0.0	1	0.1
乳頭腫	0	0.0	0	0.0	1	0.5	1	0.1
形質細胞腫	0	0.0	0	0.0	1	0.5	1	0.1
胸膜悪性中皮腫	1	0.2	0	0.0	0	0.0	1	0.1
前立腺癌	0	0.0	1	0.2	1	0.5	1	0.1
皮膚乳頭腫	0	0.0	0	0.0	1	0.5	1	0.1
子宮平滑筋腫	0	0.0	0	0.0	1	0.5	1	0.1

	CA204-004				Phase 1/2 Pooled E-Ld		Pooled E-Ld	
	E-Ld N = 318 P-Y = 621.89		Ld N = 317 P-Y = 572.78		E-Ld N = 133 P-Y = 221.87		E-Ld N = 451 P-Y = 843.76	
Preferred Term	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)	Event Count	Rate (IR/100 P-Y)
結腸腺癌	0	0.0	1	0.2	0	0.0	0	0.0
子宮内膜癌	0	0.0	1	0.2	0	0.0	0	0.0
芽球増加を伴う不応性貧血	0	0.0	1	0.2	0	0.0	0	0.0
扁桃癌	0	0.0	1	0.2	0	0.0	0	0.0

P-Y = person-years of exposure.
Incidence rate per 100 person-years of exposure (IR/100 P-Y) = event count * 100 / person-years of exposure.
Based on CRF entry for studies CA204-004, CA204-005 and CA204-007 and on all PT under the SOC of 'neoplasms benign, malignant and unspecified (including cysts and polyps)' for study HuLuc63-1703.
Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
Phase 1/2 Pooled E-Ld: HuLuc63-1703, CA204-005, and CA204-007.
MedDRA 17.0
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ae-mer-spm.sas 13FEB2015:00:49:53

APPENDIX 53　　日和見感染の発現割合（004 試験、治験薬投与例）

	E-Ld N = 318			Ld N = 317		
Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	70 (22.0)	11 (3.5)	0	41 (12.9)	4 (1.3)	1 (0.3)
帯状疱疹	19 (6.0)	5 (1.6)	0	9 (2.8)	2 (0.6)	0
口腔ヘルペス	17 (5.3)	0	0	13 (4.1)	0	0
口腔カンジダ症	11 (3.5)	0	0	7 (2.2)	0	0
ヘルペスウイルス感染	7 (2.2)	0	0	0	0	0
カンジダ感染	5 (1.6)	0	0	4 (1.3)	0	0
真菌感染	3 (0.9)	0	0	1 (0.3)	0	0
皮膚真菌感染	3 (0.9)	0	0	0	0	0
ニューモシスチス・イロベチイ肺炎	3 (0.9)	3 (0.9)	0	1 (0.3)	0	1 (0.3)
陰部ヘルペス	2 (0.6)	0	0	1 (0.3)	0	0
単純ヘルペス	2 (0.6)	0	0	2 (0.6)	0	0
口腔真菌感染	2 (0.6)	0	0	3 (0.9)	1 (0.3)	0
アスペルギルス感染	1 (0.3)	0	0	0	0	0
気管支肺アスペルギルス症	1 (0.3)	1 (0.3)	0	0	0	0
脳アスペルギルス症	1 (0.3)	1 (0.3)	0	0	0	0
サイトメガロウイルス感染	1 (0.3)	1 (0.3)	0	0	0	0
真菌性耳感染	1 (0.3)	0	0	0	0	0
食道カンジダ症	1 (0.3)	0	0	0	0	0
真菌性肺炎	1 (0.3)	1 (0.3)	0	0	0	0
消化器カンジダ症	0	0	0	1 (0.3)	0	0
眼部単純ヘルペス	0	0	0	1 (0.3)	0	0
眼帯状疱疹	0	0	0	1 (0.3)	1 (0.3)	0
真菌性尿路感染	0	0	0	1 (0.3)	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-ae-opport-infection-tx.sas　　09APR2015:08:31:32

APPENDIX 54　　日和見感染の発現割合（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 31			Ld N = 29		
Preferred Term (%)	Any Grade	Grade 3-4	Grade 5	Any Grade	Grade 3-4	Grade 5
TOTAL SUBJECTS WITH AN EVENT	6 (19.4)	0	0	2 (6.9)	1 (3.4)	0
単純ヘルペス	2 (6.5)	0	0	0	0	0
帯状疱疹	2 (6.5)	0	0	1 (3.4)	1 (3.4)	0
口腔カンジダ症	2 (6.5)	0	0	1 (3.4)	0	0
口腔ヘルペス	0	0	0	1 (3.4)	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ae-opport-infection-tx.sas　　19JUN2015:07:24:49

APPENDIX 55　　初回感染発現時のリンパ球絶対数（004 試験、日本人部分集団、治験薬投与例）

	E-Ld N = 25	Ld N = 23
ALC AT TIME OF FIRST INFECTION OF ANY GRADE (10^9/L)		
N	25	21
MEAN	0.8554	1.0639
MEDIAN	0.7000	1.0470
MIN , MAX	0.130 , 1.785	0.336 , 1.892
Q1 , Q3	0.5380 , 1.1840	0.8050 , 1.4000
STANDARD DEVIATION	0.48987	0.42845

Absolute Lymphocyte Count.
ALC values within +/- 7 days of the time of their first infection are considered.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ae-infection-it.sas　　19JUN2015:07:24:46

APPENDIX 56　幹細胞移植歴の有無別の感染の発現割合（004 試験、日本人部分集団、治験薬投与例）

System Organ Class (%) Preferred Term (%)	No		Yes	
	E-Ld N = 20	Ld N = 16	E-Ld N = 11	Ld N = 13
TOTAL SUBJECTS WITH AN EVENT	14 (70.0)	13 (81.3)	11 (100.0)	10 (76.9)
感染症および寄生虫症	14 (70.0)	13 (81.3)	11 (100.0)	10 (76.9)
鼻咽頭炎	6 (30.0)	8 (50.0)	9 (81.8)	7 (53.8)
肺炎	4 (20.0)	1 (6.3)	5 (45.5)	1 (7.7)
気管支炎	4 (20.0)	4 (25.0)	1 (9.1)	4 (30.8)
結膜炎	3 (15.0)	0	0	0
インフルエンザ	3 (15.0)	0	0	2 (15.4)
膀胱炎	2 (10.0)	0	0	0
単純ヘルペス	1 (5.0)	0	1 (9.1)	0
帯状疱疹	2 (10.0)	1 (6.3)	0	0
口腔カンジダ症	1 (5.0)	0	1 (9.1)	1 (7.7)
歯周炎	1 (5.0)	1 (6.3)	1 (9.1)	1 (7.7)
咽頭炎	2 (10.0)	0	0	1 (7.7)
非定型マイコバクテリア感染	0	0	1 (9.1)	0
気管支肺炎	1 (5.0)	0	0	0
蜂巣炎	1 (5.0)	0	0	0
ウイルス性結膜炎	0	0	1 (9.1)	0
感染性腸炎	0	0	1 (9.1)	0
胃腸炎	1 (5.0)	1 (6.3)	0	2 (15.4)
ウイルス性胃腸炎	1 (5.0)	0	0	2 (15.4)
感染性皮膚嚢腫	1 (5.0)	0	0	0
口唇感染	0	0	1 (9.1)	0
大葉性肺炎	1 (5.0)	0	0	0
骨髄炎	1 (5.0)	0	0	0
肺炎球菌性肺炎	1 (5.0)	0	0	0

System Organ Class (%) Preferred Term (%)	No		Yes	
	E-Ld N = 20	Ld N = 16	E-Ld N = 11	Ld N = 13
腎盂腎炎	1 (5.0)	0	0	0
敗血症	1 (5.0)	0	0	0
副鼻腔炎	1 (5.0)	0	0	0
股部白癬	1 (5.0)	0	0	0
手白癬	1 (5.0)	0	0	0
足部白癬	1 (5.0)	1 (6.3)	0	0
上気道感染	0	0	1 (9.1)	3 (23.1)
尿路感染	1 (5.0)	0	0	1 (7.7)
ウイルス性胃炎	0	0	0	1 (7.7)
歯肉炎	0	0	0	1 (7.7)
感染	0	0	0	1 (7.7)
爪真菌症	0	1 (6.3)	0	0
口腔ヘルペス	0	1 (6.3)	0	0
インフルエンザ性肺炎	0	1 (6.3)	0	0
皮下組織膿瘍	0	1 (6.3)	0	0
歯感染	0	0	0	1 (7.7)

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-ae-infection-sct.sas 19JUN2015:07:24:30

APPENDIX 57　　幹細胞移植歴の有無別のリンパ球絶対数の最悪重症度（004 試験、日本人部分集団、治験薬投与例）

Lab Test Description Toxicity Grade	No E-Ld N = 20	No Ld N = 16	Yes E-Ld N = 11	Yes Ld N = 13
LYMPHOCYTES (ABSOLUTE)				
GRADE 0	0	0	0	0
GRADE 1	0	4 (25.0)	1 (9.1)	0
GRADE 2	3 (15.0)	4 (25.0)	1 (9.1)	4 (30.8)
GRADE 3	9 (45.0)	5 (31.3)	8 (72.7)	9 (69.2)
GRADE 4	8 (40.0)	3 (18.8)	1 (9.1)	0
ANY GRADE	20 (100.0)	16 (100.0)	11 (100.0)	13 (100.0)
GRADE 3-4	17 (85.0)	8 (50.0)	9 (81.8)	9 (69.2)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-alc-si-sct.sas 19JUN2015:07:24:39

APPENDIX 58　投与開始 24 ヵ月以降の有害事象の発現割合（004 試験及び統合 E-LD 群、治験薬投与例）

	CA204-004 E-Ld		CA204-004 Ld		Pooled E-Ld	
SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	<= 24 N = 318	> 24 N = 101	<= 24 N = 317	> 24 N = 54	<= 24 N = 451	> 24 N = 140
TOTAL SUBJECTS WITH AN EVENT	316 (99.4)	76 (75.2)	314 (99.1)	39 (72.2)	449 (99.6)	114 (81.4)
一般・全身障害および投与部位の状態	262 (82.4)	21 (20.8)	236 (74.4)	13 (24.1)	383 (84.9)	43 (30.7)
疲労	148 (46.5)	6 (5.9)	119 (37.5)	6 (11.1)	222 (49.2)	14 (10.0)
発熱	119 (37.4)	2 (2.0)	77 (24.3)	1 (1.9)	171 (37.9)	8 (5.7)
末梢性浮腫	81 (25.5)	3 (3.0)	69 (21.8)	4 (7.4)	115 (25.5)	11 (7.9)
無力症	68 (21.4)	4 (4.0)	53 (16.7)	0	95 (21.1)	7 (5.0)
悪寒	24 (7.5)	0	12 (3.8)	1 (1.9)	40 (8.9)	1 (0.7)
胸痛	25 (7.9)	1 (1.0)	10 (3.2)	1 (1.9)	31 (6.9)	1 (0.7)
局所腫脹	10 (3.1)	0	4 (1.3)	1 (1.9)	25 (5.5)	1 (0.7)
倦怠感	16 (5.0)	2 (2.0)	11 (3.5)	0	24 (5.3)	3 (2.1)
インフルエンザ様疾患	18 (5.7)	1 (1.0)	15 (4.7)	0	23 (5.1)	2 (1.4)
疼痛	13 (4.1)	1 (1.0)	7 (2.2)	1 (1.9)	20 (4.4)	3 (2.1)
非心臓性胸痛	10 (3.1)	0	5 (1.6)	0	19 (4.2)	0
疾患進行	14 (4.4)	1 (1.0)	10 (3.2)	0	14 (3.1)	1 (0.7)
浮腫	8 (2.5)	0	3 (0.9)	1 (1.9)	14 (3.1)	3 (2.1)
全身健康状態低下	8 (2.5)	2 (2.0)	5 (1.6)	1 (1.9)	10 (2.2)	2 (1.4)
胸部不快感	6 (1.9)	0	7 (2.2)	1 (1.9)	11 (2.4)	0
歩行障害	5 (1.6)	0	8 (2.5)	0	8 (1.8)	2 (1.4)
嚢胞	4 (1.3)	0	3 (0.9)	0	5 (1.1)	0
熱感	2 (0.6)	0	1 (0.3)	0	4 (0.9)	0
顔面浮腫	3 (0.9)	0	3 (0.9)	0	3 (0.7)	0
全身性浮腫	2 (0.6)	1 (1.0)	1 (0.3)	0	2 (0.4)	1 (0.7)
治癒不良	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
炎症	1 (0.3)	0	2 (0.6)	0	2 (0.4)	1 (0.7)
粘膜の炎症	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0
カテーテル留置部位疼痛	1 (0.3)	0	0	0	2 (0.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
異常感	1 (0.3)	0	0	0	2 (0.4)	0
ヘルニア	1 (0.3)	0	0	0	2 (0.4)	0
注入部位内出血	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
注入部位血管外漏出	2 (0.6)	0	0	0	2 (0.4)	0
注射部位内出血	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
注射部位血腫	2 (0.6)	0	0	0	2 (0.4)	0
注射部位出血	1 (0.3)	0	0	0	2 (0.4)	0
粘膜変色	2 (0.6)	0	0	0	2 (0.4)	0
多臓器不全	1 (0.3)	0	0	0	2 (0.4)	0
全身性炎症反応症候群	0	0	0	0	2 (0.4)	0
口渇	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
潰瘍	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
医薬品副作用	0	0	0	0	1 (0.2)	0
カテーテル留置部位炎症	1 (0.3)	0	0	0	1 (0.2)	0
カテーテル留置部位発疹	1 (0.3)	0	0	0	1 (0.2)	0
カテーテル留置部位蕁麻疹	1 (0.3)	0	0	0	1 (0.2)	0
死亡	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
活動性低下	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
医療機器不具合	1 (0.3)	0	0	0	1 (0.2)	0
医療機器機能不良	0	0	0	0	1 (0.2)	0
薬剤離脱症候群	1 (0.3)	0	0	0	1 (0.2)	0
活力増進	1 (0.3)	0	0	0	1 (0.2)	0
溢出	1 (0.3)	0	0	0	1 (0.2)	0
冷感	1 (0.3)	0	0	0	1 (0.2)	0
びくびく感	1 (0.3)	0	0	0	1 (0.2)	0
重力性浮腫	0	0	0	0	0	1 (0.7)
低体温	0	0	1 (0.3)	0	1 (0.2)	0
硬結	1 (0.3)	0	0	0	1 (0.2)	0
注射部位漏出	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
注射部位疼痛	1 (0.3)	0	0	0	1 (0.2)	0
注射部位そう痒感	1 (0.3)	0	0	0	1 (0.2)	0
注射部位反応	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
注射部位腫脹	1 (0.3)	0	0	0	1 (0.2)	0
易刺激性	0	0	0	0	1 (0.2)	0
限局性浮腫	0	0	0	0	1 (0.2)	0
医療機器による疼痛	0	0	0	0	1 (0.2)	0
粘膜出血	1 (0.3)	0	0	0	1 (0.2)	0
分泌物分泌	0	1 (1.0)	0	0	0	1 (0.7)
異物感	1 (0.3)	0	0	0	1 (0.2)	0
気象変化過敏	1 (0.3)	0	0	0	1 (0.2)	0
温度変化不耐症	1 (0.3)	0	0	0	1 (0.2)	0
圧痛	1 (0.3)	0	0	0	1 (0.2)	0
血管穿刺部位出血	0	0	0	0	1 (0.2)	0
捻髪音	0	0	1 (0.3)	0	0	0
医療機器破損	0	0	1 (0.3)	0	0	0
医療機器位置異常	0	0	1 (0.3)	0	0	0
不快感	0	0	1 (0.3)	0	0	0
顔面痛	0	0	2 (0.6)	0	0	0
腫瘤	0	0	2 (0.6)	0	0	0
小結節	0	0	1 (0.3)	0	0	0
苦悶感	0	0	1 (0.3)	0	0	0
漿膜炎	0	0	1 (0.3)	0	0	0
恥骨上痛	0	0	1 (0.3)	0	0	0
腫脹	0	0	1 (0.3)	0	0	0
ワクチン接種部位発疹	0	0	1 (0.3)	0	0	0
胃腸障害	254 (79.9)	31 (30.7)	212 (66.9)	5 (9.3)	372 (82.5)	56 (40.0)
下痢	145 (45.6)	17 (16.8)	112 (35.3)	2 (3.7)	222 (49.2)	32 (22.9)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
便秘	112 (35.2)	3 (3.0)	86 (27.1)	0	176 (39.0)	6 (4.3)
悪心	75 (23.6)	1 (1.0)	67 (21.1)	1 (1.9)	128 (28.4)	8 (5.7)
嘔吐	45 (14.2)	2 (2.0)	28 (8.8)	0	71 (15.7)	3 (2.1)
腹痛	36 (11.3)	3 (3.0)	27 (8.5)	0	53 (11.8)	6 (4.3)
消化不良	30 (9.4)	2 (2.0)	19 (6.0)	0	45 (10.0)	3 (2.1)
口内炎	27 (8.5)	0	13 (4.1)	1 (1.9)	40 (8.9)	1 (0.7)
上腹部痛	21 (6.6)	1 (1.0)	17 (5.4)	0	30 (6.7)	2 (1.4)
歯痛	14 (4.4)	1 (1.0)	7 (2.2)	1 (1.9)	19 (4.2)	1 (0.7)
胃食道逆流性疾患	11 (3.5)	1 (1.0)	5 (1.6)	1 (1.9)	17 (3.8)	3 (2.1)
口内乾燥	13 (4.1)	0	10 (3.2)	0	18 (4.0)	0
腹部膨満	7 (2.2)	0	6 (1.9)	0	16 (3.5)	1 (0.7)
放屁	7 (2.2)	0	7 (2.2)	0	9 (2.0)	1 (0.7)
痔核	3 (0.9)	0	4 (1.3)	1 (1.9)	9 (2.0)	1 (0.7)
口腔内潰瘍形成	5 (1.6)	2 (2.0)	2 (0.6)	0	7 (1.6)	3 (2.1)
胃炎	7 (2.2)	1 (1.0)	6 (1.9)	0	8 (1.8)	1 (0.7)
腹部不快感	7 (2.2)	0	5 (1.6)	0	8 (1.8)	0
血便排泄	5 (1.6)	0	3 (0.9)	0	7 (1.6)	2 (1.4)
下腹部痛	5 (1.6)	0	2 (0.6)	0	7 (1.6)	0
齲歯	4 (1.3)	1 (1.0)	5 (1.6)	0	6 (1.3)	1 (0.7)
嚥下障害	6 (1.9)	0	6 (1.9)	0	7 (1.6)	0
口腔内痛	5 (1.6)	0	1 (0.3)	0	7 (1.6)	0
口腔障害	5 (1.6)	0	1 (0.3)	0	5 (1.1)	1 (0.7)
口の錯感覚	2 (0.6)	1 (1.0)	1 (0.3)	0	5 (1.1)	1 (0.7)
アフタ性口内炎	4 (1.3)	0	5 (1.6)	0	5 (1.1)	0
単径ヘルニア	4 (1.3)	0	2 (0.6)	0	5 (1.1)	0
直腸出血	5 (1.6)	0	2 (0.6)	0	5 (1.1)	0
口唇炎	4 (1.3)	0	0	0	4 (0.9)	0
便失禁	3 (0.9)	0	1 (0.3)	0	4 (0.9)	0
胃腸障害	4 (1.3)	0	1 (0.3)	0	4 (0.9)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
胃腸出血	2 (0.6)	0	1 (0.3)	0	4 (0.9)	0
消化管運動障害	2 (0.6)	0	0	0	4 (0.9)	0
口唇腫脹	2 (0.6)	0	0	0	4 (0.9)	0
小腸炎	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
腸炎	3 (0.9)	0	1 (0.3)	1 (1.9)	3 (0.7)	0
食中毒	1 (0.3)	2 (2.0)	0	0	1 (0.2)	2 (1.4)
歯肉痛	3 (0.9)	0	3 (0.9)	0	3 (0.7)	0
口の感覚鈍麻	2 (0.6)	0	0	0	3 (0.7)	0
口腔内出血	2 (0.6)	0	0	0	2 (0.4)	1 (0.7)
歯周病	3 (0.9)	0	0	0	3 (0.7)	0
大腸炎	2 (0.6)	0	4 (1.3)	0	2 (0.4)	0
消化器痛	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
胃腸音異常	1 (0.3)	0	0	0	2 (0.4)	0
歯肉潰瘍	2 (0.6)	0	0	0	2 (0.4)	0
舌痛	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
吐血	1 (0.3)	0	0	0	2 (0.4)	0
裂孔ヘルニア	2 (0.6)	0	0	0	2 (0.4)	0
腸閉塞	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
大腸ポリープ	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
嚥下痛	2 (0.6)	0	5 (1.6)	0	2 (0.4)	0
食道痛	2 (0.6)	0	0	0	2 (0.4)	0
口腔粘膜紅斑	2 (0.6)	0	0	0	2 (0.4)	0
急性膵炎	2 (0.6)	0	0	0	2 (0.4)	0
耳下腺腫大	1 (0.3)	0	0	0	2 (0.4)	0
唾液腺結石	1 (0.3)	0	0	0	2 (0.4)	0
舌苔	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
舌障害	2 (0.6)	0	0	0	2 (0.4)	0
舌潰瘍	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
歯の障害	0	0	0	0	2 (0.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
歯の脱落	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
臍ヘルニア	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
腹部ヘルニア	0	0	1 (0.3)	0	0	1 (0.7)
腹部腫瘤	1 (0.3)	0	0	0	1 (0.2)	0
腹部圧痛	1 (0.3)	0	0	0	1 (0.2)	0
空気嚥下	1 (0.3)	0	0	0	1 (0.2)	0
裂肛	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
肛門出血	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
唾液欠乏	1 (0.3)	0	0	0	1 (0.2)	0
歯組織の壊死	1 (0.3)	0	0	0	1 (0.2)	0
憩室穿孔	0	0	0	0	1 (0.2)	0
十二指腸潰瘍	1 (0.3)	0	0	0	1 (0.2)	0
心窩部不快感	0	0	2 (0.6)	0	1 (0.2)	0
おくび	0	0	0	0	1 (0.2)	0
変色便	0	0	0	0	1 (0.2)	0
胃障害	1 (0.3)	0	0	0	1 (0.2)	0
胃ポリープ	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
胃潰瘍	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
萎縮性胃炎	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
びらん性胃炎	1 (0.3)	0	0	0	1 (0.2)	0
消化管浮腫	1 (0.3)	0	0	0	1 (0.2)	0
消化管穿孔	0	0	0	0	1 (0.2)	0
歯肉出血	0	0	0	0	1 (0.2)	0
歯肉びらん	0	0	0	0	0	1 (0.7)
歯肉紅斑	1 (0.3)	0	0	0	1 (0.2)	0
歯肉の炎症	1 (0.3)	0	0	0	1 (0.2)	0
歯肉腫脹	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
痔出血	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
大腸穿孔	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
口唇水疱	1 (0.3)	0	0	0	1 (0.2)	0
口唇痛	1 (0.3)	0	0	0	1 (0.2)	0
メレナ	0	0	1 (0.3)	0	1 (0.2)	0
粘液便	0	0	0	0	1 (0.2)	0
口腔内不快感	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
肛門周囲痛	0	0	1 (0.3)	0	1 (0.2)	0
直腸しぶり	0	0	0	0	1 (0.2)	0
唾液腺障害	0	0	0	0	1 (0.2)	0
歯の知覚過敏	1 (0.3)	0	0	0	1 (0.2)	0
壊死性口内炎	1 (0.3)	0	0	0	1 (0.2)	0
舌水疱形成	1 (0.3)	0	0	0	1 (0.2)	0
食道静脈瘤	0	0	0	0	1 (0.2)	0
腹壁反跳痛	0	0	1 (0.3)	0	0	0
胆汁酸吸収不良	0	0	2 (0.6)	0	0	0
便意切迫	0	0	1 (0.3)	0	0	0
腸憩室	0	0	1 (0.3)	0	0	0
十二指腸胃逆流	0	0	1 (0.3)	0	0	0
軟便	0	0	1 (0.3)	0	0	0
歯肉障害	0	0	1 (0.3)	0	0	0
イレウス	0	0	1 (0.3)	0	0	0
麻痺性イレウス	0	0	1 (0.3)	0	0	0
閉塞性単径ヘルニア	0	0	1 (0.3)	0	0	0
腸出血	0	0	2 (0.6)	0	0	0
大腸潰瘍	0	0	1 (0.3)	0	0	0
口唇乾燥	0	0	1 (0.3)	0	0	0
口唇潰瘍	0	0	2 (0.6)	0	0	0
下部消化管出血	0	0	1 (0.3)	0	0	0
吸収不良	0	0	1 (0.3)	0	0	0
食道炎	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
口腔知覚不全	0	0	1 (0.3)	0	0	0
膵炎	0	0	2 (0.6)	0	0	0
逆流性胃炎	0	0	1 (0.3)	0	0	0
亜イレウス	0	0	1 (0.3)	0	0	0
舌変色	0	0	1 (0.3)	0	0	0
上部消化管出血	0	0	1 (0.3)	0	0	0
感染症および寄生虫症	258 (81.1)	32 (31.7)	236 (74.4)	16 (29.6)	367 (81.4)	63 (45.0)
上気道感染	70 (22.0)	9 (8.9)	54 (17.0)	2 (3.7)	115 (25.5)	24 (17.1)
鼻咽頭炎	77 (24.2)	9 (8.9)	61 (19.2)	4 (7.4)	100 (22.2)	18 (12.9)
気管支炎	54 (17.0)	4 (4.0)	51 (16.1)	1 (1.9)	78 (17.3)	5 (3.6)
肺炎	46 (14.5)	3 (3.0)	35 (11.0)	2 (3.7)	61 (13.5)	8 (5.7)
尿路感染	27 (8.5)	2 (2.0)	31 (9.8)	0	45 (10.0)	4 (2.9)
鼻炎	22 (6.9)	1 (1.0)	12 (3.8)	0	34 (7.5)	4 (2.9)
気道感染	34 (10.7)	1 (1.0)	30 (9.5)	0	36 (8.0)	1 (0.7)
インフルエンザ	18 (5.7)	1 (1.0)	19 (6.0)	2 (3.7)	28 (6.2)	4 (2.9)
副鼻腔炎	18 (5.7)	4 (4.0)	14 (4.4)	3 (5.6)	30 (6.7)	7 (5.0)
下気道感染	24 (7.5)	4 (4.0)	16 (5.0)	1 (1.9)	24 (5.3)	5 (3.6)
帯状疱疹	19 (6.0)	0	9 (2.8)	0	24 (5.3)	0
蜂巣炎	12 (3.8)	0	7 (2.2)	0	23 (5.1)	1 (0.7)
口腔ヘルペス	16 (5.0)	1 (1.0)	13 (4.1)	0	19 (4.2)	1 (0.7)
咽頭炎	17 (5.3)	0	12 (3.8)	0	19 (4.2)	1 (0.7)
口腔カンジダ症	11 (3.5)	0	7 (2.2)	0	18 (4.0)	2 (1.4)
胃腸炎	12 (3.8)	1 (1.0)	10 (3.2)	0	15 (3.3)	3 (2.1)
ウイルス感染	13 (4.1)	1 (1.0)	8 (2.5)	0	15 (3.3)	1 (0.7)
気管支肺炎	9 (2.8)	1 (1.0)	4 (1.3)	0	12 (2.7)	1 (0.7)
結膜炎	12 (3.8)	0	12 (3.8)	0	13 (2.9)	0
肺感染	8 (2.5)	0	6 (1.9)	1 (1.9)	11 (2.4)	0
敗血症	5 (1.6)	0	7 (2.2)	0	10 (2.2)	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
感染	8 (2.5)	0	14 (4.4)	1 (1.9)	10 (2.2)	0
膀胱炎	7 (2.2)	0	6 (1.9)	0	8 (1.8)	0
ウイルス性胃腸炎	4 (1.3)	0	6 (1.9)	0	5 (1.1)	3 (2.1)
耳感染	4 (1.3)	1 (1.0)	3 (0.9)	0	5 (1.1)	2 (1.4)
ヘルペスウイルス感染	7 (2.2)	0	0	0	7 (1.6)	0
毛包炎	4 (1.3)	0	2 (0.6)	0	6 (1.3)	0
喉頭炎	4 (1.3)	0	0	0	6 (1.3)	0
大葉性肺炎	3 (0.9)	0	4 (1.3)	0	5 (1.1)	1 (0.7)
カンジダ感染	5 (1.6)	1 (1.0)	4 (1.3)	0	5 (1.1)	1 (0.7)
眼感染	4 (1.3)	0	3 (0.9)	0	5 (1.1)	0
真菌感染	3 (0.9)	0	1 (0.3)	0	4 (0.9)	1 (0.7)
皮膚真菌感染	3 (0.9)	0	0	0	5 (1.1)	0
限局性感染	1 (0.3)	0	7 (2.2)	0	2 (0.4)	3 (2.1)
口腔感染	4 (1.3)	0	0	0	5 (1.1)	0
歯感染	3 (0.9)	1 (1.0)	6 (1.9)	3 (5.6)	4 (0.9)	1 (0.7)
クロストリジウム・ディフィシレ大腸炎	2 (0.6)	1 (1.0)	1 (0.3)	0	3 (0.7)	1 (0.7)
歯肉炎	1 (0.3)	0	3 (0.9)	0	3 (0.7)	1 (0.7)
骨髄炎	4 (1.3)	0	3 (0.9)	0	4 (0.9)	0
歯周炎	3 (0.9)	0	2 (0.6)	0	4 (0.9)	0
肺炎球菌性肺炎	4 (1.3)	0	0	1 (1.9)	4 (0.9)	0
ウイルス性上気道感染	0	1 (1.0)	3 (0.9)	1 (1.9)	2 (0.4)	2 (1.4)
異型肺炎	2 (0.6)	0	0	0	3 (0.7)	0
クロストリジウム・ディフィシレ感染	1 (0.3)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
ウイルス性消化管感染	1 (0.3)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
単純ヘルペス	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0
口唇感染	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
爪真菌症	2 (0.6)	0	3 (0.9)	0	3 (0.7)	0
口腔真菌感染	2 (0.6)	0	3 (0.9)	0	3 (0.7)	0
ニューモシスチス・イロベチイ肺炎	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
術後創感染	1 (0.3)	0	1 (0.3)	0	3 (0.7)	0
膿疱性皮疹	1 (0.3)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
ライノウイルス感染	3 (0.9)	0	0	0	3 (0.7)	0
足部白癬	3 (0.9)	0	2 (0.6)	0	3 (0.7)	0
急性扁桃炎	1 (0.3)	0	0	0	2 (0.4)	0
アスペルギルス感染	1 (0.3)	0	0	0	2 (0.4)	0
細菌感染	2 (0.6)	0	0	0	2 (0.4)	0
ウイルス性結膜炎	1 (0.3)	0	0	0	2 (0.4)	0
熱性感染症	1 (0.3)	0	0	0	2 (0.4)	0
せつ	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
陰部ヘルペス	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
歯肉膿瘍	2 (0.6)	0	0	0	2 (0.4)	0
H1N1 インフルエンザ	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
麦粒腫	0	0	0	0	2 (0.4)	0
咬傷感染	1 (0.3)	0	0	0	2 (0.4)	0
中耳炎	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
歯髄炎	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
敗血症性ショック	2 (0.6)	0	5 (1.6)	0	2 (0.4)	0
副鼻腔気管支炎	2 (0.6)	0	0	0	2 (0.4)	0
皮膚感染	1 (0.3)	0	3 (0.9)	0	2 (0.4)	0
ブドウ球菌感染	1 (0.3)	0	0	0	2 (0.4)	0
股部白癬	2 (0.6)	0	0	0	2 (0.4)	0
歯膿瘍	2 (0.6)	0	3 (0.9)	0	2 (0.4)	0
気管炎	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
細菌性尿路感染	2 (0.6)	0	0	0	2 (0.4)	0
ウイルス性下痢	2 (0.6)	0	0	0	2 (0.4)	0
創傷感染	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
膿瘍	1 (0.3)	0	0	0	1 (0.2)	0
急性副鼻腔炎	0	0	1 (0.3)	0	0	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
非定型マイコバクテリア感染	0	1 (1.0)	0	0	0	1 (0.7)
菌血症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
細菌性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
体部白癬	1 (0.3)	0	0	0	1 (0.2)	0
細気管支炎	1 (0.3)	0	0	0	1 (0.2)	0
気管支肺アスペルギルス症	1 (0.3)	0	0	0	1 (0.2)	0
カンピロバクター胃腸炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
脳アスペルギルス症	1 (0.3)	0	0	0	1 (0.2)	0
慢性副鼻腔炎	1 (0.3)	0	0	0	1 (0.2)	0
サイトメガロウイルス感染	1 (0.3)	0	0	0	1 (0.2)	0
医療機器関連感染	1 (0.3)	0	0	0	1 (0.2)	0
憩室炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
真菌性耳感染	1 (0.3)	0	0	0	1 (0.2)	0
心内膜炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
感染性腸炎	1 (0.3)	0	0	0	1 (0.2)	0
腸球菌感染	1 (0.3)	0	0	0	1 (0.2)	0
ウイルス性腸炎	1 (0.3)	0	0	0	1 (0.2)	0
丹毒	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
伝染性紅斑	0	0	1 (0.3)	0	1 (0.2)	0
大腸菌性尿路感染	1 (0.3)	0	0	0	1 (0.2)	0
消化管感染	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
性器感染	1 (0.3)	0	0	0	1 (0.2)	0
泌尿生殖器感染	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
切開部位感染	1 (0.3)	0	0	0	1 (0.2)	0
感染性嚢腫	1 (0.3)	0	0	0	1 (0.2)	0
感染性皮膚嚢腫	1 (0.3)	0	0	0	1 (0.2)	0
感染性大腸炎	1 (0.3)	0	0	0	1 (0.2)	0
クレブシエラ感染	1 (0.3)	0	0	0	1 (0.2)	0
迷路炎	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
ライム病	1 (0.3)	0	0	0	1 (0.2)	0
髄膜炎	0	0	0	0	1 (0.2)	0
ブドウ球菌性髄膜炎	1 (0.3)	0	0	0	1 (0.2)	0
粘膜感染	1 (0.3)	0	0	0	1 (0.2)	0
爪感染	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
好中球減少性敗血症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
食道カンジダ症	1 (0.3)	0	0	0	1 (0.2)	0
膵炎	0	0	0	0	1 (0.2)	0
口腔ウイルス感染	1 (0.3)	0	0	0	1 (0.2)	0
外耳炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
直腸周囲膿瘍	1 (0.3)	0	0	0	1 (0.2)	0
百日咳	1 (0.3)	0	0	0	1 (0.2)	0
咽頭扁桃炎	1 (0.3)	0	0	0	1 (0.2)	0
肺炎球菌性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
細菌性肺炎	1 (0.3)	0	0	0	1 (0.2)	0
真菌性肺炎	1 (0.3)	0	0	0	1 (0.2)	0
インフルエンザ性肺炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
レジオネラ菌性肺炎	0	0	0	0	1 (0.2)	0
RS ウイルス肺炎	0	0	0	0	1 (0.2)	0
レンサ球菌性肺炎	1 (0.3)	0	0	0	1 (0.2)	0
ウイルス性肺炎	0	0	0	0	0	1 (0.7)
処置後感染	0	0	0	0	1 (0.2)	0
腎盂腎炎	1 (0.3)	0	0	0	1 (0.2)	0
RS ウイルス感染	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
皮膚カンジダ	0	0	0	0	1 (0.2)	0
軟部組織感染	0	0	0	0	1 (0.2)	0
スフィンゴモナス・パウシモビリス感染	1 (0.3)	0	0	0	1 (0.2)	0
脊髄感染	0	0	0	0	1 (0.2)	0
ブドウ球菌性菌血症	0	0	1 (0.3)	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
レンサ球菌感染	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
手白癬	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
扁桃炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
細菌性上気道感染	0	0	0	0	1 (0.2)	0
シュードモナス性尿路感染	1 (0.3)	0	0	0	1 (0.2)	0
尿路性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
腟感染	0	0	0	0	1 (0.2)	0
水痘	1 (0.3)	0	0	0	1 (0.2)	0
ウイルス性咽頭炎	1 (0.3)	0	0	0	1 (0.2)	0
ウイルス性鼻炎	0	0	1 (0.3)	0	1 (0.2)	0
内臓リーシュマニア症	0	0	0	0	1 (0.2)	0
外陰部腟カンジダ症	0	0	0	0	1 (0.2)	0
ブドウ球菌性創感染	0	0	0	0	1 (0.2)	0
腹部膿瘍	0	0	0	1 (1.9)	0	0
顎膿瘍	0	0	2 (0.6)	0	0	0
四肢膿瘍	0	0	1 (0.3)	0	0	0
口腔膿瘍	0	0	1 (0.3)	0	0	0
細菌性関節炎	0	0	2 (0.6)	0	0	0
骨膿瘍	0	0	1 (0.3)	0	0	0
ウイルス性気管支炎	0	0	1 (0.3)	0	0	0
カンピロバクター感染	0	0	1 (0.3)	0	0	0
カテーテル留置部位感染	0	0	2 (0.6)	0	0	0
男性外性器蜂巣炎	0	0	1 (0.3)	0	0	0
医療機器関連敗血症	0	0	1 (0.3)	0	0	0
糖尿病性足感染	0	0	1 (0.3)	0	0	0
眼内炎	0	0	1 (0.3)	0	0	0
ウイルス性胃炎	0	0	1 (0.3)	0	0	0
消化器カンジダ症	0	0	1 (0.3)	0	0	0
ヘモフィルス感染	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
埋込み部位膿瘍	0	0	1 (0.3)	0	0	0
リステリア症	0	0	1 (0.3)	0	0	0
肺膿瘍	0	0	1 (0.3)	1 (1.9)	0	0
眼部単純ヘルペス	0	0	1 (0.3)	0	0	0
眼帯状疱疹	0	0	1 (0.3)	0	0	0
パラインフルエンザウイルス感染	0	0	3 (0.9)	0	0	0
爪囲炎	0	0	2 (0.6)	0	0	0
腹膜炎	0	0	1 (0.3)	0	0	0
急性腎盂腎炎	0	0	1 (0.3)	0	0	0
膿性痰	0	0	2 (0.6)	0	0	0
ブドウ球菌性敗血症	0	0	1 (0.3)	0	0	0
レンサ球菌性菌血症	0	0	1 (0.3)	0	0	0
皮下組織膿瘍	0	0	1 (0.3)	0	0	0
気管気管支炎	0	0	1 (0.3)	0	0	0
腸球菌性尿路感染	0	0	1 (0.3)	0	0	0
真菌性尿路感染	0	0	1 (0.3)	0	0	0
泌尿生殖器細菌感染	0	0	1 (0.3)	0	0	0
筋骨格系および結合組織障害	217 (68.2)	25 (24.8)	214 (67.5)	9 (16.7)	320 (71.0)	46 (32.9)
筋痙縮	95 (29.9)	2 (2.0)	84 (26.5)	1 (1.9)	154 (34.1)	7 (5.0)
背部痛	87 (27.4)	6 (5.9)	87 (27.4)	3 (5.6)	129 (28.6)	15 (10.7)
関節痛	50 (15.7)	7 (6.9)	39 (12.3)	1 (1.9)	76 (16.9)	15 (10.7)
四肢痛	50 (15.7)	4 (4.0)	32 (10.1)	0	74 (16.4)	10 (7.1)
筋骨格痛	38 (11.9)	5 (5.0)	28 (8.8)	0	51 (11.3)	7 (5.0)
骨痛	31 (9.7)	3 (3.0)	40 (12.6)	0	46 (10.2)	4 (2.9)
筋力低下	36 (11.3)	1 (1.0)	24 (7.6)	1 (1.9)	42 (9.3)	1 (0.7)
筋骨格系胸痛	30 (9.4)	2 (2.0)	26 (8.2)	0	40 (8.9)	2 (1.4)
筋肉痛	20 (6.3)	3 (3.0)	23 (7.3)	0	29 (6.4)	6 (4.3)
頚部痛	15 (4.7)	1 (1.0)	10 (3.2)	1 (1.9)	18 (4.0)	2 (1.4)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
顎痛	7 (2.2)	3 (3.0)	2 (0.6)	0	12 (2.7)	3 (2.1)
筋骨格硬直	8 (2.5)	0	2 (0.6)	0	10 (2.2)	1 (0.7)
脊椎痛	8 (2.5)	0	5 (1.6)	0	9 (2.0)	1 (0.7)
側腹部痛	8 (2.5)	0	2 (0.6)	0	9 (2.0)	1 (0.7)
ミオパチー	8 (2.5)	0	5 (1.6)	0	9 (2.0)	0
関節腫脹	5 (1.6)	0	9 (2.8)	0	8 (1.8)	1 (0.7)
筋骨格不快感	2 (0.6)	0	5 (1.6)	0	6 (1.3)	0
骨壊死	4 (1.3)	2 (2.0)	2 (0.6)	0	4 (0.9)	2 (1.4)
四肢不快感	3 (0.9)	0	1 (0.3)	0	5 (1.1)	0
変形性関節症	2 (0.6)	1 (1.0)	1 (0.3)	0	3 (0.7)	2 (1.4)
顎骨壊死	4 (1.3)	0	9 (2.8)	2 (3.7)	5 (1.1)	0
関節炎	4 (1.3)	0	3 (0.9)	0	4 (0.9)	0
単径部痛	4 (1.3)	0	2 (0.6)	0	4 (0.9)	0
重感	3 (0.9)	0	0	0	3 (0.7)	0
尾骨痛	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
筋拘縮	2 (0.6)	0	0	0	2 (0.4)	0
筋肉内出血	2 (0.6)	0	0	0	2 (0.4)	0
筋緊張	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
筋攣縮	2 (0.6)	0	0	0	2 (0.4)	0
頚部腫瘤	1 (0.3)	0	0	0	1 (0.2)	1 (0.7)
骨炎	1 (0.3)	0	0	0	2 (0.4)	0
腱痛	1 (0.3)	0	0	0	2 (0.4)	0
筋萎縮症	1 (0.3)	0	0	0	1 (0.2)	0
骨病変	1 (0.3)	0	0	0	1 (0.2)	0
バニオン	1 (0.3)	0	0	0	1 (0.2)	0
滑液包炎	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
頚部脊柱管狭窄症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
四肢拘縮	1 (0.3)	0	0	0	1 (0.2)	0
筋膜炎	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
瘻孔	0	0	0	0	1 (0.2)	0
痛風性関節炎	0	0	1 (0.3)	0	1 (0.2)	0
出血性関節症	1 (0.3)	0	0	0	1 (0.2)	0
椎間板突出	1 (0.3)	0	0	0	1 (0.2)	0
関節摩擦音	1 (0.3)	0	0	0	1 (0.2)	0
関節滲出液	0	0	0	0	0	1 (0.7)
関節可動域低下	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
運動性低下	1 (0.3)	0	0	0	1 (0.2)	0
筋萎縮	1 (0.3)	0	0	0	1 (0.2)	0
筋腫瘤	1 (0.3)	0	0	0	1 (0.2)	0
骨溶解	1 (0.3)	0	0	0	1 (0.2)	0
骨減少症	0	0	0	0	1 (0.2)	0
骨粗鬆症	0	0	0	0	1 (0.2)	0
足底筋膜炎	1 (0.3)	0	0	0	1 (0.2)	0
恥骨痛	1 (0.3)	0	0	0	1 (0.2)	0
肩回旋筋腱板症候群	0	0	1 (0.3)	0	0	1 (0.7)
脊柱管狭窄症	0	1 (1.0)	0	0	0	1 (0.7)
顎関節症候群	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
腱炎	1 (0.3)	0	5 (1.6)	0	1 (0.2)	0
腱鞘炎	0	0	0	0	1 (0.2)	0
開口障害	1 (0.3)	0	0	0	1 (0.2)	0
骨障害	0	0	0	1 (1.9)	0	0
外骨腫	0	0	1 (0.3)	0	0	0
瘻孔分泌物	0	0	1 (0.3)	0	0	0
関節硬直	0	0	4 (1.3)	0	0	0
病的骨折	0	0	1 (0.3)	0	0	0
横紋筋融解症	0	0	2 (0.6)	0	0	0
変形性脊椎症	0	0	2 (0.6)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
神経系障害	200 (62.9)	10 (9.9)	170 (53.6)	6 (11.1)	299 (66.3)	29 (20.7)
頭痛	48 (15.1)	1 (1.0)	24 (7.6)	0	74 (16.4)	6 (4.3)
末梢性ニューロパチー	43 (13.5)	4 (4.0)	26 (8.2)	0	69 (15.3)	12 (8.6)
浮動性めまい	45 (14.2)	2 (2.0)	37 (11.7)	0	68 (15.1)	5 (3.6)
味覚異常	32 (10.1)	0	20 (6.3)	0	54 (12.0)	1 (0.7)
錯感覚	32 (10.1)	0	29 (9.1)	0	44 (9.8)	1 (0.7)
末梢性感覚ニューロパチー	29 (9.1)	0	34 (10.7)	2 (3.7)	39 (8.6)	0
振戦	29 (9.1)	0	29 (9.1)	0	39 (8.6)	0
感覚鈍麻	21 (6.6)	1 (1.0)	11 (3.5)	0	28 (6.2)	3 (2.1)
失神	7 (2.2)	1 (1.0)	4 (1.3)	0	17 (3.8)	3 (2.1)
記憶障害	8 (2.5)	1 (1.0)	9 (2.8)	0	14 (3.1)	1 (0.7)
傾眠	11 (3.5)	0	8 (2.5)	0	15 (3.3)	0
多発ニューロパチー	11 (3.5)	0	6 (1.9)	0	11 (2.4)	0
平衡障害	6 (1.9)	0	5 (1.6)	0	9 (2.0)	0
認知障害	7 (2.2)	0	2 (0.6)	0	7 (1.6)	0
神経痛	4 (1.3)	0	1 (0.3)	0	6 (1.3)	1 (0.7)
副鼻腔炎に伴う頭痛	1 (0.3)	1 (1.0)	1 (0.3)	0	4 (0.9)	3 (2.1)
健忘	4 (1.3)	0	3 (0.9)	0	6 (1.3)	0
末梢性運動ニューロパチー	5 (1.6)	1 (1.0)	0	0	5 (1.1)	1 (0.7)
失神寸前の状態	4 (1.3)	0	2 (0.6)	0	5 (1.1)	0
坐骨神経痛	3 (0.9)	0	1 (0.3)	0	4 (0.9)	1 (0.7)
味覚消失	2 (0.6)	0	0	0	4 (0.9)	0
嗜眠	2 (0.6)	1 (1.0)	4 (1.3)	0	3 (0.7)	1 (0.7)
精神運動亢進	1 (0.3)	0	1 (0.3)	0	4 (0.9)	0
反射消失	3 (0.9)	0	3 (0.9)	1 (1.9)	3 (0.7)	0
運動失調	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
痙攣	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0
注意力障害	1 (0.3)	0	3 (0.9)	0	2 (0.4)	1 (0.7)
体位性めまい	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
知覚過敏	2 (0.6)	0	0	0	2 (0.4)	1 (0.7)
片頭痛	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
一過性脳虚血発作	1 (0.3)	0	1 (0.3)	0	3 (0.7)	0
手根管症候群	0	0	1 (0.3)	0	0	2 (1.4)
脳血管発作	1 (0.3)	0	1 (0.3)	1 (1.9)	2 (0.4)	0
局在性痙攣	2 (0.6)	0	0	0	2 (0.4)	0
振動覚低下	2 (0.6)	0	0	0	2 (0.4)	0
筋緊張亢進	2 (0.6)	0	0	0	2 (0.4)	0
味覚減退	0	0	3 (0.9)	0	2 (0.4)	0
反射減弱	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
失語症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
灼熱感	0	0	2 (0.6)	0	1 (0.2)	0
頚動脈閉塞	0	0	0	0	1 (0.2)	1 (0.7)
脳梗塞	1 (0.3)	0	0	0	1 (0.2)	0
脳虚血	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
頚髄神経根障害	1 (0.3)	0	0	0	1 (0.2)	0
認知症	1 (0.3)	0	0	0	1 (0.2)	0
異常感覚	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
構語障害	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
ジスキネジア	1 (0.3)	0	0	0	1 (0.2)	0
ジストニア	1 (0.3)	0	0	0	1 (0.2)	0
顔面神経障害	1 (0.3)	0	0	0	1 (0.2)	0
顔面部神経痛	0	0	0	0	1 (0.2)	0
大発作痙攣	0	0	0	0	1 (0.2)	1 (0.7)
頭部不快感	1 (0.3)	0	0	0	1 (0.2)	0
頭部動揺	1 (0.3)	0	0	0	1 (0.2)	0
筋緊張低下	1 (0.3)	0	0	0	1 (0.2)	0
肋間神経痛	1 (0.3)	0	0	0	1 (0.2)	0
意識消失	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
固有感覚の欠如	0	0	0	0	1 (0.2)	0
不全単麻痺	1 (0.3)	0	0	0	1 (0.2)	0
神経学的症状	1 (0.3)	0	0	0	1 (0.2)	0
おとがいしびれ症候群	0	0	0	0	1 (0.2)	0
視神経炎	1 (0.3)	0	0	0	1 (0.2)	0
不全対麻痺	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
パーキンソニズム	1 (0.3)	0	0	0	1 (0.2)	0
嗅覚錯誤	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
睡眠の質低下	1 (0.3)	0	0	0	1 (0.2)	0
ヘルペス後神経痛	1 (0.3)	0	2 (0.6)	1 (1.9)	1 (0.2)	0
下肢静止不能症候群	1 (0.3)	0	0	0	1 (0.2)	0
感覚消失	1 (0.3)	0	0	1 (1.9)	1 (0.2)	0
脊髄圧迫	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
緊張性頭痛	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
一過性全健忘	0	0	0	0	1 (0.2)	0
三叉神経痛	0	0	0	0	1 (0.2)	0
第７脳神経麻痺	1 (0.3)	0	0	0	1 (0.2)	0
視野欠損	0	0	0	0	1 (0.2)	0
白質病変	0	0	0	0	1 (0.2)	0
軸索型ニューロパチー	0	0	1 (0.3)	0	0	0
小脳症候群	0	0	1 (0.3)	0	0	0
脳出血	0	0	1 (0.3)	0	0	0
間代	0	0	1 (0.3)	0	0	0
複合性局所疼痛症候群	0	0	1 (0.3)	0	0	0
脳症	0	0	2 (0.6)	0	0	0
蟻走感	0	0	1 (0.3)	0	0	0
不全片麻痺	0	0	2 (0.6)	0	0	0
過眠症	0	0	1 (0.3)	0	0	0
単ニューロパチー	0	0	2 (0.6)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
不随意性筋収縮	0	0	2 (0.6)	0	0	0
神経毒性	0	0	2 (0.6)	0	0	0
眼振	0	0	1 (0.3)	0	0	0
対麻痺	0	0	1 (0.3)	0	0	0
パーキンソン病	0	0	1 (0.3)	0	0	0
精神運動機能障害	0	0	1 (0.3)	0	0	0
脊髄障害	0	0	1 (0.3)	0	0	0
てんかん重積状態	0	0	0	1 (1.9)	0	0
血管性脳症	0	0	1 (0.3)	0	0	0
血液およびリンパ系障害	199 (62.6)	18 (17.8)	191 (60.3)	11 (20.4)	288 (63.9)	30 (21.4)
貧血	122 (38.4)	10 (9.9)	115 (36.3)	7 (13.0)	172 (38.1)	17 (12.1)
好中球減少症	106 (33.3)	6 (5.9)	133 (42.0)	6 (11.1)	146 (32.4)	11 (7.9)
血小板減少症	85 (26.7)	4 (4.0)	71 (22.4)	3 (5.6)	123 (27.3)	6 (4.3)
リンパ球減少症	41 (12.9)	7 (6.9)	21 (6.6)	1 (1.9)	73 (16.2)	12 (8.6)
白血球減少症	24 (7.5)	2 (2.0)	24 (7.6)	2 (3.7)	50 (11.1)	6 (4.3)
発熱性好中球減少症	10 (3.1)	0	7 (2.2)	0	17 (3.8)	1 (0.7)
汎血球減少症	8 (2.5)	0	0	0	10 (2.2)	0
リンパ節症	2 (0.6)	0	2 (0.6)	0	6 (1.3)	0
内出血発生の増加傾向	2 (0.6)	0	3 (0.9)	0	3 (0.7)	1 (0.7)
好酸球増加症	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
鉄欠乏性貧血	0	1 (1.0)	0	0	2 (0.4)	1 (0.7)
白血球増加症	1 (0.3)	0	2 (0.6)	0	3 (0.7)	0
顆粒球減少症	1 (0.3)	0	0	0	2 (0.4)	0
血小板増加症	0	0	0	0	2 (0.4)	0
骨髄機能不全	1 (0.3)	0	0	0	1 (0.2)	0
血液毒性	1 (0.3)	0	0	0	1 (0.2)	0
ヘモグロビン血症	0	0	0	0	1 (0.2)	0
微小血管症性溶血性貧血	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
単球増加症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
形質細胞増加症	1 (0.3)	0	0	0	1 (0.2)	0
脾腫	0	0	0	0	1 (0.2)	0
腹部リンパ節腫脹	0	0	1 (0.3)	0	0	0
大球性貧血	0	0	1 (0.3)	0	0	0
播種性血管内凝固	0	0	1 (0.3)	0	0	0
出血性素因	0	0	1 (0.3)	0	0	0
リンパ節炎	0	0	1 (0.3)	0	0	0
大赤血球症	0	0	1 (0.3)	0	0	0
単球減少症	0	0	1 (0.3)	0	0	0
脾臓梗塞	0	0	1 (0.3)	0	0	0
呼吸器、胸郭および縦郭障害	192 (60.4)	16 (15.8)	162 (51.1)	8 (14.8)	281 (62.3)	38 (27.1)
咳嗽	99 (31.1)	5 (5.0)	57 (18.0)	2 (3.7)	129 (28.6)	17 (12.1)
呼吸困難	67 (21.1)	3 (3.0)	58 (18.3)	2 (3.7)	96 (21.3)	10 (7.1)
口腔咽頭痛	30 (9.4)	3 (3.0)	14 (4.4)	0	40 (8.9)	5 (3.6)
発声障害	24 (7.5)	0	29 (9.1)	1 (1.9)	36 (8.0)	1 (0.7)
労作性呼吸困難	17 (5.3)	1 (1.0)	13 (4.1)	0	33 (7.3)	3 (2.1)
鼻出血	19 (6.0)	0	18 (5.7)	1 (1.9)	30 (6.7)	2 (1.4)
湿性咳嗽	18 (5.7)	1 (1.0)	4 (1.3)	0	27 (6.0)	1 (0.7)
鼻閉	9 (2.8)	2 (2.0)	6 (1.9)	0	21 (4.7)	4 (2.9)
鼻漏	9 (2.8)	0	2 (0.6)	0	18 (4.0)	3 (2.1)
肺塞栓症	11 (3.5)	0	8 (2.5)	0	16 (3.5)	1 (0.7)
副鼻腔うっ血	9 (2.8)	0	2 (0.6)	0	14 (3.1)	2 (1.4)
しゃっくり	10 (3.1)	0	10 (3.2)	0	15 (3.3)	0
喘鳴	11 (3.5)	0	5 (1.6)	0	12 (2.7)	0
慢性閉塞性肺疾患	9 (2.8)	0	4 (1.3)	0	9 (2.0)	1 (0.7)
肺障害	5 (1.6)	0	1 (0.3)	0	8 (1.8)	2 (1.4)
低酸素症	5 (1.6)	0	2 (0.6)	0	8 (1.8)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
ラ音	6 (1.9)	0	3 (0.9)	0	6 (1.3)	2 (1.4)
アレルギー性鼻炎	7 (2.2)	1 (1.0)	2 (0.6)	0	8 (1.8)	1 (0.7)
胸水	5 (1.6)	0	4 (1.3)	0	7 (1.6)	0
胸膜痛	3 (0.9)	0	1 (0.3)	0	5 (1.1)	1 (0.7)
上気道咳症候群	1 (0.3)	0	0	0	4 (0.9)	2 (1.4)
肺臓炎	4 (1.3)	1 (1.0)	3 (0.9)	0	5 (1.1)	1 (0.7)
上気道の炎症	4 (1.3)	2 (2.0)	4 (1.3)	1 (1.9)	4 (0.9)	2 (1.4)
副鼻腔分泌過多	0	0	0	0	4 (0.9)	0
気道うっ血	3 (0.9)	1 (1.0)	2 (0.6)	0	3 (0.7)	1 (0.7)
喘息	2 (0.6)	0	0	0	3 (0.7)	0
変色痰	2 (0.6)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
咽喉刺激感	1 (0.3)	0	1 (0.3)	0	3 (0.7)	0
急性呼吸不全	1 (0.3)	0	0	0	2 (0.4)	0
無気肺	1 (0.3)	0	1 (0.3)	0	1 (0.2)	1 (0.7)
気管支反応性亢進	2 (0.6)	0	0	0	2 (0.4)	0
喀血	0	0	2 (0.6)	1 (1.9)	1 (0.2)	1 (0.7)
低換気	2 (0.6)	0	0	1 (1.9)	2 (0.4)	0
間質性肺疾患	0	1 (1.0)	3 (0.9)	1 (1.9)	1 (0.2)	1 (0.7)
鼻部不快感	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
胸膜炎	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
肺水腫	1 (0.3)	0	0	0	1 (0.2)	1 (0.7)
呼吸障害	2 (0.6)	0	0	0	2 (0.4)	0
無呼吸	0	0	0	0	1 (0.2)	0
気管支浮腫	1 (0.3)	0	0	0	1 (0.2)	0
気管支拡張症	1 (0.3)	0	0	0	1 (0.2)	0
慢性気管支炎	1 (0.3)	0	0	0	1 (0.2)	0
気管支痙攣	1 (0.3)	0	0	0	1 (0.2)	0
咽喉乾燥	0	0	1 (0.3)	0	1 (0.2)	0
過換気	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
上気道分泌増加	0	0	1 (0.3)	0	1 (0.2)	0
喉頭痛	1 (0.3)	0	0	0	1 (0.2)	0
鼻乾燥	0	0	0	0	1 (0.2)	0
鼻の炎症	0	1 (1.0)	0	0	0	1 (0.7)
鼻閉塞	1 (0.3)	0	0	0	1 (0.2)	0
夜間呼吸困難	1 (0.3)	0	0	0	1 (0.2)	0
閉塞性細気管支炎	1 (0.3)	0	0	0	1 (0.2)	0
閉塞性気道障害	1 (0.3)	0	0	0	1 (0.2)	0
器質化肺炎	1 (0.3)	0	0	0	1 (0.2)	0
口腔咽頭プラーク	1 (0.3)	0	0	0	1 (0.2)	0
呼吸時疼痛	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
咽頭紅斑	1 (0.3)	0	0	0	1 (0.2)	0
咽頭の炎症	0	0	0	0	0	1 (0.7)
気胸	0	0	0	0	1 (0.2)	0
肺胞出血	1 (0.3)	0	0	0	1 (0.2)	0
肺うっ血	0	0	0	0	1 (0.2)	0
肺出血	1 (0.3)	0	0	0	1 (0.2)	0
肺梗塞	0	0	0	0	1 (0.2)	0
肺腫瘤	0	0	1 (0.3)	0	1 (0.2)	0
呼吸不全	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
低音性連続性ラ音	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
副鼻腔障害	1 (0.3)	0	0	0	1 (0.2)	0
睡眠時無呼吸症候群	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
上気道性喘鳴	0	0	0	0	1 (0.2)	0
窒息感	1 (0.3)	0	0	0	1 (0.2)	0
頻呼吸	0	0	0	0	1 (0.2)	0
咽喉絞扼感	0	0	0	0	1 (0.2)	0
扁桃肥大	1 (0.3)	0	0	0	1 (0.2)	0
上気道閉塞	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
上気道うっ血	0	0	0	0	1 (0.2)	0
声帯障害	1 (0.3)	0	0	0	1 (0.2)	0
急性肺水腫	0	0	1 (0.3)	0	0	0
アレルギー性副鼻腔炎	0	0	1 (0.3)	0	0	0
気管支障害	0	0	1 (0.3)	0	0	0
鼻部障害	0	0	1 (0.3)	0	0	0
口腔咽頭不快感	0	0	1 (0.3)	0	0	0
肺高血圧症	0	0	1 (0.3)	0	0	0
呼吸性アルカローシス	0	0	1 (0.3)	0	0	0
呼吸窮迫	0	0	1 (0.3)	0	0	0
気道の炎症	0	0	1 (0.3)	0	0	0
鼻痛	0	0	1 (0.3)	0	0	0
くしゃみ	0	0	1 (0.3)	0	0	0
痰貯留	0	0	1 (0.3)	0	0	0
扁桃潰瘍	0	0	1 (0.3)	0	0	0
気管の炎症	0	0	1 (0.3)	0	0	0
血管運動性鼻炎	0	0	1 (0.3)	0	0	0
皮膚および皮下組織障害	181 (56.9)	12 (11.9)	143 (45.1)	5 (9.3)	263 (58.3)	25 (17.9)
発疹	58 (18.2)	2 (2.0)	57 (18.0)	1 (1.9)	90 (20.0)	4 (2.9)
多汗症	37 (11.6)	0	22 (6.9)	0	54 (12.0)	0
そう痒症	31 (9.7)	2 (2.0)	28 (8.8)	0	42 (9.3)	2 (1.4)
寝汗	22 (6.9)	0	9 (2.8)	0	41 (9.1)	1 (0.7)
紅斑	21 (6.6)	1 (1.0)	17 (5.4)	0	33 (7.3)	1 (0.7)
皮膚乾燥	12 (3.8)	1 (1.0)	7 (2.2)	1 (1.9)	19 (4.2)	2 (1.4)
蕁麻疹	14 (4.4)	0	4 (1.3)	0	17 (3.8)	0
斑状出血	6 (1.9)	1 (1.0)	1 (0.3)	1 (1.9)	12 (2.7)	2 (1.4)
皮膚病変	8 (2.5)	1 (1.0)	7 (2.2)	1 (1.9)	11 (2.4)	3 (2.1)
点状出血	7 (2.2)	0	2 (0.6)	0	9 (2.0)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
斑状丘疹状皮疹	5 (1.6)	0	4 (1.3)	0	8 (1.8)	1 (0.7)
脱毛症	4 (1.3)	0	6 (1.9)	0	7 (1.6)	1 (0.7)
全身性皮疹	1 (0.3)	1 (1.0)	0	0	7 (1.6)	1 (0.7)
紫斑	4 (1.3)	1 (1.0)	3 (0.9)	0	5 (1.1)	1 (0.7)
皮膚潰瘍	5 (1.6)	0	2 (0.6)	0	6 (1.3)	0
そう痒性皮疹	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
皮膚変色	2 (0.6)	1 (1.0)	2 (0.6)	0	4 (0.9)	1 (0.7)
アレルギー性皮膚炎	2 (0.6)	0	2 (0.6)	0	4 (0.9)	0
嵌入爪	1 (0.3)	1 (1.0)	2 (0.6)	0	3 (0.7)	1 (0.7)
皮膚腫瘤	4 (1.3)	0	2 (0.6)	0	4 (0.9)	0
日光性角化症	2 (0.6)	1 (1.0)	4 (1.3)	0	2 (0.4)	1 (0.7)
丘疹	1 (0.3)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
斑状皮疹	2 (0.6)	0	1 (0.3)	0	3 (0.7)	0
皮膚剥脱	0	0	1 (0.3)	0	2 (0.4)	1 (0.7)
顔面腫脹	1 (0.3)	1 (1.0)	1 (0.3)	0	2 (0.4)	1 (0.7)
ざ瘡	0	0	1 (0.3)	0	1 (0.2)	1 (0.7)
水疱	0	0	1 (0.3)	0	2 (0.4)	0
褥瘡性潰瘍	2 (0.6)	0	0	0	2 (0.4)	0
皮膚嚢腫	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
皮膚炎	2 (0.6)	0	2 (0.6)	1 (1.9)	2 (0.4)	0
薬疹	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
毛髪成長異常	2 (0.6)	0	0	0	2 (0.4)	0
過角化	2 (0.6)	0	0	0	2 (0.4)	0
爪の障害	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
爪破損	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
全身性そう痒症	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
丘疹性皮疹	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
痂皮	0	0	0	0	2 (0.4)	0
皮膚亀裂	0	0	1 (0.3)	0	2 (0.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
皮膚色素過剰	1 (0.3)	0	0	1 (1.9)	2 (0.4)	0
血管浮腫	1 (0.3)	0	0	0	1 (0.2)	0
ざ瘡様皮膚炎	0	0	1 (0.3)	0	1 (0.2)	0
接触性皮膚炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
びまん性脱毛症	1 (0.3)	0	0	0	1 (0.2)	0
全身紅斑	0	0	0	0	1 (0.2)	0
皮下出血	0	0	0	0	0	1 (0.7)
毛髪変色	1 (0.3)	0	0	0	1 (0.2)	0
毛髪障害	0	0	0	0	1 (0.2)	0
男性型多毛症	0	0	0	0	1 (0.2)	0
白斑	1 (0.3)	0	0	0	1 (0.2)	0
後天性リポジストロフィー	1 (0.3)	0	0	0	1 (0.2)	0
斑	1 (0.3)	0	1 (0.3)	1 (1.9)	1 (0.2)	0
汗疹	0	0	0	0	1 (0.2)	0
爪床出血	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
爪変色	0	0	0	0	1 (0.2)	0
皮膚疼痛	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
天疱瘡	1 (0.3)	0	0	0	1 (0.2)	0
陰茎潰瘍形成	0	0	0	0	1 (0.2)	0
光線性皮膚症	1 (0.3)	0	0	0	1 (0.2)	0
色素沈着障害	0	0	0	0	1 (0.2)	0
アレルギー性そう痒症	0	0	0	0	1 (0.2)	0
乾癬	0	0	1 (0.3)	0	1 (0.2)	0
膿疱性乾癬	1 (0.3)	0	0	0	1 (0.2)	0
紅斑性皮疹	0	0	2 (0.6)	0	1 (0.2)	0
酒さ	0	0	1 (0.3)	0	1 (0.2)	0
皮膚灼熱感	1 (0.3)	0	0	0	1 (0.2)	0
皮膚障害	1 (0.3)	0	0	0	1 (0.2)	0
皮膚びらん	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
皮膚出血	1 (0.3)	0	0	0	1 (0.2)	0
皮膚壊死	1 (0.3)	0	0	0	1 (0.2)	0
皮膚反応	1 (0.3)	0	0	0	1 (0.2)	0
皮膚腫脹	0	0	0	0	0	1 (0.7)
うっ滞性皮膚炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
毛細血管拡張症	1 (0.3)	0	0	0	1 (0.2)	0
中毒性皮疹	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
乾皮症	1 (0.3)	0	0	0	1 (0.2)	0
皮脂欠乏症	0	0	1 (0.3)	0	0	0
蝶形皮疹	0	0	1 (0.3)	0	0	0
冷汗	0	0	1 (0.3)	0	0	0
剥脱性皮膚炎	0	0	1 (0.3)	0	0	0
皮膚症	0	0	1 (0.3)	0	0	0
湿疹	0	0	1 (0.3)	0	0	0
紅色症	0	0	0	1 (1.9)	0	0
脂肪肥大症	0	0	1 (0.3)	0	0	0
爪床の炎症	0	0	1 (0.3)	0	0	0
神経皮膚炎	0	0	1 (0.3)	0	0	0
皮膚脆弱性	0	0	0	1 (1.9)	0	0
皮膚色素減少	0	0	1 (0.3)	0	0	0
皮膚硬結	0	0	1 (0.3)	0	0	0
尋常性白斑	0	0	1 (0.3)	0	0	0
黄色板腫	0	0	1 (0.3)	0	0	0
黄色皮膚	0	0	1 (0.3)	0	0	0
代謝および栄養障害	175 (55.0)	16 (15.8)	150 (47.3)	10 (18.5)	253 (56.1)	28 (20.0)
食欲減退	64 (20.1)	2 (2.0)	39 (12.3)	1 (1.9)	88 (19.5)	5 (3.6)
高血糖	55 (17.3)	5 (5.0)	43 (13.6)	2 (3.7)	86 (19.1)	8 (5.7)
低カリウム血症	49 (15.4)	6 (5.9)	47 (14.8)	1 (1.9)	75 (16.6)	8 (5.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
低カルシウム血症	42 (13.2)	6 (5.9)	31 (9.8)	1 (1.9)	55 (12.2)	7 (5.0)
低ナトリウム血症	18 (5.7)	2 (2.0)	12 (3.8)	0	27 (6.0)	2 (1.4)
低アルブミン血症	14 (4.4)	1 (1.0)	10 (3.2)	1 (1.9)	24 (5.3)	1 (0.7)
低マグネシウム血症	16 (5.0)	0	6 (1.9)	0	20 (4.4)	2 (1.4)
低リン酸血症	11 (3.5)	3 (3.0)	9 (2.8)	1 (1.9)	20 (4.4)	3 (2.1)
高カリウム血症	11 (3.5)	2 (2.0)	4 (1.3)	1 (1.9)	21 (4.7)	2 (1.4)
脱水	13 (4.1)	2 (2.0)	6 (1.9)	1 (1.9)	19 (4.2)	5 (3.6)
高カルシウム血症	12 (3.8)	0	12 (3.8)	1 (1.9)	17 (3.8)	0
高尿酸血症	13 (4.1)	0	7 (2.2)	0	15 (3.3)	0
糖尿病	7 (2.2)	0	2 (0.6)	0	9 (2.0)	0
痛風	4 (1.3)	0	2 (0.6)	0	8 (1.8)	0
低血糖症	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
ビタミンＤ欠乏	1 (0.3)	0	2 (0.6)	0	5 (1.1)	0
耐糖能障害	3 (0.9)	0	3 (0.9)	0	4 (0.9)	0
高ナトリウム血症	0	0	2 (0.6)	0	4 (0.9)	0
体液貯留	3 (0.9)	0	0	0	3 (0.7)	0
高リン酸塩血症	1 (0.3)	0	0	0	3 (0.7)	0
高トリグリセリド血症	0	0	0	0	2 (0.4)	1 (0.7)
低クロール血症	2 (0.6)	0	0	0	3 (0.7)	0
鉄欠乏	3 (0.9)	0	1 (0.3)	1 (1.9)	3 (0.7)	0
高マグネシウム血症	1 (0.3)	0	0	0	2 (0.4)	0
アシドーシス	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
食欲障害	1 (0.3)	0	0	0	1 (0.2)	0
悪液質	1 (0.3)	0	0	0	1 (0.2)	0
成長障害	1 (0.3)	0	0	0	1 (0.2)	0
過小食	1 (0.3)	0	0	0	1 (0.2)	0
食欲亢進	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
栄養障害	1 (0.3)	0	0	0	1 (0.2)	0
代謝性アシドーシス	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
多飲症	1 (0.3)	0	0	0	1 (0.2)	0
腫瘍崩壊症候群	0	0	1 (0.3)	0	1 (0.2)	0
2 型糖尿病	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
ビタミン B12 欠乏	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
水分過負荷	0	0	1 (0.3)	0	0	0
ヘモジデリン沈着症	0	0	1 (0.3)	0	0	0
高コレステロール血症	0	0	2 (0.6)	2 (3.7)	0	0
高脂血症	0	0	1 (0.3)	0	0	0
血液量減少症	0	0	1 (0.3)	0	0	0
乳酸アシドーシス	0	0	1 (0.3)	0	0	0
肥満	0	0	1 (0.3)	0	0	0
テタニー	0	0	1 (0.3)	0	0	0
臨床検査	150 (47.2)	14 (13.9)	121 (38.2)	5 (9.3)	206 (45.7)	28 (20.0)
体重減少	41 (12.9)	4 (4.0)	19 (6.0)	0	55 (12.2)	5 (3.6)
血中クレアチニン増加	29 (9.1)	1 (1.0)	22 (6.9)	0	42 (9.3)	3 (2.1)
アラニンアミノトランスフェラーゼ増加	24 (7.5)	0	32 (10.1)	1 (1.9)	37 (8.2)	3 (2.1)
アスパラギン酸アミノトランスフェラーゼ増加	20 (6.3)	1 (1.0)	27 (8.5)	1 (1.9)	29 (6.4)	4 (2.9)
血小板数減少	15 (4.7)	1 (1.0)	5 (1.6)	0	16 (3.5)	3 (2.1)
血中乳酸脱水素酵素増加	8 (2.5)	1 (1.0)	6 (1.9)	1 (1.9)	14 (3.1)	1 (0.7)
腎クレアチニン・クリアランス減少	12 (3.8)	1 (1.0)	3 (0.9)	0	14 (3.1)	2 (1.4)
血中アルカリホスファターゼ増加	7 (2.2)	1 (1.0)	8 (2.5)	0	12 (2.7)	3 (2.1)
ヘモグロビン減少	9 (2.8)	1 (1.0)	8 (2.5)	0	13 (2.9)	1 (0.7)
血中重炭酸塩減少	1 (0.3)	0	1 (0.3)	0	12 (2.7)	0
C一反応性蛋白増加	11 (3.5)	0	14 (4.4)	0	12 (2.7)	0
体重増加	5 (1.6)	0	6 (1.9)	0	11 (2.4)	1 (0.7)
白血球数減少	7 (2.2)	1 (1.0)	4 (1.3)	0	9 (2.0)	2 (1.4)
国際標準比増加	7 (2.2)	0	4 (1.3)	0	10 (2.2)	2 (1.4)
血中カリウム減少	6 (1.9)	0	8 (2.5)	0	9 (2.0)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
γ-グルタミルトランスフェラーゼ増加	6 (1.9)	1 (1.0)	13 (4.1)	2 (3.7)	8 (1.8)	1 (0.7)
好中球数減少	8 (2.5)	0	6 (1.9)	0	8 (1.8)	0
血中ブドウ糖増加	5 (1.6)	0	0	0	7 (1.6)	0
血中マグネシウム減少	4 (1.3)	0	3 (0.9)	0	6 (1.3)	1 (0.7)
血中尿素増加	2 (0.6)	0	1 (0.3)	0	6 (1.3)	2 (1.4)
心雑音	3 (0.9)	0	0	0	5 (1.1)	2 (1.4)
血中カルシウム減少	6 (1.9)	0	2 (0.6)	0	6 (1.3)	0
好中球数増加	1 (0.3)	0	2 (0.6)	0	4 (0.9)	2 (1.4)
糸球体濾過率減少	4 (1.3)	0	6 (1.9)	2 (3.7)	5 (1.1)	0
活性化部分トロンボプラスチン時間延長	1 (0.3)	0	2 (0.6)	0	4 (0.9)	0
血中アルブミン減少	3 (0.9)	0	1 (0.3)	0	3 (0.7)	1 (0.7)
血中リン減少	2 (0.6)	0	2 (0.6)	0	4 (0.9)	0
フィブリンＤダイマー増加	4 (1.3)	0	2 (0.6)	0	4 (0.9)	0
フィブリン分解産物増加	4 (1.3)	0	1 (0.3)	0	4 (0.9)	0
血中クレアチニン	3 (0.9)	0	3 (0.9)	0	3 (0.7)	0
血圧上昇	2 (0.6)	0	1 (0.3)	0	2 (0.4)	1 (0.7)
血中ナトリウム減少	2 (0.6)	0	0	0	3 (0.7)	0
血中尿酸増加	2 (0.6)	0	4 (1.3)	0	3 (0.7)	0
糸球体濾過率	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
肝機能検査異常	2 (0.6)	1 (1.0)	0	0	2 (0.4)	1 (0.7)
プロトロンビン時間延長	0	0	0	0	2 (0.4)	3 (2.1)
アミラーゼ増加	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
アスパラギン酸アミノトランスフェラーゼ減少	0	0	0	0	2 (0.4)	0
血中クレアチン増加	2 (0.6)	0	0	0	2 (0.4)	0
血中クレアチンホスホキナーゼ増加	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
血中クレアチニン減少	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
血中免疫グロブリンＧ減少	2 (0.6)	1 (1.0)	0	0	2 (0.4)	1 (0.7)
拡張期血圧低下	1 (0.3)	0	0	0	2 (0.4)	0
体温上昇	1 (0.3)	0	0	0	2 (0.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
クロストリジウム検査陽性	1 (0.3)	1 (1.0)	2 (0.6)	0	1 (0.2)	1 (0.7)
腎クレアチニン・クリアランス	2 (0.6)	0	0	0	2 (0.4)	0
駆出率減少	0	0	0	0	1 (0.2)	1 (0.7)
心電図 QT 延長	0	0	0	0	2 (0.4)	1 (0.7)
グルタミン酸脱水素酵素増加	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
眼圧上昇	2 (0.6)	0	0	0	2 (0.4)	0
リンパ球数減少	2 (0.6)	0	0	0	2 (0.4)	0
総蛋白減少	0	0	0	0	2 (0.4)	0
総蛋白増加	0	0	0	0	2 (0.4)	0
尿量減少	1 (0.3)	0	0	0	2 (0.4)	0
白血球数増加	0	0	0	0	1 (0.2)	1 (0.7)
アラニンアミノトランスフェラーゼ	1 (0.3)	0	0	0	1 (0.2)	0
血中アルブミン増加	0	0	0	0	1 (0.2)	0
血中アルカリホスファターゼ	1 (0.3)	0	0	0	1 (0.2)	0
血中ビリルビン増加	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
血中カルシウム増加	0	0	1 (0.3)	0	1 (0.2)	0
血中クロール減少	0	0	1 (0.3)	0	1 (0.2)	0
血中クロール増加	0	0	0	0	1 (0.2)	0
血中フィブリノゲン増加	1 (0.3)	0	0	0	1 (0.2)	0
血中ブドウ糖減少	0	0	1 (0.3)	0	1 (0.2)	0
血中鉄減少	1 (0.3)	0	0	0	1 (0.2)	0
血中カリウム増加	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
血中テストステロン減少	0	0	0	0	0	1 (0.7)
血中甲状腺刺激ホルモン減少	1 (0.3)	0	0	0	1 (0.2)	0
血中トリグリセリド増加	0	0	0	0	0	1 (0.7)
体温低下	0	0	0	0	1 (0.2)	0
腎クレアチニン・クリアランス異常	1 (0.3)	0	0	0	1 (0.2)	0
サイトメガロウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
心電図 QRS 群延長	0	0	0	0	0	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
心電図異常T波	0	0	0	0	1 (0.2)	0
好酸球数増加	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
大腸菌検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
線維素溶解	1 (0.3)	0	0	0	1 (0.2)	0
努力呼気量減少	1 (0.3)	0	0	0	1 (0.2)	0
ヘマトクリット減少	0	0	0	0	0	1 (0.7)
ヘモグロビン	1 (0.3)	0	0	0	1 (0.2)	0
心拍数不整	0	0	0	0	1 (0.2)	0
心音異常	0	0	0	0	1 (0.2)	0
肝酵素上昇	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
ヒトライノウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
免疫グロブリン減少	0	0	0	0	1 (0.2)	0
A型インフルエンザウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
深吸気量異常	1 (0.3)	0	0	0	1 (0.2)	0
国際標準比	1 (0.3)	0	0	0	1 (0.2)	0
眼圧検査異常	1 (0.3)	0	0	0	1 (0.2)	0
リンパ球形態異常	1 (0.3)	0	0	0	1 (0.2)	0
好中球数	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
便潜血	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
酸素飽和度低下	1 (0.3)	0	0	0	1 (0.2)	0
プロカルシトニン増加	1 (0.3)	0	0	0	1 (0.2)	0
前立腺特異性抗原増加	1 (0.3)	0	0	0	1 (0.2)	0
肺の身体的診察結果異常	1 (0.3)	0	0	0	1 (0.2)	0
QRS軸異常	0	0	0	0	0	1 (0.7)
血清フェリチン減少	1 (0.3)	0	0	0	1 (0.2)	0
喀痰培養陽性	1 (0.3)	0	0	0	1 (0.2)	0
トランスアミナーゼ上昇	0	0	0	0	1 (0.2)	0
トロポニン増加	1 (0.3)	0	0	0	1 (0.2)	0
水痘ウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
ウイルス検査陽性	0	1 (1.0)	0	0	0	1 (0.7)
ビタミンB1減少	1 (0.3)	0	0	0	1 (0.2)	0
抗体検査異常	0	0	1 (0.3)	0	0	0
抱合ビリルビン増加	0	0	1 (0.3)	0	0	0
血中コリンエステラーゼ減少	0	0	1 (0.3)	0	0	0
収縮期血圧上昇	0	0	1 (0.3)	0	0	0
血中甲状腺刺激ホルモン増加	0	0	1 (0.3)	0	0	0
脳性ナトリウム利尿ペプチド増加	0	0	1 (0.3)	0	0	0
呼吸音異常	0	0	1 (0.3)	0	0	0
カンピロバクター検査陽性	0	0	1 (0.3)	0	0	0
心電図異常	0	0	2 (0.6)	0	0	0
グリコヘモグロビン増加	0	0	1 (0.3)	0	0	0
心拍数増加	0	0	2 (0.6)	0	0	0
国際標準比異常	0	0	1 (0.3)	0	0	0
臨床検査異常	0	0	1 (0.3)	0	0	0
単球数増加	0	0	1 (0.3)	0	0	0
脳性ナトリウム利尿ペプチド前駆体N端フラグメント増加	0	0	1 (0.3)	0	0	0
QOL低下	0	0	1 (0.3)	0	0	0
頚静脈圧低下	0	0	1 (0.3)	0	0	0
ビタミンD減少	0	0	1 (0.3)	0	0	0
精神障害	134 (42.1)	5 (5.0)	121 (38.2)	2 (3.7)	197 (43.7)	14 (10.0)
不眠症	72 (22.6)	1 (1.0)	82 (25.9)	0	110 (24.4)	7 (5.0)
不安	23 (7.2)	0	21 (6.6)	0	35 (7.8)	1 (0.7)
うつ病	16 (5.0)	0	14 (4.4)	0	26 (5.8)	0
錯乱状態	19 (6.0)	2 (2.0)	10 (3.2)	1 (1.9)	22 (4.9)	4 (2.9)
気分変化	20 (6.3)	2 (2.0)	8 (2.5)	0	21 (4.7)	2 (1.4)
激越	5 (1.6)	0	8 (2.5)	1 (1.9)	7 (1.6)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
抑うつ気分	5 (1.6)	0	3 (0.9)	0	6 (1.3)	1 (0.7)
易刺激性	6 (1.9)	1 (1.0)	7 (2.2)	0	7 (1.6)	1 (0.7)
気分動揺	2 (0.6)	0	2 (0.6)	0	7 (1.6)	0
神経過敏	6 (1.9)	0	1 (0.3)	0	7 (1.6)	0
落ち着きのなさ	3 (0.9)	0	4 (1.3)	0	5 (1.1)	0
睡眠障害	3 (0.9)	0	4 (1.3)	0	4 (0.9)	0
譫妄	3 (0.9)	0	0	0	3 (0.7)	0
異常行動	2 (0.6)	0	0	0	2 (0.4)	0
感情不安定	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
攻撃性	0	0	3 (0.9)	0	2 (0.4)	0
失見当識	2 (0.6)	0	0	0	2 (0.4)	0
精神状態変化	2 (0.6)	0	0	0	2 (0.4)	0
ストレス	0	0	0	0	2 (0.4)	0
怒り	1 (0.3)	0	0	0	1 (0.2)	0
自殺既遂	1 (0.3)	0	0	0	1 (0.2)	0
情動障害	0	0	0	0	0	1 (0.7)
多幸気分	1 (0.3)	0	0	0	1 (0.2)	0
幻覚	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
リビド消失	0	0	1 (0.3)	0	1 (0.2)	0
精神障害	0	0	0	0	1 (0.2)	0
外見に対する無関心	1 (0.3)	0	0	0	1 (0.2)	0
妄想症	0	1 (1.0)	0	0	0	1 (0.7)
人格変化	0	0	0	0	1 (0.2)	0
レム睡眠異常	1 (0.3)	0	0	0	1 (0.2)	0
異常な夢	0	0	1 (0.3)	0	0	0
無感情	0	0	1 (0.3)	0	0	0
精神緩慢	0	0	2 (0.6)	0	0	0
感情的苦悩	0	0	1 (0.3)	0	0	0
幻聴	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
幻視	0	0	1 (0.3)	0	0	0
血管障害	114 (35.8)	6 (5.9)	82 (25.9)	3 (5.6)	155 (34.4)	12 (8.6)
低血圧	29 (9.1)	2 (2.0)	11 (3.5)	1 (1.9)	36 (8.0)	5 (3.6)
高血圧	27 (8.5)	2 (2.0)	17 (5.4)	2 (3.7)	34 (7.5)	3 (2.1)
深部静脈血栓症	22 (6.9)	1 (1.0)	12 (3.8)	0	32 (7.1)	1 (0.7)
潮紅	16 (5.0)	0	6 (1.9)	0	25 (5.5)	0
血腫	14 (4.4)	0	8 (2.5)	0	16 (3.5)	0
ほてり	5 (1.6)	0	6 (1.9)	0	11 (2.4)	1 (0.7)
蒼白	8 (2.5)	0	4 (1.3)	0	8 (1.8)	0
表在性血栓性静脈炎	5 (1.6)	0	2 (0.6)	0	7 (1.6)	0
静脈炎	4 (1.3)	0	5 (1.6)	0	6 (1.3)	1 (0.7)
血栓症	3 (0.9)	0	5 (1.6)	0	4 (0.9)	0
表在性静脈炎	1 (0.3)	0	0	0	3 (0.7)	0
四肢静脈血栓症	2 (0.6)	0	0	0	3 (0.7)	0
起立性低血圧	2 (0.6)	0	6 (1.9)	0	2 (0.4)	0
末梢冷感	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
血栓性静脈炎	2 (0.6)	0	6 (1.9)	0	2 (0.4)	0
静脈瘤	1 (0.3)	0	1 (0.3)	0	1 (0.2)	1 (0.7)
静脈不全	2 (0.6)	0	0	0	2 (0.4)	0
静脈血栓症	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
進行性高血圧	0	0	0	0	0	1 (0.7)
動脈瘤	1 (0.3)	0	0	0	1 (0.2)	0
大動脈瘤破裂	1 (0.3)	0	0	0	1 (0.2)	0
大動脈狭窄	1 (0.3)	0	0	0	1 (0.2)	0
動脈硬化症	0	1 (1.0)	0	1 (1.9)	0	1 (0.7)
循環虚脱	0	0	0	0	1 (0.2)	0
出血	1 (0.3)	0	0	0	1 (0.2)	0
充血	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
高血圧クリーゼ	0	0	0	0	1 (0.2)	0
腹腔内血腫	1 (0.3)	0	0	0	1 (0.2)	0
頚静脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
リンパ浮腫	1 (0.3)	0	0	0	1 (0.2)	0
リンパ漏	1 (0.3)	0	0	0	1 (0.2)	0
骨盤静脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
末梢動脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
末梢性虚血	1 (0.3)	0	0	0	1 (0.2)	0
静脈穿刺不良	0	0	0	0	1 (0.2)	0
鎖骨下静脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
収縮期高血圧	0	0	0	0	1 (0.2)	0
血管痛	1 (0.3)	0	0	0	1 (0.2)	0
血管拡張	1 (0.3)	0	0	0	1 (0.2)	0
毛細血管脆弱	0	0	1 (0.3)	0	0	0
塞栓症	0	0	1 (0.3)	0	0	0
末梢動脈狭窄	0	0	2 (0.6)	0	0	0
静脈湖	0	0	1 (0.3)	0	0	0
傷害、中毒および処置合併症	104 (32.7)	9 (8.9)	81 (25.6)	5 (9.3)	141 (31.3)	22 (15.7)
挫傷	33 (10.4)	3 (3.0)	25 (7.9)	1 (1.9)	41 (9.1)	7 (5.0)
転倒	12 (3.8)	1 (1.0)	11 (3.5)	0	22 (4.9)	3 (2.1)
擦過傷	10 (3.1)	1 (1.0)	2 (0.6)	1 (1.9)	13 (2.9)	2 (1.4)
創傷	7 (2.2)	0	1 (0.3)	1 (1.9)	10 (2.2)	0
脊椎圧迫骨折	7 (2.2)	0	2 (0.6)	0	8 (1.8)	0
注入に伴う反応	4 (1.3)	0	0	0	7 (1.6)	1 (0.7)
歯牙破折	3 (0.9)	1 (1.0)	1 (0.3)	0	5 (1.1)	3 (2.1)
靭帯捻挫	3 (0.9)	0	1 (0.3)	0	6 (1.3)	0
四肢損傷	3 (0.9)	1 (1.0)	3 (0.9)	0	4 (0.9)	1 (0.7)
処置による疼痛	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
肋骨骨折	4 (1.3)	1 (1.0)	4 (1.3)	0	4 (0.9)	1 (0.7)
肉離れ	3 (0.9)	0	1 (0.3)	1 (1.9)	4 (0.9)	0
上肢骨折	3 (0.9)	0	0	0	4 (0.9)	0
上腕骨骨折	2 (0.6)	0	0	0	3 (0.7)	0
サンバーン	1 (0.3)	0	0	0	3 (0.7)	0
偶発的過量投与	0	0	0	0	2 (0.4)	0
節足動物咬傷	0	0	2 (0.6)	0	0	2 (1.4)
大腿骨骨折	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
頭部損傷	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
瘢痕ヘルニア	1 (0.3)	0	0	0	1 (0.2)	1 (0.7)
関節脱臼	1 (0.3)	0	1 (0.3)	0	1 (0.2)	1 (0.7)
裂傷	1 (0.3)	0	5 (1.6)	0	1 (0.2)	1 (0.7)
腰椎骨折	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
引っかき傷	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
皮下血腫	2 (0.6)	0	0	0	2 (0.4)	0
熱傷	2 (0.6)	0	0	0	2 (0.4)	0
外傷性血腫	2 (0.6)	0	0	0	2 (0.4)	0
足関節部骨折	0	0	1 (0.3)	0	1 (0.2)	0
節足動物刺傷	0	0	0	0	1 (0.2)	0
気圧性中耳炎	1 (0.3)	0	0	0	1 (0.2)	0
化学的損傷	1 (0.3)	0	0	0	1 (0.2)	0
鎖骨骨折	1 (0.3)	0	0	0	1 (0.2)	0
上顆炎	1 (0.3)	0	0	0	1 (0.2)	0
顔面損傷	1 (0.3)	0	0	0	1 (0.2)	0
大腿骨頚部骨折	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
足骨折	0	0	1 (0.3)	0	1 (0.2)	0
体内異物	1 (0.3)	0	0	0	1 (0.2)	0
放射線胃腸炎	0	0	0	0	1 (0.2)	0
熱中症	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
股関節部骨折	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
腸骨骨折	1 (0.3)	0	0	0	1 (0.2)	0
誤った投与経路	0	0	0	0	1 (0.2)	0
関節損傷	0	0	0	0	0	1 (0.7)
靭帯断裂	0	0	0	0	1 (0.2)	0
口唇損傷	1 (0.3)	0	0	0	1 (0.2)	0
下肢骨折	1 (0.3)	0	0	0	1 (0.2)	0
半月板損傷	0	0	1 (0.3)	0	1 (0.2)	0
口腔内損傷	1 (0.3)	0	0	0	1 (0.2)	0
視神経損傷	0	0	0	0	1 (0.2)	0
過量投与	1 (0.3)	0	0	0	1 (0.2)	0
骨盤骨折	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
処置後浮腫	1 (0.3)	0	0	0	1 (0.2)	0
処置後腫脹	0	0	0	0	0	1 (0.7)
外傷後頚部症候群	0	0	0	0	0	1 (0.7)
外傷後疼痛	0	0	0	0	0	1 (0.7)
放射線嚥下障害	0	0	0	0	0	1 (0.7)
珪肺症	0	0	0	0	1 (0.2)	0
骨格損傷	0	0	0	0	1 (0.2)	0
脊柱損傷	0	0	0	0	1 (0.2)	0
ストーマ部疼痛	0	0	0	0	1 (0.2)	0
腱損傷	0	1 (1.0)	0	0	0	1 (0.7)
腱断裂	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
歯の完全脱臼	0	0	0	0	1 (0.2)	0
ワクチン接種合併症	1 (0.3)	0	0	0	1 (0.2)	0
創合併症	0	0	0	0	1 (0.2)	0
術後貧血	0	0	1 (0.3)	0	0	0
圧迫骨折	0	0	2 (0.6)	0	0	0
脳振盪	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
頭蓋脳損傷	0	0	3 (0.9)	0	0	0
外傷性難聴	0	0	1 (0.3)	0	0	0
顔面骨骨折	0	0	1 (0.3)	0	0	0
外傷性血尿	0	0	1 (0.3)	0	0	0
心臓損傷	0	0	1 (0.3)	0	0	0
損傷	0	0	1 (0.3)	0	0	0
筋断裂	0	0	1 (0.3)	0	0	0
爪損傷	0	0	1 (0.3)	0	0	0
膝蓋骨骨折	0	0	2 (0.6)	0	0	0
処置後合併症	0	0	1 (0.3)	0	0	0
処置後出血	0	0	1 (0.3)	1 (1.9)	0	0
放射線性食道炎	0	0	1 (0.3)	0	0	0
橈骨骨折	0	0	2 (0.6)	0	0	0
交通事故	0	0	2 (0.6)	0	0	0
肩甲骨骨折	0	0	1 (0.3)	0	0	0
瘢痕	0	0	1 (0.3)	0	0	0
漿液腫	0	0	1 (0.3)	0	0	0
皮膚損傷	0	0	1 (0.3)	0	0	0
軟部組織損傷	0	0	2 (0.6)	0	0	0
膀胱尿道吻合部狭窄	0	0	1 (0.3)	0	0	0
硬膜下血腫	0	0	1 (0.3)	0	0	0
胸椎骨折	0	0	1 (0.3)	0	0	0
外傷性切断	0	0	1 (0.3)	0	0	0
外傷性骨折	0	0	2 (0.6)	0	0	0
眼障害	95 (29.9)	8 (7.9)	69 (21.8)	4 (7.4)	137 (30.4)	17 (12.1)
白内障	34 (10.7)	6 (5.9)	17 (5.4)	4 (7.4)	43 (9.5)	9 (6.4)
霧視	26 (8.2)	1 (1.0)	16 (5.0)	0	44 (9.8)	5 (3.6)
視力低下	10 (3.1)	0	6 (1.9)	0	12 (2.7)	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
眼乾燥	8 (2.5)	0	7 (2.2)	0	12 (2.7)	0
眼刺激	1 (0.3)	1 (1.0)	3 (0.9)	0	7 (1.6)	1 (0.7)
眼痛	7 (2.2)	0	5 (1.6)	0	8 (1.8)	0
流涙増加	6 (1.9)	0	3 (0.9)	0	8 (1.8)	0
視力障害	6 (1.9)	0	0	0	8 (1.8)	0
結膜出血	4 (1.3)	0	4 (1.3)	0	4 (0.9)	1 (0.7)
複視	2 (0.6)	0	1 (0.3)	0	4 (0.9)	0
眼充血	1 (0.3)	0	4 (1.3)	0	4 (0.9)	0
眼脂	1 (0.3)	0	0	0	2 (0.4)	1 (0.7)
眼出血	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0
眼そう痒症	1 (0.3)	0	2 (0.6)	0	3 (0.7)	0
緑内障	1 (0.3)	0	3 (0.9)	0	3 (0.7)	0
眼窩周囲浮腫	1 (0.3)	0	1 (0.3)	0	3 (0.7)	0
硝子体浮遊物	0	0	1 (0.3)	0	3 (0.7)	0
眼の異常感	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
眼瞼炎	2 (0.6)	0	0	0	2 (0.4)	0
結膜充血	2 (0.6)	0	0	0	2 (0.4)	0
結膜炎	0	0	0	0	1 (0.2)	2 (1.4)
眼の障害	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
眼部腫脹	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
眼瞼浮腫	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
羞明	1 (0.3)	0	0	0	2 (0.4)	0
網膜剥離	1 (0.3)	0	0	0	2 (0.4)	0
強膜充血	1 (0.3)	0	0	0	2 (0.4)	0
失明	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
核性白内障	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
アレルギー性結膜炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
後天性涙道狭窄	1 (0.3)	0	0	0	1 (0.2)	0
眼球浮腫	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
眼瞼嚢胞	0	0	0	0	1 (0.2)	0
眼の異物感	1 (0.3)	0	0	0	1 (0.2)	0
角膜炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
涙腺肥大	1 (0.3)	0	0	0	1 (0.2)	0
黄斑浮腫	1 (0.3)	0	0	0	1 (0.2)	0
近視	1 (0.3)	0	0	0	1 (0.2)	0
眼部不快感	0	0	1 (0.3)	0	1 (0.2)	0
光視症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
瞳孔不同	0	0	0	0	1 (0.2)	0
網膜変性	0	0	0	0	1 (0.2)	0
網膜裂孔	0	0	0	0	0	1 (0.7)
角膜瘢痕	0	0	1 (0.3)	0	0	0
縮瞳	0	0	1 (0.3)	0	0	0
正常眼圧緑内障	0	0	1 (0.3)	0	0	0
高眼圧症	0	0	1 (0.3)	0	0	0
視神経萎縮	0	0	1 (0.3)	0	0	0
潰瘍性角膜炎	0	0	1 (0.3)	0	0	0
腎および尿路障害	71 (22.3)	5 (5.0)	54 (17.0)	3 (5.6)	92 (20.4)	10 (7.1)
排尿困難	12 (3.8)	2 (2.0)	10 (3.2)	0	16 (3.5)	4 (2.9)
腎不全	10 (3.1)	1 (1.0)	10 (3.2)	1 (1.9)	14 (3.1)	1 (0.7)
血尿	6 (1.9)	1 (1.0)	5 (1.6)	1 (1.9)	8 (1.8)	2 (1.4)
頻尿	8 (2.5)	0	4 (1.3)	1 (1.9)	9 (2.0)	1 (0.7)
急性腎不全	8 (2.5)	0	7 (2.2)	0	9 (2.0)	1 (0.7)
尿閉	6 (1.9)	0	7 (2.2)	0	7 (1.6)	0
腎機能障害	6 (1.9)	0	4 (1.3)	0	6 (1.3)	0
尿失禁	4 (1.3)	0	2 (0.6)	0	6 (1.3)	0
夜間頻尿	2 (0.6)	0	4 (1.3)	0	3 (0.7)	0
蛋白尿	3 (0.9)	0	0	0	3 (0.7)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
腎嚢胞	1 (0.3)	1 (1.0)	0	0	2 (0.4)	1 (0.7)
糖尿	2 (0.6)	0	0	0	2 (0.4)	0
多尿	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
腎仙痛	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
高窒素血症	1 (0.3)	0	0	0	1 (0.2)	0
膀胱痙縮	0	0	0	0	1 (0.2)	0
着色尿	1 (0.3)	0	0	0	1 (0.2)	0
糸球体腎炎	0	0	0	0	1 (0.2)	0
ヘモグロビン尿	1 (0.3)	0	0	0	1 (0.2)	0
尿路出血	1 (0.3)	0	0	0	1 (0.2)	0
水腎症	1 (0.3)	0	0	0	1 (0.2)	0
高カルシウム尿症	0	0	0	0	1 (0.2)	0
失禁	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
下部尿路症状	0	0	0	0	1 (0.2)	0
排尿異常	1 (0.3)	0	0	0	1 (0.2)	0
尿意切迫	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
腎結石症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
神経因性膀胱	1 (0.3)	0	0	0	1 (0.2)	0
閉塞性尿路疾患	1 (0.3)	0	0	0	1 (0.2)	0
腎前性腎不全	1 (0.3)	0	0	0	1 (0.2)	0
腎盂腎杯拡張症	1 (0.3)	0	0	0	1 (0.2)	0
腎尿細管性アシドーシス	1 (0.3)	0	0	0	1 (0.2)	0
尿道分泌物	1 (0.3)	0	0	0	1 (0.2)	0
排尿躊躇	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
尿生殖器障害	1 (0.3)	0	0	0	1 (0.2)	0
膀胱脱	0	0	1 (0.3)	0	0	0
白血球尿	0	0	1 (0.3)	0	0	0
乏尿	0	0	1 (0.3)	0	0	0
慢性腎不全	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
腎臓痛	0	0	1 (0.3)	0	0	0
尿路閉塞	0	0	2 (0.6)	0	0	0
心臓障害	54 (17.0)	4 (4.0)	53 (16.7)	2 (3.7)	76 (16.9)	7 (5.0)
動悸	13 (4.1)	0	5 (1.6)	0	19 (4.2)	0
心房細動	9 (2.8)	1 (1.0)	18 (5.7)	0	15 (3.3)	1 (0.7)
頻脈	8 (2.5)	0	11 (3.5)	0	15 (3.3)	0
期外収縮	6 (1.9)	0	1 (0.3)	0	7 (1.6)	0
洞性徐脈	2 (0.6)	1 (1.0)	2 (0.6)	0	4 (0.9)	1 (0.7)
狭心症	4 (1.3)	0	6 (1.9)	0	4 (0.9)	0
不整脈	4 (1.3)	0	3 (0.9)	0	4 (0.9)	0
徐脈	1 (0.3)	0	2 (0.6)	0	4 (0.9)	0
洞性頻脈	4 (1.3)	0	0	0	4 (0.9)	0
心房粗動	2 (0.6)	0	0	0	3 (0.7)	0
うっ血性心不全	2 (0.6)	0	2 (0.6)	1 (1.9)	2 (0.4)	1 (0.7)
心筋虚血	0	2 (2.0)	4 (1.3)	0	0	3 (2.1)
第一度房室ブロック	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
心不全	2 (0.6)	0	3 (0.9)	0	2 (0.4)	0
心拡大	1 (0.3)	0	0	0	2 (0.4)	0
上室性期外収縮	2 (0.6)	0	0	0	2 (0.4)	0
心室性期外収縮	1 (0.3)	0	0	0	1 (0.2)	1 (0.7)
急性冠動脈症候群	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
上室性不整脈	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
完全房室ブロック	1 (0.3)	0	0	0	1 (0.2)	0
右脚ブロック	0	0	0	0	0	1 (0.7)
心停止	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
心肺停止	1 (0.3)	0	0	0	1 (0.2)	0
心筋症	0	0	0	0	0	1 (0.7)
心血管障害	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
冠動脈閉塞	0	0	0	0	0	1 (0.7)
心房拡張	1 (0.3)	0	0	0	1 (0.2)	0
左室機能不全	0	0	1 (0.3)	1 (1.9)	1 (0.2)	0
左室肥大	0	0	0	0	0	1 (0.7)
僧帽弁閉鎖不全症	1 (0.3)	0	0	0	1 (0.2)	0
上室性頻脈	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
頻脈性不整脈	1 (0.3)	0	0	0	1 (0.2)	0
心室不全	1 (0.3)	0	0	0	1 (0.2)	0
急性心筋梗塞	0	0	2 (0.6)	0	0	0
心房頻脈	0	0	1 (0.3)	0	0	0
心臓瘤	0	0	1 (0.3)	0	0	0
左室不全	0	0	1 (0.3)	0	0	0
心筋梗塞	0	0	3 (0.9)	0	0	0
結節性不整脈	0	0	1 (0.3)	0	0	0
心膜炎	0	0	1 (0.3)	0	0	0
洞不全症候群	0	0	0	1 (1.9)	0	0
心室性不整脈	0	0	1 (0.3)	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	39 (12.3)	4 (4.0)	30 (9.5)	0	46 (10.2)	10 (7.1)
基底細胞癌	4 (1.3)	1 (1.0)	3 (0.9)	0	6 (1.3)	2 (1.4)
皮膚有棘細胞癌	6 (1.9)	0	2 (0.6)	0	6 (1.3)	1 (0.7)
悪性新生物進行	5 (1.6)	0	4 (1.3)	0	5 (1.1)	0
形質細胞性骨髄腫	5 (1.6)	0	5 (1.6)	0	5 (1.1)	0
脂肪腫	3 (0.9)	0	0	0	4 (0.9)	0
骨髄異形成症候群	1 (0.3)	1 (1.0)	3 (0.9)	0	2 (0.4)	2 (1.4)
形質細胞腫	3 (0.9)	0	2 (0.6)	0	4 (0.9)	0
皮膚乳頭腫	3 (0.9)	0	1 (0.3)	0	3 (0.7)	1 (0.7)
扁平上皮癌	1 (0.3)	0	0	0	2 (0.4)	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
膀胱移行上皮癌	1 (0.3)	0	0	0	2 (0.4)	0
肺の悪性新生物	2 (0.6)	0	0	0	2 (0.4)	0
結腸腺癌	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
乳癌	1 (0.3)	0	0	0	1 (0.2)	0
乳腺線維腫	1 (0.3)	0	0	0	1 (0.2)	0
慢性リンパ性白血病	1 (0.3)	0	0	0	1 (0.2)	0
赤白血病	0	1 (1.0)	0	0	0	1 (0.7)
消化器新生物	1 (0.3)	0	0	0	1 (0.2)	0
乳房脂肪腫	1 (0.3)	0	0	0	1 (0.2)	0
乳腺上皮内小葉癌	0	0	0	0	0	1 (0.7)
悪性黒色腫	0	0	0	0	0	1 (0.7)
悪性胸水	1 (0.3)	0	0	0	1 (0.2)	0
髄膜腫	1 (0.3)	0	0	0	1 (0.2)	0
中皮腫	1 (0.3)	0	0	0	1 (0.2)	0
乳頭腫	0	0	0	0	0	1 (0.7)
前立腺癌	0	0	1 (0.3)	0	1 (0.2)	0
前立腺腺腫	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
脂漏性角化症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
皮膚癌	1 (0.3)	0	0	0	1 (0.2)	0
甲状腺新生物	1 (0.3)	0	0	0	1 (0.2)	0
子宮平滑筋腫	0	0	0	0	0	1 (0.7)
子宮内膜癌	0	0	1 (0.3)	0	0	0
血管腫	0	0	1 (0.3)	0	0	0
骨血管腫	0	0	1 (0.3)	0	0	0
遠隔転移を伴う肺癌	0	0	1 (0.3)	0	0	0
表皮内悪性黒色腫	0	0	1 (0.3)	0	0	0
原発巣不明の悪性新生物	0	0	1 (0.3)	0	0	0
扁桃癌	0	0	1 (0.3)	0	0	0
腫瘍熱	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
耳および迷路障害	29 (9.1)	2 (2.0)	29 (9.1)	1 (1.9)	44 (9.8)	4 (2.9)
回転性めまい	12 (3.8)	0	8 (2.5)	0	18 (4.0)	1 (0.7)
耳痛	8 (2.5)	1 (1.0)	3 (0.9)	0	10 (2.2)	1 (0.7)
聴力低下	5 (1.6)	0	2 (0.6)	1 (1.9)	8 (1.8)	1 (0.7)
耳鳴	5 (1.6)	0	6 (1.9)	0	7 (1.6)	0
難聴	3 (0.9)	0	2 (0.6)	0	4 (0.9)	0
耳不快感	3 (0.9)	0	1 (0.3)	0	4 (0.9)	0
両耳難聴	2 (0.6)	0	0	0	2 (0.4)	0
耳垢栓塞	0	1 (1.0)	3 (0.9)	0	0	1 (0.7)
片耳難聴	1 (0.3)	0	0	0	1 (0.2)	0
聴覚障害	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
中耳の炎症	1 (0.3)	0	0	0	1 (0.2)	0
耳漏	0	0	1 (0.3)	0	1 (0.2)	0
耳の障害	0	0	1 (0.3)	0	0	0
耳そう痒症	0	0	1 (0.3)	0	0	0
老人性難聴	0	0	1 (0.3)	0	0	0
頭位性回転性めまい	0	0	1 (0.3)	0	0	0
肝胆道系障害	24 (7.5)	2 (2.0)	11 (3.5)	0	32 (7.1)	2 (1.4)
高ビリルビン血症	9 (2.8)	0	5 (1.6)	0	12 (2.7)	0
胆嚢炎	2 (0.6)	1 (1.0)	0	0	4 (0.9)	1 (0.7)
胆石症	2 (0.6)	1 (1.0)	1 (0.3)	0	3 (0.7)	1 (0.7)
肝機能異常	4 (1.3)	0	3 (0.9)	0	4 (0.9)	0
肝炎	1 (0.3)	0	0	0	2 (0.4)	0
肝腫大	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
胆管炎	1 (0.3)	0	0	0	1 (0.2)	0
急性胆嚢炎	1 (0.3)	0	0	0	1 (0.2)	0
慢性胆嚢炎	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
胆汁うっ滞	1 (0.3)	0	0	0	1 (0.2)	0
薬物性肝障害	1 (0.3)	0	0	0	1 (0.2)	0
肝不全	1 (0.3)	0	0	0	1 (0.2)	0
肝細胞損傷	1 (0.3)	0	0	0	1 (0.2)	0
肝毒性	1 (0.3)	0	0	0	1 (0.2)	0
肝障害	0	0	0	0	1 (0.2)	0
肝損傷	1 (0.3)	0	0	0	1 (0.2)	0
アルコール性肝疾患	0	0	1 (0.3)	0	0	0
生殖系および乳房障害	14 (4.4)	1 (1.0)	27 (8.5)	0	23 (5.1)	5 (3.6)
良性前立腺肥大症	1 (0.3)	0	3 (0.9)	0	4 (0.9)	0
骨盤痛	3 (0.9)	0	6 (1.9)	0	4 (0.9)	0
乳房痛	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
勃起不全	1 (0.3)	0	2 (0.6)	0	1 (0.2)	1 (0.7)
生殖器病変	2 (0.6)	0	0	0	2 (0.4)	0
前立腺炎	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
外陰腟不快感	0	1 (1.0)	2 (0.6)	0	1 (0.2)	1 (0.7)
外陰腟そう痒症	0	0	1 (0.3)	0	1 (0.2)	1 (0.7)
乳房石灰化	0	0	0	0	0	1 (0.7)
乳房腫瘤	0	0	0	0	0	1 (0.7)
乳房圧痛	0	0	0	0	1 (0.2)	0
性器びらん	1 (0.3)	0	0	0	1 (0.2)	0
女性化乳房	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
陰部そう痒症	1 (0.3)	0	0	0	1 (0.2)	0
精巣痛	1 (0.3)	0	0	0	1 (0.2)	0
腟びらん	1 (0.3)	0	0	0	1 (0.2)	0
腟出血	0	0	3 (0.9)	0	1 (0.2)	0
腟の炎症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
膀胱瘤	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
卵巣嚢胞	0	0	1 (0.3)	0	0	0
陰茎浮腫	0	0	1 (0.3)	0	0	0
陰嚢血瘤	0	0	1 (0.3)	0	0	0
陰嚢浮腫	0	0	1 (0.3)	0	0	0
子宮痛	0	0	1 (0.3)	0	0	0
腟分泌物	0	0	2 (0.6)	0	0	0
外陰腟痛	0	0	2 (0.6)	0	0	0
内分泌障害	16 (5.0)	2 (2.0)	11 (3.5)	0	21 (4.7)	2 (1.4)
クッシング様症状	8 (2.5)	2 (2.0)	4 (1.3)	0	10 (2.2)	2 (1.4)
甲状腺機能低下症	2 (0.6)	0	3 (0.9)	0	4 (0.9)	0
副腎機能不全	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
副甲状腺機能亢進症	1 (0.3)	0	0	0	2 (0.4)	0
甲状腺機能亢進症	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
自己免疫性甲状腺炎	0	0	1 (0.3)	0	1 (0.2)	0
クッシング症候群	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
続発性副甲状腺機能亢進症	1 (0.3)	0	0	0	1 (0.2)	0
ステロイド離脱症候群	1 (0.3)	0	0	0	1 (0.2)	0
免疫系障害	12 (3.8)	0	8 (2.5)	0	22 (4.9)	1 (0.7)
過敏症	6 (1.9)	0	3 (0.9)	0	8 (1.8)	0
季節性アレルギー	3 (0.9)	0	1 (0.3)	0	6 (1.3)	1 (0.7)
薬物過敏症	1 (0.3)	0	1 (0.3)	0	4 (0.9)	0
アナフィラキシー反応	0	0	0	0	2 (0.4)	0
節足動物咬傷アレルギー	0	0	0	0	1 (0.2)	0
免疫グロブリン療法アレルギー	1 (0.3)	0	0	0	1 (0.2)	0
自己免疫障害	1 (0.3)	0	0	0	1 (0.2)	0
低γグロブリン血症	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
外科および内科処置	4 (1.3)	2 (2.0)	2 (0.6)	0	5 (1.1)	2 (1.4)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
歯根端切除	1 (0.3)	0	0	0	1 (0.2)	0
中心静脈カテーテル留置	0	0	0	0	1 (0.2)	0
病変部切除	0	1 (1.0)	0	0	0	1 (0.7)
皮膚新生物切除	1 (0.3)	0	0	0	1 (0.2)	0
縫合	1 (0.3)	0	0	0	1 (0.2)	0
腱手術	1 (0.3)	0	0	0	1 (0.2)	0
抜歯	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
四肢手術	0	0	1 (0.3)	0	0	0
先天性、家族性および遺伝性障害	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
包茎	1 (0.3)	0	0	0	1 (0.2)	0
心房中隔欠損症	0	0	1 (0.3)	0	0	0
歯原性嚢胞	0	0	1 (0.3)	0	0	0
腓骨部筋萎縮症	0	0	1 (0.3)	0	0	0
社会環境	0	0	2 (0.6)	0	0	0
日常生活動作障害者	0	0	1 (0.3)	0	0	0
歩行障害者	0	0	1 (0.3)	0	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
AE onset occurring on or within 24 months after the first dose of any study drug will be summarized in the <=24 months column.
AE onset occurring after 24 months of the first dose of any study drug will be summarized in the > 24 months column.
A subject who reported multiple events mapped to the same SOC/preferred term is counted once within the time category (<= 24, or >24 months).
All treated subjects are included in the <= 24 months category. Only treated subjects who are followed for AE beyond 24 months are included in the > 24 months category.
Sorting is done by decreasing order based on the 'any grade' column of the pooled E-Ld arm.
Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ae-longterm.sas 13FEB2015:00:55:33

APPENDIX 59　投与開始 24 ヵ月以降の GRADE 3 又は 4 の有害事象の発現割合（004 試験及び統合 E-LD 群、治験薬投与例）

	CA204-004 E-Ld		CA204-004 Ld		Pooled E-Ld	
SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	<= 24 N = 318	> 24 N = 101	<= 24 N = 317	> 24 N = 54	<= 24 N = 451	> 24 N = 140
TOTAL SUBJECTS WITH AN EVENT	245 (77.0)	32 (31.7)	208 (65.6)	15 (27.8)	349 (77.4)	52 (37.1)
一般・全身障害および投与部位の状態	61 (19.2)	3 (3.0)	49 (15.5)	1 (1.9)	79 (17.5)	5 (3.6)
疲労	26 (8.2)	2 (2.0)	25 (7.9)	1 (1.9)	37 (8.2)	3 (2.1)
発熱	8 (2.5)	0	9 (2.8)	0	10 (2.2)	0
末梢性浮腫	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
無力症	14 (4.4)	1 (1.0)	12 (3.8)	0	15 (3.3)	2 (1.4)
悪寒	0	0	0	0	0	0
胸痛	2 (0.6)	0	1 (0.3)	0	4 (0.9)	0
局所腫脹	0	0	0	0	0	0
倦怠感	4 (1.3)	0	0	0	4 (0.9)	0
インフルエンザ様疾患	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
疼痛	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
非心臓性胸痛	0	0	0	0	0	0
疾患進行	7 (2.2)	0	2 (0.6)	0	7 (1.6)	0
浮腫	0	0	0	0	0	0
全身健康状態低下	4 (1.3)	0	1 (0.3)	0	4 (0.9)	0
胸部不快感	0	0	0	0	0	0
歩行障害	1 (0.3)	0	0	0	1 (0.2)	0
嚢胞	0	0	0	0	0	0
熱感	0	0	0	0	0	0
顔面浮腫	0	0	0	0	0	0
全身性浮腫	1 (0.3)	0	0	0	1 (0.2)	0
治癒不良	0	0	0	0	0	0
炎症	0	0	0	0	0	0
粘膜の炎症	0	0	0	0	0	0
カテーテル留置部位疼痛	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
異常感	0	0	0	0	0	0
ヘルニア	0	0	0	0	0	0
注入部位内出血	0	0	0	0	0	0
注入部位血管外漏出	0	0	0	0	0	0
注射部位内出血	0	0	0	0	0	0
注射部位血腫	0	0	0	0	0	0
注射部位出血	0	0	0	0	0	0
粘膜変色	0	0	0	0	0	0
多臓器不全	1 (0.3)	0	0	0	1 (0.2)	0
全身性炎症反応症候群	0	0	0	0	1 (0.2)	0
口渇	0	0	0	0	0	0
潰瘍	0	0	0	0	0	0
医薬品副作用	0	0	0	0	0	0
カテーテル留置部位炎症	0	0	0	0	0	0
カテーテル留置部位発疹	0	0	0	0	0	0
カテーテル留置部位蕁麻疹	0	0	0	0	0	0
死亡	0	0	0	0	0	0
活動性低下	0	0	0	0	0	0
医療機器不具合	0	0	0	0	0	0
医療機器機能不良	0	0	0	0	1 (0.2)	0
薬剤離脱症候群	0	0	0	0	0	0
活力増進	0	0	0	0	0	0
溢出	0	0	0	0	0	0
冷感	0	0	0	0	0	0
びくびく感	0	0	0	0	0	0
重力性浮腫	0	0	0	0	0	0
低体温	0	0	0	0	0	0
硬結	0	0	0	0	0	0
注射部位漏出	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
注射部位疼痛	0	0	0	0	0	0
注射部位そう痒感	0	0	0	0	0	0
注射部位反応	0	0	0	0	0	0
注射部位腫脹	0	0	0	0	0	0
易刺激性	0	0	0	0	1 (0.2)	0
限局性浮腫	0	0	0	0	0	0
医療機器による疼痛	0	0	0	0	0	0
粘膜出血	1 (0.3)	0	0	0	1 (0.2)	0
分泌物分泌	0	0	0	0	0	0
異物感	0	0	0	0	0	0
気象変化過敏	0	0	0	0	0	0
温度変化不耐症	0	0	0	0	0	0
圧痛	0	0	0	0	0	0
血管穿刺部位出血	0	0	0	0	0	0
捻髪音	0	0	0	0	0	0
医療機器破損	0	0	0	0	0	0
医療機器位置異常	0	0	1 (0.3)	0	0	0
不快感	0	0	0	0	0	0
顔面痛	0	0	0	0	0	0
腫瘤	0	0	0	0	0	0
小結節	0	0	0	0	0	0
苦悶感	0	0	0	0	0	0
漿膜炎	0	0	0	0	0	0
恥骨上痛	0	0	0	0	0	0
腫脹	0	0	0	0	0	0
ワクチン接種部位発疹	0	0	0	0	0	0
胃腸障害	27 (8.5)	5 (5.0)	27 (8.5)	0	43 (9.5)	9 (6.4)
下痢	13 (4.1)	4 (4.0)	13 (4.1)	0	23 (5.1)	8 (5.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
便秘	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
悪心	3 (0.9)	0	2 (0.6)	0	4 (0.9)	0
嘔吐	1 (0.3)	0	3 (0.9)	0	2 (0.4)	0
腹痛	1 (0.3)	0	0	0	1 (0.2)	0
消化不良	0	0	0	0	0	0
口内炎	0	0	0	0	0	0
上腹部痛	1 (0.3)	0	0	0	1 (0.2)	0
歯痛	1 (0.3)	0	0	0	2 (0.4)	0
胃食道逆流性疾患	1 (0.3)	1 (1.0)	1 (0.3)	0	1 (0.2)	1 (0.7)
口内乾燥	0	0	0	0	0	0
腹部膨満	0	0	0	0	0	0
放屁	0	0	0	0	0	0
痔核	0	0	1 (0.3)	0	0	0
口腔内潰瘍形成	0	0	0	0	0	0
胃炎	0	0	0	0	1 (0.2)	0
腹部不快感	0	0	1 (0.3)	0	0	0
血便排泄	0	0	0	0	0	0
下腹部痛	0	0	0	0	0	0
齲歯	0	0	0	0	0	0
嚥下障害	0	0	0	0	0	0
口腔内痛	0	0	0	0	0	0
口腔障害	0	0	0	0	0	0
口の錯感覚	0	0	0	0	0	0
アフタ性口内炎	0	0	0	0	0	0
単径ヘルニア	0	0	0	0	0	0
直腸出血	1 (0.3)	0	0	0	1 (0.2)	0
口唇炎	0	0	0	0	0	0
便失禁	0	0	0	0	0	0
胃腸障害	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
胃腸出血	2 (0.6)	0	1 (0.3)	0	4 (0.9)	0
消化管運動障害	0	0	0	0	0	0
口唇腫脹	0	0	0	0	0	0
小腸炎	0	0	0	0	0	0
腸炎	0	0	0	0	0	0
食中毒	0	0	0	0	0	0
歯肉痛	0	0	0	0	0	0
口の感覚鈍麻	0	0	0	0	0	0
口腔内出血	1 (0.3)	0	0	0	1 (0.2)	0
歯周病	0	0	0	0	0	0
大腸炎	1 (0.3)	0	0	0	1 (0.2)	0
消化器痛	0	0	0	0	0	0
胃腸音異常	0	0	0	0	0	0
歯肉潰瘍	0	0	0	0	0	0
舌痛	0	0	0	0	0	0
吐血	1 (0.3)	0	0	0	2 (0.4)	0
裂孔ヘルニア	0	0	0	0	0	0
腸閉塞	0	0	0	0	0	0
大腸ポリープ	0	0	0	0	0	0
嚥下痛	0	0	1 (0.3)	0	0	0
食道痛	0	0	0	0	0	0
口腔粘膜紅斑	0	0	0	0	0	0
急性膵炎	1 (0.3)	0	0	0	1 (0.2)	0
耳下腺腫大	0	0	0	0	0	0
唾液腺結石	0	0	0	0	0	0
舌苔	0	0	0	0	0	0
舌障害	0	0	0	0	0	0
舌潰瘍	0	0	0	0	0	0
歯の障害	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
歯の脱落	0	0	0	0	0	0
臍ヘルニア	0	0	0	0	0	0
腹部ヘルニア	0	0	0	0	0	0
腹部腫瘤	0	0	0	0	0	0
腹部圧痛	0	0	0	0	0	0
空気嚥下	0	0	0	0	0	0
裂肛	0	0	0	0	0	0
肛門出血	0	0	0	0	0	0
唾液欠乏	0	0	0	0	0	0
歯組織の壊死	0	0	0	0	0	0
憩室穿孔	0	0	0	0	1 (0.2)	0
十二指腸潰瘍	0	0	0	0	0	0
心窩部不快感	0	0	0	0	0	0
おくび	0	0	0	0	0	0
変色便	0	0	0	0	0	0
胃障害	0	0	0	0	0	0
胃ポリープ	0	0	0	0	0	0
胃潰瘍	0	0	1 (0.3)	0	0	0
萎縮性胃炎	0	0	0	0	0	0
びらん性胃炎	0	0	0	0	0	0
消化管浮腫	0	0	0	0	0	0
消化管穿孔	0	0	0	0	0	0
歯肉出血	0	0	0	0	0	0
歯肉びらん	0	0	0	0	0	0
歯肉紅斑	0	0	0	0	0	0
歯肉の炎症	0	0	0	0	0	0
歯肉腫脹	0	0	0	0	0	0
痔出血	0	0	0	0	0	0
大腸穿孔	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
口唇水疱	0	0	0	0	0	0
口唇痛	0	0	0	0	0	0
メレナ	0	0	0	0	1 (0.2)	0
粘液便	0	0	0	0	0	0
口腔内不快感	0	0	0	0	0	0
肛門周囲痛	0	0	0	0	0	0
直腸しぶり	0	0	0	0	0	0
唾液腺障害	0	0	0	0	0	0
歯の知覚過敏	0	0	0	0	0	0
壊死性口内炎	0	0	0	0	0	0
舌水疱形成	0	0	0	0	0	0
食道静脈瘤	0	0	0	0	0	0
腹壁反跳痛	0	0	1 (0.3)	0	0	0
胆汁酸吸収不良	0	0	1 (0.3)	0	0	0
便意切迫	0	0	0	0	0	0
腸憩室	0	0	0	0	0	0
十二指腸胃逆流	0	0	0	0	0	0
軟便	0	0	0	0	0	0
歯肉障害	0	0	0	0	0	0
イレウス	0	0	1 (0.3)	0	0	0
麻痺性イレウス	0	0	0	0	0	0
閉塞性鼠径ヘルニア	0	0	1 (0.3)	0	0	0
腸出血	0	0	0	0	0	0
大腸潰瘍	0	0	0	0	0	0
口唇乾燥	0	0	0	0	0	0
口唇潰瘍	0	0	0	0	0	0
下部消化管出血	0	0	1 (0.3)	0	0	0
吸収不良	0	0	0	0	0	0
食道炎	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
口腔知覚不全	0	0	0	0	0	0
膵炎	0	0	1 (0.3)	0	0	0
逆流性胃炎	0	0	0	0	0	0
亜イレウス	0	0	1 (0.3)	0	0	0
舌変色	0	0	1 (0.3)	0	0	0
上部消化管出血	0	0	1 (0.3)	0	0	0
感染症および寄生虫症	88 (27.7)	3 (3.0)	75 (23.7)	3 (5.6)	116 (25.7)	10 (7.1)
上気道感染	2 (0.6)	0	4 (1.3)	0	6 (1.3)	0
鼻咽頭炎	0	0	0	0	0	0
気管支炎	4 (1.3)	1 (1.0)	7 (2.2)	0	7 (1.6)	1 (0.7)
肺炎	31 (9.7)	2 (2.0)	22 (6.9)	1 (1.9)	39 (8.6)	4 (2.9)
尿路感染	4 (1.3)	0	7 (2.2)	0	4 (0.9)	1 (0.7)
鼻炎	0	0	0	0	0	0
気道感染	8 (2.5)	0	4 (1.3)	0	8 (1.8)	0
インフルエンザ	2 (0.6)	0	3 (0.9)	1 (1.9)	4 (0.9)	0
副鼻腔炎	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
下気道感染	3 (0.9)	0	4 (1.3)	0	3 (0.7)	1 (0.7)
帯状疱疹	5 (1.6)	0	2 (0.6)	0	6 (1.3)	0
蜂巣炎	5 (1.6)	0	1 (0.3)	0	6 (1.3)	0
口腔ヘルペス	0	0	0	0	0	0
咽頭炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
口腔カンジダ症	0	0	0	0	0	0
胃腸炎	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
ウイルス感染	1 (0.3)	0	0	0	1 (0.2)	0
気管支肺炎	6 (1.9)	0	2 (0.6)	0	7 (1.6)	0
結膜炎	0	0	0	0	0	0
肺感染	2 (0.6)	0	0	1 (1.9)	3 (0.7)	0
敗血症	3 (0.9)	0	3 (0.9)	0	6 (1.3)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
感染	3 (0.9)	0	3 (0.9)	0	3 (0.7)	0
膀胱炎	0	0	0	0	0	0
ウイルス性胃腸炎	0	0	3 (0.9)	0	0	0
耳感染	0	0	0	0	0	0
ヘルペスウイルス感染	0	0	0	0	0	0
毛包炎	0	0	0	0	0	0
喉頭炎	0	0	0	0	0	0
大葉性肺炎	2 (0.6)	0	4 (1.3)	0	2 (0.4)	1 (0.7)
カンジダ感染	0	0	0	0	0	0
眼感染	0	0	0	0	0	0
真菌感染	0	0	0	0	0	0
皮膚真菌感染	0	0	0	0	0	0
限局性感染	0	0	0	0	0	0
口腔感染	0	0	0	0	0	0
歯感染	0	0	0	0	1 (0.2)	0
クロストリジウム・ディフィシレ大腸炎	1 (0.3)	0	0	0	2 (0.4)	0
歯肉炎	0	0	0	0	0	0
骨髄炎	2 (0.6)	0	2 (0.6)	0	2 (0.4)	0
歯周炎	0	0	0	0	0	0
肺炎球菌性肺炎	3 (0.9)	0	0	0	3 (0.7)	0
ウイルス性上気道感染	0	0	0	0	0	0
異型肺炎	2 (0.6)	0	0	0	2 (0.4)	0
クロストリジウム・ディフィシレ感染	0	0	1 (0.3)	0	0	1 (0.7)
ウイルス性消化管感染	0	0	0	0	0	0
単純ヘルペス	0	0	0	0	0	0
口唇感染	0	0	0	0	0	0
爪真菌症	0	0	0	0	0	0
口腔真菌感染	0	0	1 (0.3)	0	0	0
ニューモシスチス・イロベチイ肺炎	3 (0.9)	0	0	0	3 (0.7)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
術後創感染	0	0	1 (0.3)	0	1 (0.2)	0
膿疱性皮疹	0	0	0	0	0	0
ライノウイルス感染	0	0	0	0	0	0
足部白癬	0	0	0	0	0	0
急性扁桃炎	0	0	0	0	0	0
アスペルギルス感染	0	0	0	0	1 (0.2)	0
細菌感染	0	0	0	0	0	0
ウイルス性結膜炎	0	0	0	0	0	0
熱性感染症	1 (0.3)	0	0	0	1 (0.2)	0
せつ	0	0	0	0	0	0
陰部ヘルペス	0	0	0	0	0	0
歯肉膿瘍	0	0	0	0	0	0
H1N1 インフルエンザ	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
麦粒腫	0	0	0	0	0	0
咬傷感染	0	0	0	0	0	0
中耳炎	0	0	0	0	0	0
歯髄炎	0	0	0	0	0	0
敗血症性ショック	1 (0.3)	0	4 (1.3)	0	1 (0.2)	0
副鼻腔気管支炎	0	0	0	0	0	0
皮膚感染	0	0	1 (0.3)	0	0	0
ブドウ球菌感染	1 (0.3)	0	0	0	1 (0.2)	0
股部白癬	0	0	0	0	0	0
歯膿瘍	0	0	0	0	0	0
気管炎	0	0	0	0	0	0
細菌性尿路感染	1 (0.3)	0	0	0	1 (0.2)	0
ウイルス性下痢	1 (0.3)	0	0	0	1 (0.2)	0
創傷感染	1 (0.3)	0	0	0	1 (0.2)	0
膿瘍	0	0	0	0	0	0
急性副鼻腔炎	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
非定型マイコバクテリア感染	0	0	0	0	0	0
菌血症	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
細菌性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
体部白癬	0	0	0	0	0	0
細気管支炎	0	0	0	0	0	0
気管支肺アスペルギルス症	1 (0.3)	0	0	0	1 (0.2)	0
カンピロバクター胃腸炎	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
脳アスペルギルス症	1 (0.3)	0	0	0	1 (0.2)	0
慢性副鼻腔炎	0	0	0	0	0	0
サイトメガロウイルス感染	1 (0.3)	0	0	0	1 (0.2)	0
医療機器関連感染	1 (0.3)	0	0	0	1 (0.2)	0
憩室炎	0	0	0	0	0	0
真菌性耳感染	0	0	0	0	0	0
心内膜炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
感染性腸炎	1 (0.3)	0	0	0	1 (0.2)	0
腸球菌感染	0	0	0	0	0	0
ウイルス性腸炎	0	0	0	0	0	0
丹毒	0	0	0	0	0	0
伝染性紅斑	0	0	1 (0.3)	0	1 (0.2)	0
大腸菌性尿路感染	0	0	0	0	0	0
消化管感染	0	0	1 (0.3)	0	0	0
性器感染	0	0	0	0	0	0
泌尿生殖器感染	0	0	0	0	0	0
切開部位感染	0	0	0	0	0	0
感染性嚢腫	0	0	0	0	0	0
感染性皮膚嚢腫	0	0	0	0	0	0
感染性大腸炎	0	0	0	0	0	0
クレブシエラ感染	1 (0.3)	0	0	0	1 (0.2)	0
迷路炎	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
ライム病	0	0	0	0	0	0
髄膜炎	0	0	0	0	1 (0.2)	0
ブドウ球菌性髄膜炎	0	0	0	0	0	0
粘膜感染	0	0	0	0	0	0
爪感染	0	0	0	0	0	0
好中球減少性敗血症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
食道カンジダ症	0	0	0	0	0	0
膵炎	0	0	0	0	0	0
口腔ウイルス感染	0	0	0	0	0	0
外耳炎	0	0	0	0	0	0
直腸周囲膿瘍	0	0	0	0	0	0
百日咳	0	0	0	0	0	0
咽頭扁桃炎	0	0	0	0	0	0
肺炎球菌性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
細菌性肺炎	1 (0.3)	0	0	0	1 (0.2)	0
真菌性肺炎	1 (0.3)	0	0	0	1 (0.2)	0
インフルエンザ性肺炎	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
レジオネラ菌性肺炎	0	0	0	0	1 (0.2)	0
RS ウイルス肺炎	0	0	0	0	0	0
レンサ球菌性肺炎	0	0	0	0	0	0
ウイルス性肺炎	0	0	0	0	0	1 (0.7)
処置後感染	0	0	0	0	0	0
腎盂腎炎	1 (0.3)	0	0	0	1 (0.2)	0
RS ウイルス感染	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
皮膚カンジダ	0	0	0	0	0	0
軟部組織感染	0	0	0	0	1 (0.2)	0
スフィンゴモナス・パウシモビリス感染	1 (0.3)	0	0	0	1 (0.2)	0
脊髄感染	0	0	0	0	1 (0.2)	0
ブドウ球菌性菌血症	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
レンサ球菌感染	0	0	0	0	0	0
手白癬	0	0	0	0	0	0
扁桃炎	1 (0.3)	0	0	0	1 (0.2)	0
細菌性上気道感染	0	0	0	0	0	0
シュードモナス性尿路感染	0	0	0	0	0	0
尿路性敗血症	1 (0.3)	0	0	0	1 (0.2)	0
腟感染	0	0	0	0	0	0
水痘	0	0	0	0	0	0
ウイルス性咽頭炎	0	0	0	0	0	0
ウイルス性鼻炎	0	0	0	0	0	0
内臓リーシュマニア症	0	0	0	0	1 (0.2)	0
外陰部腟カンジダ症	0	0	0	0	0	0
ブドウ球菌性創感染	0	0	0	0	0	0
腹部膿瘍	0	0	0	0	0	0
顎膿瘍	0	0	0	0	0	0
四肢膿瘍	0	0	0	0	0	0
口腔膿瘍	0	0	1 (0.3)	0	0	0
細菌性関節炎	0	0	1 (0.3)	0	0	0
骨膿瘍	0	0	0	0	0	0
ウイルス性気管支炎	0	0	0	0	0	0
カンピロバクター感染	0	0	0	0	0	0
カテーテル留置部位感染	0	0	1 (0.3)	0	0	0
男性外性器蜂巣炎	0	0	0	0	0	0
医療機器関連敗血症	0	0	0	0	0	0
糖尿病性足感染	0	0	0	0	0	0
眼内炎	0	0	1 (0.3)	0	0	0
ウイルス性胃炎	0	0	0	0	0	0
消化器カンジダ症	0	0	0	0	0	0
ヘモフィルス感染	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
埋込み部位膿瘍	0	0	0	0	0	0
リステリア症	0	0	1 (0.3)	0	0	0
肺膿瘍	0	0	0	1 (1.9)	0	0
眼部単純ヘルペス	0	0	0	0	0	0
眼帯状疱疹	0	0	1 (0.3)	0	0	0
パラインフルエンザウイルス感染	0	0	0	0	0	0
爪囲炎	0	0	0	0	0	0
腹膜炎	0	0	0	0	0	0
急性腎盂腎炎	0	0	1 (0.3)	0	0	0
膿性痰	0	0	0	0	0	0
ブドウ球菌性敗血症	0	0	1 (0.3)	0	0	0
レンサ球菌性菌血症	0	0	1 (0.3)	0	0	0
皮下組織膿瘍	0	0	0	0	0	0
気管気管支炎	0	0	0	0	0	0
腸球菌性尿路感染	0	0	1 (0.3)	0	0	0
真菌性尿路感染	0	0	0	0	0	0
泌尿生殖器細菌感染	0	0	0	0	0	0
筋骨格系および結合組織障害	39 (12.3)	3 (3.0)	32 (10.1)	5 (9.3)	57 (12.6)	5 (3.6)
筋痙縮	1 (0.3)	0	3 (0.9)	0	3 (0.7)	0
背部痛	16 (5.0)	0	12 (3.8)	2 (3.7)	21 (4.7)	1 (0.7)
関節痛	4 (1.3)	0	2 (0.6)	0	6 (1.3)	1 (0.7)
四肢痛	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
筋骨格痛	5 (1.6)	0	2 (0.6)	0	8 (1.8)	1 (0.7)
骨痛	0	1 (1.0)	3 (0.9)	0	2 (0.4)	1 (0.7)
筋力低下	6 (1.9)	0	3 (0.9)	1 (1.9)	7 (1.6)	0
筋骨格系胸痛	1 (0.3)	0	0	0	2 (0.4)	0
筋肉痛	0	0	0	0	1 (0.2)	0
頚部痛	2 (0.6)	1 (1.0)	0	0	2 (0.4)	1 (0.7)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
顎痛	0	0	0	0	0	0
筋骨格硬直	0	0	0	0	0	0
脊椎痛	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
側腹部痛	0	0	0	0	0	0
ミオパチー	2 (0.6)	0	0	0	2 (0.4)	0
関節腫脹	0	0	0	0	0	0
筋骨格不快感	0	0	0	0	0	0
骨壊死	1 (0.3)	1 (1.0)	0	0	1 (0.2)	1 (0.7)
四肢不快感	0	0	0	0	0	0
変形性関節症	1 (0.3)	0	0	0	2 (0.4)	0
顎骨壊死	1 (0.3)	0	4 (1.3)	2 (3.7)	2 (0.4)	0
関節炎	0	0	0	0	0	0
単径部痛	0	0	0	0	0	0
重感	0	0	0	0	0	0
尾骨痛	0	0	0	0	0	0
筋拘縮	0	0	0	0	0	0
筋肉内出血	0	0	0	0	0	0
筋緊張	0	0	0	0	0	0
筋攣縮	0	0	0	0	0	0
頚部腫瘤	0	0	0	0	0	0
骨炎	0	0	0	0	0	0
腱痛	0	0	0	0	0	0
筋萎縮症	0	0	0	0	0	0
骨病変	1 (0.3)	0	0	0	1 (0.2)	0
バニオン	0	0	0	0	0	0
滑液包炎	0	0	0	0	0	0
頚部脊柱管狭窄症	0	0	1 (0.3)	0	0	0
四肢拘縮	0	0	0	0	0	0
筋膜炎	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
瘻孔	0	0	0	0	0	0
痛風性関節炎	0	0	1 (0.3)	0	0	0
出血性関節症	0	0	0	0	0	0
椎間板突出	0	0	0	0	0	0
関節摩擦音	0	0	0	0	0	0
関節滲出液	0	0	0	0	0	0
関節可動域低下	0	0	0	0	0	0
運動性低下	0	0	0	0	0	0
筋萎縮	0	0	0	0	0	0
筋腫瘤	1 (0.3)	0	0	0	1 (0.2)	0
骨溶解	0	0	0	0	0	0
骨減少症	0	0	0	0	0	0
骨粗鬆症	0	0	0	0	0	0
足底筋膜炎	0	0	0	0	0	0
恥骨痛	0	0	0	0	0	0
肩回旋筋腱板症候群	0	0	0	0	0	0
脊柱管狭窄症	0	1 (1.0)	0	0	0	1 (0.7)
顎関節症候群	0	0	0	0	0	0
腱炎	1 (0.3)	0	0	0	1 (0.2)	0
腱鞘炎	0	0	0	0	0	0
開口障害	0	0	0	0	0	0
骨障害	0	0	0	0	0	0
外骨腫	0	0	0	0	0	0
瘻孔分泌物	0	0	1 (0.3)	0	0	0
関節硬直	0	0	0	0	0	0
病的骨折	0	0	1 (0.3)	0	0	0
横紋筋融解症	0	0	2 (0.6)	0	0	0
変形性脊椎症	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
神経系障害	34 (10.7)	2 (2.0)	27 (8.5)	2 (3.7)	47 (10.4)	5 (3.6)
頭痛	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
末梢性ニューロパチー	4 (1.3)	1 (1.0)	5 (1.6)	0	5 (1.1)	2 (1.4)
浮動性めまい	2 (0.6)	0	0	0	2 (0.4)	0
味覚異常	0	0	0	0	0	0
錯感覚	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
末梢性感覚ニューロパチー	4 (1.3)	0	2 (0.6)	0	4 (0.9)	0
振戦	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
感覚鈍麻	1 (0.3)	0	0	0	1 (0.2)	0
失神	7 (2.2)	1 (1.0)	3 (0.9)	0	13 (2.9)	3 (2.1)
記憶障害	0	0	0	0	2 (0.4)	0
傾眠	1 (0.3)	0	0	0	1 (0.2)	0
多発ニューロパチー	1 (0.3)	0	0	0	1 (0.2)	0
平衡障害	1 (0.3)	0	0	0	1 (0.2)	0
認知障害	1 (0.3)	0	0	0	1 (0.2)	0
神経痛	0	0	0	0	0	0
副鼻腔炎に伴う頭痛	0	0	0	0	0	0
健忘	0	0	0	0	0	0
末梢性運動ニューロパチー	2 (0.6)	0	0	0	2 (0.4)	0
失神寸前の状態	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
坐骨神経痛	0	0	0	0	0	0
味覚消失	0	0	0	0	0	0
嗜眠	1 (0.3)	0	2 (0.6)	0	2 (0.4)	0
精神運動亢進	0	0	1 (0.3)	0	0	0
反射消失	0	0	0	0	0	0
運動失調	1 (0.3)	0	0	0	1 (0.2)	0
痙攣	1 (0.3)	0	0	0	1 (0.2)	0
注意力障害	0	0	0	0	0	0
体位性めまい	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
知覚過敏	0	0	0	0	0	0
片頭痛	0	0	0	0	0	0
一過性脳虚血発作	1 (0.3)	0	0	0	3 (0.7)	0
手根管症候群	0	0	0	0	0	0
脳血管発作	1 (0.3)	0	1 (0.3)	1 (1.9)	2 (0.4)	0
局在性痙攣	0	0	0	0	0	0
振動覚低下	0	0	0	0	0	0
筋緊張亢進	0	0	0	0	0	0
味覚減退	0	0	0	0	0	0
反射減弱	0	0	0	0	0	0
失語症	1 (0.3)	0	0	0	1 (0.2)	0
灼熱感	0	0	0	0	0	0
頚動脈閉塞	0	0	0	0	0	0
脳梗塞	1 (0.3)	0	0	0	1 (0.2)	0
脳虚血	0	0	1 (0.3)	0	0	0
頚髄神経根障害	0	0	0	0	0	0
認知症	0	0	0	0	0	0
異常感覚	0	0	0	0	0	0
構語障害	0	0	0	0	0	0
ジスキネジア	0	0	0	0	0	0
ジストニア	0	0	0	0	0	0
顔面神経障害	0	0	0	0	0	0
顔面部神経痛	0	0	0	0	0	0
大発作痙攣	0	0	0	0	0	0
頭部不快感	0	0	0	0	0	0
頭部動揺	0	0	0	0	0	0
筋緊張低下	0	0	0	0	0	0
肋間神経痛	0	0	0	0	0	0
意識消失	0	0	2 (0.6)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
固有感覚の欠如	0	0	0	0	0	0
不全単麻痺	0	0	0	0	0	0
神経学的症状	1 (0.3)	0	0	0	1 (0.2)	0
おとがいしびれ症候群	0	0	0	0	0	0
視神経炎	1 (0.3)	0	0	0	1 (0.2)	0
不全対麻痺	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
パーキンソニズム	0	0	0	0	0	0
嗅覚錯誤	0	0	0	0	0	0
睡眠の質低下	0	0	0	0	0	0
ヘルペス後神経痛	0	0	1 (0.3)	0	0	0
下肢静止不能症候群	0	0	0	0	0	0
感覚消失	0	0	0	0	0	0
脊髄圧迫	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
緊張性頭痛	0	0	0	0	0	0
一過性全健忘	0	0	0	0	0	0
三叉神経痛	0	0	0	0	0	0
第 7 脳神経麻痺	0	0	0	0	0	0
視野欠損	0	0	0	0	0	0
白質病変	0	0	0	0	0	0
軸索型ニューロパチー	0	0	0	0	0	0
小脳症候群	0	0	0	0	0	0
脳出血	0	0	0	0	0	0
間代	0	0	0	0	0	0
複合性局所疼痛症候群	0	0	1 (0.3)	0	0	0
脳症	0	0	1 (0.3)	0	0	0
蟻走感	0	0	0	0	0	0
不全片麻痺	0	0	1 (0.3)	0	0	0
過眠症	0	0	0	0	0	0
単ニューロパチー	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
不随意性筋収縮	0	0	0	0	0	0
神経毒性	0	0	1 (0.3)	0	0	0
眼振	0	0	0	0	0	0
対麻痺	0	0	1 (0.3)	0	0	0
パーキンソン病	0	0	0	0	0	0
精神運動機能障害	0	0	0	0	0	0
脊髄障害	0	0	1 (0.3)	0	0	0
てんかん重積状態	0	0	0	1 (1.9)	0	0
血管性脳症	0	0	0	0	0	0
血液およびリンパ系障害	133 (41.8)	14 (13.9)	141 (44.5)	4 (7.4)	196 (43.5)	21 (15.0)
貧血	46 (14.5)	3 (3.0)	51 (16.1)	2 (3.7)	60 (13.3)	5 (3.6)
好中球減少症	77 (24.2)	5 (5.0)	104 (32.8)	2 (3.7)	106 (23.5)	8 (5.7)
血小板減少症	36 (11.3)	1 (1.0)	36 (11.4)	0	58 (12.9)	2 (1.4)
リンパ球減少症	27 (8.5)	7 (6.9)	10 (3.2)	0	51 (11.3)	9 (6.4)
白血球減少症	12 (3.8)	1 (1.0)	12 (3.8)	0	23 (5.1)	2 (1.4)
発熱性好中球減少症	6 (1.9)	0	6 (1.9)	0	12 (2.7)	1 (0.7)
汎血球減少症	4 (1.3)	0	0	0	6 (1.3)	0
リンパ節症	0	0	0	0	0	0
内出血発生の増加傾向	0	0	0	0	0	0
好酸球増加症	1 (0.3)	0	0	0	1 (0.2)	0
鉄欠乏性貧血	0	0	0	0	0	0
白血球増加症	0	0	0	0	0	0
顆粒球減少症	0	0	0	0	0	0
血小板増加症	0	0	0	0	0	0
骨髄機能不全	1 (0.3)	0	0	0	1 (0.2)	0
血液毒性	0	0	0	0	0	0
ヘモグロビン血症	0	0	0	0	1 (0.2)	0
微小血管症性溶血性貧血	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
単球増加症	0	0	0	0	0	0
形質細胞増加症	1 (0.3)	0	0	0	1 (0.2)	0
脾腫	0	0	0	0	0	0
腹部リンパ節腫脹	0	0	1 (0.3)	0	0	0
大球性貧血	0	0	0	0	0	0
播種性血管内凝固	0	0	0	0	0	0
出血性素因	0	0	1 (0.3)	0	0	0
リンパ節炎	0	0	0	0	0	0
大赤血球症	0	0	0	0	0	0
単球減少症	0	0	0	0	0	0
脾臓梗塞	0	0	0	0	0	0
呼吸器、胸郭および縦郭障害	30 (9.4)	0	24 (7.6)	0	44 (9.8)	3 (2.1)
咳嗽	1 (0.3)	0	0	0	1 (0.2)	0
呼吸困難	6 (1.9)	0	11 (3.5)	0	10 (2.2)	2 (1.4)
口腔咽頭痛	0	0	0	0	0	0
発声障害	0	0	1 (0.3)	0	0	0
労作性呼吸困難	0	0	0	0	0	0
鼻出血	2 (0.6)	0	0	0	3 (0.7)	0
湿性咳嗽	0	0	0	0	0	0
鼻閉	0	0	0	0	0	0
鼻漏	0	0	0	0	0	0
肺塞栓症	10 (3.1)	0	7 (2.2)	0	14 (3.1)	0
副鼻腔うっ血	0	0	0	0	0	0
しゃっくり	0	0	0	0	0	0
喘鳴	0	0	0	0	0	0
慢性閉塞性肺疾患	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
肺障害	2 (0.6)	0	0	0	4 (0.9)	1 (0.7)
低酸素症	4 (1.3)	0	2 (0.6)	0	5 (1.1)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
ラ音	0	0	0	0	0	0
アレルギー性鼻炎	0	0	0	0	0	0
胸水	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
胸膜痛	0	0	1 (0.3)	0	0	0
上気道咳症候群	0	0	0	0	0	0
肺臓炎	0	0	2 (0.6)	0	0	0
上気道の炎症	0	0	0	0	0	0
副鼻腔分泌過多	0	0	0	0	0	0
気道うっ血	1 (0.3)	0	0	0	1 (0.2)	0
喘息	1 (0.3)	0	0	0	1 (0.2)	0
変色痰	0	0	0	0	0	0
咽喉刺激感	0	0	0	0	0	0
急性呼吸不全	1 (0.3)	0	0	0	2 (0.4)	0
無気肺	0	0	0	0	0	0
気管支反応性亢進	1 (0.3)	0	0	0	1 (0.2)	0
喀血	0	0	1 (0.3)	0	1 (0.2)	0
低換気	0	0	0	0	0	0
間質性肺疾患	0	0	1 (0.3)	0	0	0
鼻部不快感	0	0	0	0	0	0
胸膜炎	0	0	0	0	0	0
肺水腫	0	0	0	0	0	0
呼吸障害	0	0	0	0	0	0
無呼吸	0	0	0	0	1 (0.2)	0
気管支浮腫	0	0	0	0	0	0
気管支拡張症	0	0	0	0	0	0
慢性気管支炎	1 (0.3)	0	0	0	1 (0.2)	0
気管支痙攣	0	0	0	0	0	0
咽喉乾燥	0	0	0	0	0	0
過換気	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
上気道分泌増加	0	0	0	0	0	0
喉頭痛	0	0	0	0	0	0
鼻乾燥	0	0	0	0	0	0
鼻の炎症	0	0	0	0	0	0
鼻閉塞	0	0	0	0	0	0
夜間呼吸困難	0	0	0	0	0	0
閉塞性細気管支炎	1 (0.3)	0	0	0	1 (0.2)	0
閉塞性気道障害	0	0	0	0	0	0
器質化肺炎	1 (0.3)	0	0	0	1 (0.2)	0
口腔咽頭プラーク	0	0	0	0	0	0
呼吸時疼痛	0	0	0	0	0	0
咽頭紅斑	0	0	0	0	0	0
咽頭の炎症	0	0	0	0	0	0
気胸	0	0	0	0	0	0
肺胞出血	1 (0.3)	0	0	0	1 (0.2)	0
肺うっ血	0	0	0	0	0	0
肺出血	0	0	0	0	0	0
肺梗塞	0	0	0	0	1 (0.2)	0
肺腫瘤	0	0	0	0	0	0
呼吸不全	1 (0.3)	0	0	0	1 (0.2)	0
低音性連続性ラ音	0	0	0	0	0	0
副鼻腔障害	0	0	0	0	0	0
睡眠時無呼吸症候群	1 (0.3)	0	0	0	1 (0.2)	0
上気道性喘鳴	0	0	0	0	1 (0.2)	0
窒息感	0	0	0	0	0	0
頻呼吸	0	0	0	0	0	0
咽喉絞扼感	0	0	0	0	0	0
扁桃肥大	0	0	0	0	0	0
上気道閉塞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
上気道うっ血	0	0	0	0	0	0
声帯障害	0	0	0	0	0	0
急性肺水腫	0	0	1 (0.3)	0	0	0
アレルギー性副鼻腔炎	0	0	0	0	0	0
気管支障害	0	0	0	0	0	0
鼻部障害	0	0	0	0	0	0
口腔咽頭不快感	0	0	0	0	0	0
肺高血圧症	0	0	1 (0.3)	0	0	0
呼吸性アルカローシス	0	0	1 (0.3)	0	0	0
呼吸窮迫	0	0	0	0	0	0
気道の炎症	0	0	0	0	0	0
鼻痛	0	0	0	0	0	0
くしゃみ	0	0	0	0	0	0
痰貯留	0	0	0	0	0	0
扁桃潰瘍	0	0	0	0	0	0
気管の炎症	0	0	0	0	0	0
血管運動性鼻炎	0	0	0	0	0	0
皮膚および皮下組織障害	9 (2.8)	0	8 (2.5)	0	13 (2.9)	0
発疹	1 (0.3)	0	5 (1.6)	0	3 (0.7)	0
多汗症	0	0	0	0	0	0
そう痒症	0	0	0	0	0	0
寝汗	0	0	0	0	0	0
紅斑	0	0	0	0	0	0
皮膚乾燥	0	0	0	0	0	0
蕁麻疹	0	0	0	0	0	0
斑状出血	0	0	0	0	0	0
皮膚病変	0	0	0	0	0	0
点状出血	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
斑状丘疹状皮疹	2 (0.6)	0	0	0	2 (0.4)	0
脱毛症	0	0	0	0	0	0
全身性皮疹	0	0	0	0	1 (0.2)	0
紫斑	0	0	0	0	0	0
皮膚潰瘍	0	0	1 (0.3)	0	0	0
そう痒性皮疹	1 (0.3)	0	0	0	1 (0.2)	0
皮膚変色	0	0	0	0	0	0
アレルギー性皮膚炎	0	0	0	0	1 (0.2)	0
嵌入爪	0	0	0	0	0	0
皮膚腫瘤	0	0	0	0	0	0
日光性角化症	0	0	0	0	0	0
丘疹	0	0	0	0	0	0
斑状皮疹	0	0	1 (0.3)	0	0	0
皮膚剥脱	0	0	0	0	0	0
顔面腫脹	0	0	0	0	0	0
ざ瘡	0	0	0	0	0	0
水疱	0	0	0	0	0	0
褥瘡性潰瘍	1 (0.3)	0	0	0	1 (0.2)	0
皮膚嚢腫	0	0	0	0	0	0
皮膚炎	0	0	0	0	0	0
薬疹	0	0	1 (0.3)	0	1 (0.2)	0
毛髪成長異常	0	0	0	0	0	0
過角化	0	0	0	0	0	0
爪の障害	0	0	0	0	0	0
爪破損	0	0	0	0	0	0
全身性そう痒症	0	0	0	0	0	0
丘疹性皮疹	0	0	0	0	0	0
痂皮	0	0	0	0	0	0
皮膚亀裂	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
皮膚色素過剰	0	0	0	0	0	0
血管浮腫	1 (0.3)	0	0	0	1 (0.2)	0
ざ瘡様皮膚炎	0	0	0	0	0	0
接触性皮膚炎	0	0	0	0	0	0
びまん性脱毛症	0	0	0	0	0	0
全身紅斑	0	0	0	0	0	0
皮下出血	0	0	0	0	0	0
毛髪変色	0	0	0	0	0	0
毛髪障害	0	0	0	0	0	0
男性型多毛症	0	0	0	0	0	0
白斑	0	0	0	0	0	0
後天性リポジストロフィー	0	0	0	0	0	0
斑	0	0	0	0	0	0
汗疹	0	0	0	0	0	0
爪床出血	0	0	0	0	0	0
爪変色	0	0	0	0	0	0
皮膚疼痛	0	0	0	0	0	0
天疱瘡	1 (0.3)	0	0	0	1 (0.2)	0
陰茎潰瘍形成	0	0	0	0	0	0
光線性皮膚症	0	0	0	0	0	0
色素沈着障害	0	0	0	0	0	0
アレルギー性そう痒症	0	0	0	0	0	0
乾癬	0	0	1 (0.3)	0	0	0
膿疱性乾癬	1 (0.3)	0	0	0	1 (0.2)	0
紅斑性皮疹	0	0	0	0	0	0
酒さ	0	0	0	0	0	0
皮膚灼熱感	0	0	0	0	0	0
皮膚障害	0	0	0	0	0	0
皮膚びらん	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
皮膚出血	1 (0.3)	0	0	0	1 (0.2)	0
皮膚壊死	0	0	0	0	0	0
皮膚反応	0	0	0	0	0	0
皮膚腫脹	0	0	0	0	0	0
うっ滞性皮膚炎	0	0	0	0	0	0
毛細血管拡張症	0	0	0	0	0	0
中毒性皮疹	0	0	0	0	0	0
乾皮症	0	0	0	0	0	0
皮脂欠乏症	0	0	0	0	0	0
蝶形皮疹	0	0	0	0	0	0
冷汗	0	0	0	0	0	0
剥脱性皮膚炎	0	0	0	0	0	0
皮膚症	0	0	0	0	0	0
湿疹	0	0	0	0	0	0
紅色症	0	0	0	0	0	0
脂肪肥大症	0	0	0	0	0	0
爪床の炎症	0	0	0	0	0	0
神経皮膚炎	0	0	0	0	0	0
皮膚脆弱性	0	0	0	0	0	0
皮膚色素減少	0	0	0	0	0	0
皮膚硬結	0	0	0	0	0	0
尋常性白斑	0	0	0	0	0	0
黄色板腫	0	0	0	0	0	0
黄色皮膚	0	0	0	0	0	0
代謝および栄養障害	60 (18.9)	8 (7.9)	51 (16.1)	2 (3.7)	89 (19.7)	9 (6.4)
食欲減退	5 (1.6)	0	4 (1.3)	0	6 (1.3)	0
高血糖	23 (7.2)	2 (2.0)	14 (4.4)	1 (1.9)	36 (8.0)	2 (1.4)
低カリウム血症	13 (4.1)	2 (2.0)	15 (4.7)	0	20 (4.4)	3 (2.1)

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
低カルシウム血症	10 (3.1)	1 (1.0)	4 (1.3)	0	13 (2.9)	1 (0.7)
低ナトリウム血症	4 (1.3)	0	5 (1.6)	0	6 (1.3)	0
低アルブミン血症	0	0	1 (0.3)	0	0	0
低マグネシウム血症	0	0	0	0	1 (0.2)	0
低リン酸血症	5 (1.6)	3 (3.0)	7 (2.2)	1 (1.9)	8 (1.8)	3 (2.1)
高カリウム血症	0	0	1 (0.3)	0	1 (0.2)	0
脱水	1 (0.3)	0	2 (0.6)	0	3 (0.7)	0
高カルシウム血症	4 (1.3)	0	4 (1.3)	0	6 (1.3)	0
高尿酸血症	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
糖尿病	2 (0.6)	0	0	0	3 (0.7)	0
痛風	0	0	0	0	1 (0.2)	0
低血糖症	0	0	0	0	0	0
ビタミンＤ欠乏	0	0	0	0	0	0
耐糖能障害	0	0	0	0	0	0
高ナトリウム血症	0	0	0	0	0	0
体液貯留	1 (0.3)	0	0	0	1 (0.2)	0
高リン酸塩血症	0	0	0	0	0	0
高トリグリセリド血症	0	0	0	0	0	0
低クロール血症	0	0	0	0	0	0
鉄欠乏	0	0	0	0	0	0
高マグネシウム血症	0	0	0	0	0	0
アシドーシス	0	0	0	0	0	0
食欲障害	0	0	0	0	0	0
悪液質	0	0	0	0	0	0
成長障害	1 (0.3)	0	0	0	1 (0.2)	0
過小食	1 (0.3)	0	0	0	1 (0.2)	0
食欲亢進	0	0	0	0	0	0
栄養障害	0	0	0	0	0	0
代謝性アシドーシス	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
多飲症	0	0	0	0	0	0
腫瘍崩壊症候群	0	0	1 (0.3)	0	1 (0.2)	0
2 型糖尿病	0	0	0	0	0	0
ビタミン B12 欠乏	0	0	0	0	0	0
水分過負荷	0	0	0	0	0	0
ヘモジデリン沈着症	0	0	0	0	0	0
高コレステロール血症	0	0	0	0	0	0
高脂血症	0	0	0	0	0	0
血液量減少症	0	0	0	0	0	0
乳酸アシドーシス	0	0	0	0	0	0
肥満	0	0	1 (0.3)	0	0	0
テタニー	0	0	1 (0.3)	0	0	0
臨床検査	33 (10.4)	2 (2.0)	31 (9.8)	0	51 (11.3)	4 (2.9)
体重減少	2 (0.6)	2 (2.0)	0	0	2 (0.4)	2 (1.4)
血中クレアチニン増加	1 (0.3)	0	0	0	5 (1.1)	0
アラニンアミノトランスフェラーゼ増加	1 (0.3)	0	8 (2.5)	0	4 (0.9)	1 (0.7)
アスパラギン酸アミノトランスフェラーゼ増加	0	0	7 (2.2)	0	1 (0.2)	1 (0.7)
血小板数減少	4 (1.3)	0	1 (0.3)	0	4 (0.9)	1 (0.7)
血中乳酸脱水素酵素増加	0	0	0	0	0	0
腎クレアチニン・クリアランス減少	2 (0.6)	0	0	0	2 (0.4)	0
血中アルカリホスファターゼ増加	1 (0.3)	0	0	0	1 (0.2)	0
ヘモグロビン減少	2 (0.6)	0	4 (1.3)	0	5 (1.1)	0
血中重炭酸塩減少	0	0	0	0	2 (0.4)	0
C一反応性蛋白増加	1 (0.3)	0	3 (0.9)	0	2 (0.4)	0
体重増加	0	0	1 (0.3)	0	0	0
白血球数減少	4 (1.3)	0	1 (0.3)	0	5 (1.1)	0
国際標準比増加	3 (0.9)	0	1 (0.3)	0	6 (1.3)	0
血中カリウム減少	3 (0.9)	0	0	0	3 (0.7)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
γ－グルタミルトランスフェラーゼ増加	2 (0.6)	0	2 (0.6)	0	3 (0.7)	0
好中球数減少	3 (0.9)	0	5 (1.6)	0	3 (0.7)	0
血中ブドウ糖増加	0	0	0	0	1 (0.2)	0
血中マグネシウム減少	0	0	0	0	0	0
血中尿素増加	0	0	0	0	0	0
心雑音	0	0	0	0	0	0
血中カルシウム減少	2 (0.6)	0	0	0	2 (0.4)	0
好中球数増加	0	0	0	0	0	0
糸球体濾過率減少	0	0	0	0	0	0
活性化部分トロンボプラスチン時間延長	0	0	0	0	2 (0.4)	0
血中アルブミン減少	0	0	0	0	0	0
血中リン減少	1 (0.3)	0	0	0	2 (0.4)	0
フィブリンＤダイマー増加	0	0	0	0	0	0
フィブリン分解産物増加	0	0	1 (0.3)	0	0	0
血中クレアチニン	0	0	0	0	0	0
血圧上昇	0	0	0	0	0	0
血中ナトリウム減少	2 (0.6)	0	0	0	2 (0.4)	0
血中尿酸増加	1 (0.3)	0	0	0	1 (0.2)	0
糸球体濾過率	0	0	0	0	0	0
肝機能検査異常	1 (0.3)	0	0	0	1 (0.2)	0
プロトロンビン時間延長	0	0	0	0	0	0
アミラーゼ増加	0	0	0	0	1 (0.2)	0
アスパラギン酸アミノトランスフェラーゼ減少	0	0	0	0	0	0
血中クレアチン増加	0	0	0	0	0	0
血中クレアチンホスホキナーゼ増加	0	0	1 (0.3)	0	0	0
血中クレアチニン減少	0	0	0	0	0	0
血中免疫グロブリンＧ減少	0	0	0	0	0	0
拡張期血圧低下	0	0	0	0	0	0
体温上昇	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
クロストリジウム検査陽性	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
腎クレアチニン・クリアランス	0	0	0	0	0	0
駆出率減少	0	0	0	0	0	0
心電図 QT 延長	0	0	0	0	0	0
グルタミン酸脱水素酵素増加	0	0	0	0	0	0
眼圧上昇	0	0	0	0	0	0
リンパ球数減少	1 (0.3)	0	0	0	1 (0.2)	0
総蛋白減少	0	0	0	0	0	0
総蛋白増加	0	0	0	0	0	0
尿量減少	0	0	0	0	0	0
白血球数増加	0	0	0	0	0	0
アラニンアミノトランスフェラーゼ	0	0	0	0	0	0
血中アルブミン増加	0	0	0	0	0	0
血中アルカリホスファターゼ	0	0	0	0	0	0
血中ビリルビン増加	0	0	0	0	0	0
血中カルシウム増加	0	0	0	0	0	0
血中クロール減少	0	0	0	0	0	0
血中クロール増加	0	0	0	0	0	0
血中フィブリノゲン増加	0	0	0	0	0	0
血中ブドウ糖減少	0	0	0	0	0	0
血中鉄減少	1 (0.3)	0	0	0	1 (0.2)	0
血中カリウム増加	1 (0.3)	0	0	0	1 (0.2)	0
血中テストステロン減少	0	0	0	0	0	0
血中甲状腺刺激ホルモン減少	0	0	0	0	0	0
血中トリグリセリド増加	0	0	0	0	0	0
体温低下	0	0	0	0	0	0
腎クレアチニン・クリアランス異常	0	0	0	0	0	0
サイトメガロウイルス検査陽性	0	0	0	0	0	0
心電図 QRS 群延長	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
心電図異常T波	0	0	0	0	0	0
好酸球数増加	0	0	0	0	0	0
大腸菌検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
線維素溶解	0	0	0	0	0	0
努力呼気量減少	0	0	0	0	0	0
ヘマトクリット減少	0	0	0	0	0	0
ヘモグロビン	0	0	0	0	0	0
心拍数不整	0	0	0	0	0	0
心音異常	0	0	0	0	0	0
肝酵素上昇	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
ヒトライノウイルス検査陽性	0	0	0	0	0	0
免疫グロブリン減少	0	0	0	0	0	0
A型インフルエンザウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0
深吸気量異常	0	0	0	0	0	0
国際標準比	1 (0.3)	0	0	0	1 (0.2)	0
眼圧検査異常	0	0	0	0	0	0
リンパ球形態異常	0	0	0	0	0	0
好中球数	1 (0.3)	0	0	0	1 (0.2)	0
便潜血	0	0	0	0	0	0
酸素飽和度低下	0	0	0	0	0	0
プロカルシトニン増加	0	0	0	0	0	0
前立腺特異性抗原増加	0	0	0	0	0	0
肺の身体的診察結果異常	0	0	0	0	0	0
QRS軸異常	0	0	0	0	0	0
血清フェリチン減少	0	0	0	0	0	0
喀痰培養陽性	0	0	0	0	0	0
トランスアミナーゼ上昇	0	0	0	0	0	0
トロポニン増加	0	0	0	0	0	0
水痘ウイルス検査陽性	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
ウイルス検査陽性	0	0	0	0	0	0
ビタミンB1減少	0	0	0	0	0	0
抗体検査異常	0	0	0	0	0	0
抱合ビリルビン増加	0	0	0	0	0	0
血中コリンエステラーゼ減少	0	0	0	0	0	0
収縮期血圧上昇	0	0	0	0	0	0
血中甲状腺刺激ホルモン増加	0	0	0	0	0	0
脳性ナトリウム利尿ペプチド増加	0	0	1 (0.3)	0	0	0
呼吸音異常	0	0	0	0	0	0
カンピロバクター検査陽性	0	0	0	0	0	0
心電図異常	0	0	0	0	0	0
グリコヘモグロビン増加	0	0	0	0	0	0
心拍数増加	0	0	0	0	0	0
国際標準比異常	0	0	0	0	0	0
臨床検査異常	0	0	1 (0.3)	0	0	0
単球数増加	0	0	0	0	0	0
脳性ナトリウム利尿ペプチド前駆体N端フラグメント増加	0	0	0	0	0	0
QOL低下	0	0	0	0	0	0
頚静脈圧低下	0	0	0	0	0	0
ビタミンD減少	0	0	0	0	0	0
精神障害	17 (5.3)	0	14 (4.4)	0	22 (4.9)	1 (0.7)
不眠症	6 (1.9)	0	8 (2.5)	0	7 (1.6)	1 (0.7)
不安	0	0	1 (0.3)	0	0	0
うつ病	0	0	4 (1.3)	0	1 (0.2)	0
錯乱状態	5 (1.6)	0	2 (0.6)	0	7 (1.6)	0
気分変化	0	0	0	0	0	0
激越	0	0	0	0	0	0
抑うつ気分	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
易刺激性	0	0	0	0	0	0
気分動揺	0	0	0	0	1 (0.2)	0
神経過敏	0	0	0	0	0	0
落ち着きのなさ	0	0	0	0	0	0
睡眠障害	0	0	0	0	0	0
譫妄	1 (0.3)	0	0	0	1 (0.2)	0
異常行動	0	0	0	0	0	0
感情不安定	1 (0.3)	0	0	0	1 (0.2)	0
攻撃性	0	0	1 (0.3)	0	0	0
失見当識	0	0	0	0	0	0
精神状態変化	2 (0.6)	0	0	0	2 (0.4)	0
ストレス	0	0	0	0	0	0
怒り	0	0	0	0	0	0
自殺既遂	0	0	0	0	0	0
情動障害	0	0	0	0	0	0
多幸気分	0	0	0	0	0	0
幻覚	1 (0.3)	0	0	0	1 (0.2)	0
リビド消失	0	0	0	0	0	0
精神障害	0	0	0	0	0	0
外見に対する無関心	0	0	0	0	0	0
妄想症	0	0	0	0	0	0
人格変化	0	0	0	0	0	0
レム睡眠異常	0	0	0	0	0	0
異常な夢	0	0	0	0	0	0
無感情	0	0	0	0	0	0
精神緩慢	0	0	0	0	0	0
感情的苦悩	0	0	0	0	0	0
幻聴	0	0	0	0	0	0
幻視	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
血管障害	28 (8.8)	1 (1.0)	22 (6.9)	1 (1.9)	38 (8.4)	2 (1.4)
低血圧	3 (0.9)	0	2 (0.6)	1 (1.9)	3 (0.7)	0
高血圧	4 (1.3)	0	6 (1.9)	0	6 (1.3)	0
深部静脈血栓症	17 (5.3)	1 (1.0)	7 (2.2)	0	22 (4.9)	1 (0.7)
潮紅	0	0	0	0	0	0
血腫	0	0	0	0	0	0
ほてり	0	0	0	0	0	0
蒼白	0	0	0	0	0	0
表在性血栓性静脈炎	0	0	0	0	0	0
静脈炎	0	0	0	0	1 (0.2)	0
血栓症	1 (0.3)	0	3 (0.9)	0	1 (0.2)	0
表在性静脈炎	0	0	0	0	1 (0.2)	0
四肢静脈血栓症	2 (0.6)	0	0	0	2 (0.4)	0
起立性低血圧	0	0	1 (0.3)	0	0	0
末梢冷感	0	0	0	0	0	0
血栓性静脈炎	0	0	2 (0.6)	0	0	0
静脈瘤	0	0	0	0	0	0
静脈不全	1 (0.3)	0	0	0	1 (0.2)	0
静脈血栓症	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0
進行性高血圧	0	0	0	0	0	1 (0.7)
動脈瘤	0	0	0	0	0	0
大動脈瘤破裂	0	0	0	0	0	0
大動脈狭窄	0	0	0	0	0	0
動脈硬化症	0	0	0	0	0	0
循環虚脱	0	0	0	0	0	0
出血	0	0	0	0	0	0
充血	0	0	0	0	0	0
高血圧クリーゼ	0	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
腹腔内血腫	0	0	0	0	0	0
頚静脈血栓症	0	0	0	0	0	0
リンパ浮腫	0	0	0	0	0	0
リンパ漏	0	0	0	0	0	0
骨盤静脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
末梢動脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
末梢性虚血	1 (0.3)	0	0	0	1 (0.2)	0
静脈穿刺不良	0	0	0	0	0	0
鎖骨下静脈血栓症	1 (0.3)	0	0	0	1 (0.2)	0
収縮期高血圧	0	0	0	0	0	0
血管痛	0	0	0	0	0	0
血管拡張	0	0	0	0	0	0
毛細血管脆弱	0	0	0	0	0	0
塞栓症	0	0	1 (0.3)	0	0	0
末梢動脈狭窄	0	0	0	0	0	0
静脈湖	0	0	0	0	0	0
傷害、中毒および処置合併症	10 (3.1)	0	14 (4.4)	0	12 (2.7)	0
挫傷	1 (0.3)	0	0	0	1 (0.2)	0
転倒	0	0	0	0	0	0
擦過傷	0	0	0	0	0	0
創傷	0	0	0	0	0	0
脊椎圧迫骨折	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
注入に伴う反応	0	0	0	0	0	0
歯牙破折	0	0	0	0	0	0
靭帯捻挫	0	0	0	0	0	0
四肢損傷	0	0	0	0	0	0
処置による疼痛	0	0	0	0	0	0
肋骨骨折	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
肉離れ	0	0	0	0	0	0
上肢骨折	1 (0.3)	0	0	0	2 (0.4)	0
上腕骨骨折	1 (0.3)	0	0	0	2 (0.4)	0
サンバーン	0	0	0	0	0	0
偶発的過量投与	0	0	0	0	0	0
節足動物咬傷	0	0	0	0	0	0
大腿骨骨折	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
頭部損傷	0	0	0	0	0	0
瘢痕ヘルニア	0	0	0	0	0	0
関節脱臼	0	0	0	0	0	0
裂傷	0	0	0	0	0	0
腰椎骨折	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
引っかき傷	0	0	0	0	0	0
皮下血腫	0	0	0	0	0	0
熱傷	0	0	0	0	0	0
外傷性血腫	0	0	0	0	0	0
足関節部骨折	0	0	1 (0.3)	0	0	0
節足動物刺傷	0	0	0	0	0	0
気圧性中耳炎	0	0	0	0	0	0
化学的損傷	0	0	0	0	0	0
鎖骨骨折	0	0	0	0	0	0
上顆炎	0	0	0	0	0	0
顔面損傷	0	0	0	0	0	0
大腿骨頚部骨折	0	0	1 (0.3)	0	0	0
足骨折	0	0	0	0	0	0
体内異物	0	0	0	0	0	0
放射線胃腸炎	0	0	0	0	0	0
熱中症	0	0	0	0	0	0
股関節部骨折	1 (0.3)	0	2 (0.6)	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
腸骨骨折	0	0	0	0	0	0
誤った投与経路	0	0	0	0	0	0
関節損傷	0	0	0	0	0	0
靭帯断裂	0	0	0	0	0	0
口唇損傷	0	0	0	0	0	0
下肢骨折	0	0	0	0	0	0
半月板損傷	0	0	0	0	0	0
口腔内損傷	0	0	0	0	0	0
視神経損傷	0	0	0	0	0	0
過量投与	0	0	0	0	0	0
骨盤骨折	0	0	0	0	0	0
処置後浮腫	0	0	0	0	0	0
処置後腫脹	0	0	0	0	0	0
外傷後頚部症候群	0	0	0	0	0	0
外傷後疼痛	0	0	0	0	0	0
放射線嚥下障害	0	0	0	0	0	0
珪肺症	0	0	0	0	0	0
骨格損傷	0	0	0	0	0	0
脊柱損傷	0	0	0	0	0	0
ストーマ部疼痛	0	0	0	0	0	0
腱損傷	0	0	0	0	0	0
腱断裂	0	0	1 (0.3)	0	0	0
歯の完全脱臼	0	0	0	0	0	0
ワクチン接種合併症	0	0	0	0	0	0
創合併症	0	0	0	0	0	0
術後貧血	0	0	0	0	0	0
圧迫骨折	0	0	1 (0.3)	0	0	0
脳振盪	0	0	0	0	0	0
頭蓋脳損傷	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
外傷性難聴	0	0	0	0	0	0
顔面骨骨折	0	0	0	0	0	0
外傷性血尿	0	0	0	0	0	0
心臓損傷	0	0	0	0	0	0
損傷	0	0	0	0	0	0
筋断裂	0	0	0	0	0	0
爪損傷	0	0	0	0	0	0
膝蓋骨骨折	0	0	0	0	0	0
処置後合併症	0	0	0	0	0	0
処置後出血	0	0	1 (0.3)	0	0	0
放射線性食道炎	0	0	0	0	0	0
橈骨骨折	0	0	0	0	0	0
交通事故	0	0	0	0	0	0
肩甲骨骨折	0	0	0	0	0	0
瘢痕	0	0	0	0	0	0
漿液腫	0	0	0	0	0	0
皮膚損傷	0	0	0	0	0	0
軟部組織損傷	0	0	1 (0.3)	0	0	0
膀胱尿道吻合部狭窄	0	0	1 (0.3)	0	0	0
硬膜下血腫	0	0	0	0	0	0
胸椎骨折	0	0	1 (0.3)	0	0	0
外傷性切断	0	0	0	0	0	0
外傷性骨折	0	0	2 (0.6)	0	0	0
眼障害	22 (6.9)	3 (3.0)	10 (3.2)	1 (1.9)	27 (6.0)	3 (2.1)
白内障	17 (5.3)	3 (3.0)	8 (2.5)	1 (1.9)	21 (4.7)	3 (2.1)
霧視	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
視力低下	0	0	0	0	0	0
眼乾燥	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
眼刺激	0	0	0	0	0	0
眼痛	0	0	0	0	0	0
流涙増加	0	0	0	0	0	0
視力障害	1 (0.3)	0	0	0	2 (0.4)	0
結膜出血	0	0	0	0	0	0
複視	0	0	0	0	0	0
眼充血	0	0	0	0	0	0
眼脂	0	0	0	0	0	0
眼出血	0	0	0	0	0	0
眼そう痒症	0	0	0	0	0	0
緑内障	0	0	0	0	0	0
眼窩周囲浮腫	0	0	0	0	0	0
硝子体浮遊物	0	0	0	0	0	0
眼の異常感	0	0	0	0	0	0
眼瞼炎	0	0	0	0	0	0
結膜充血	0	0	0	0	0	0
結膜炎	0	0	0	0	0	0
眼の障害	0	0	0	0	0	0
眼部腫脹	0	0	0	0	0	0
眼瞼浮腫	0	0	0	0	0	0
羞明	0	0	0	0	0	0
網膜剥離	1 (0.3)	0	0	0	1 (0.2)	0
強膜充血	0	0	0	0	0	0
失明	0	0	0	0	0	0
核性白内障	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
アレルギー性結膜炎	0	0	0	0	0	0
後天性涙道狭窄	0	0	0	0	0	0
眼球浮腫	0	0	0	0	0	0
眼瞼嚢胞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
眼の異物感	0	0	0	0	0	0
角膜炎	0	0	0	0	0	0
涙腺肥大	1 (0.3)	0	0	0	1 (0.2)	0
黄斑浮腫	1 (0.3)	0	0	0	1 (0.2)	0
近視	0	0	0	0	0	0
眼部不快感	0	0	0	0	0	0
光視症	0	0	0	0	0	0
瞳孔不同	0	0	0	0	0	0
網膜変性	0	0	0	0	0	0
網膜裂孔	0	0	0	0	0	0
角膜瘢痕	0	0	0	0	0	0
縮瞳	0	0	0	0	0	0
正常眼圧緑内障	0	0	0	0	0	0
高眼圧症	0	0	0	0	0	0
視神経萎縮	0	0	0	0	0	0
潰瘍性角膜炎	0	0	0	0	0	0
腎および尿路障害	10 (3.1)	1 (1.0)	12 (3.8)	1 (1.9)	15 (3.3)	2 (1.4)
排尿困難	0	0	0	0	0	0
腎不全	4 (1.3)	1 (1.0)	5 (1.6)	1 (1.9)	6 (1.3)	1 (0.7)
血尿	0	0	0	0	0	0
頻尿	0	0	0	0	0	0
急性腎不全	4 (1.3)	0	5 (1.6)	0	5 (1.1)	1 (0.7)
尿閉	1 (0.3)	0	0	0	1 (0.2)	0
腎機能障害	0	0	0	0	0	0
尿失禁	0	0	1 (0.3)	0	0	0
夜間頻尿	0	0	0	0	0	0
蛋白尿	0	0	0	0	0	0
腎嚢胞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
糖尿	0	0	0	0	0	0
多尿	0	0	0	0	0	0
腎仙痛	0	0	0	0	1 (0.2)	0
高窒素血症	0	0	0	0	0	0
膀胱痙縮	0	0	0	0	0	0
着色尿	0	0	0	0	0	0
糸球体腎炎	0	0	0	0	1 (0.2)	0
ヘモグロビン尿	0	0	0	0	0	0
尿路出血	1 (0.3)	0	0	0	1 (0.2)	0
水腎症	0	0	0	0	0	0
高カルシウム尿症	0	0	0	0	0	0
失禁	0	0	0	0	0	0
下部尿路症状	0	0	0	0	0	0
排尿異常	0	0	0	0	0	0
尿意切迫	0	0	0	0	0	0
腎結石症	0	0	0	0	0	0
神経因性膀胱	1 (0.3)	0	0	0	1 (0.2)	0
閉塞性尿路疾患	0	0	0	0	0	0
腎前性腎不全	0	0	0	0	0	0
腎盂腎杯拡張症	0	0	0	0	0	0
腎尿細管性アシドーシス	0	0	0	0	0	0
尿道分泌物	0	0	0	0	0	0
排尿躊躇	0	0	0	0	0	0
尿生殖器障害	0	0	0	0	0	0
膀胱脱	0	0	0	0	0	0
白血球尿	0	0	0	0	0	0
乏尿	0	0	1 (0.3)	0	0	0
慢性腎不全	0	0	0	0	0	0
腎臓痛	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
尿路閉塞	0	0	0	0	0	0
心臓障害	12 (3.8)	1 (1.0)	17 (5.4)	2 (3.7)	16 (3.5)	1 (0.7)
動悸	0	0	0	0	0	0
心房細動	4 (1.3)	0	7 (2.2)	0	6 (1.3)	0
頻脈	0	0	1 (0.3)	0	1 (0.2)	0
期外収縮	0	0	0	0	0	0
洞性徐脈	0	0	0	0	0	0
狭心症	0	0	2 (0.6)	0	0	0
不整脈	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
徐脈	0	0	0	0	1 (0.2)	0
洞性頻脈	0	0	0	0	0	0
心房粗動	0	0	0	0	1 (0.2)	0
うっ血性心不全	2 (0.6)	0	1 (0.3)	1 (1.9)	2 (0.4)	0
心筋虚血	0	1 (1.0)	1 (0.3)	0	0	1 (0.7)
第一度房室ブロック	0	0	0	0	0	0
心不全	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
心拡大	0	0	0	0	0	0
上室性期外収縮	0	0	0	0	0	0
心室性期外収縮	0	0	0	0	0	0
急性冠動脈症候群	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
上室性不整脈	0	0	1 (0.3)	0	0	0
完全房室ブロック	1 (0.3)	0	0	0	1 (0.2)	0
右脚ブロック	0	0	0	0	0	0
心停止	1 (0.3)	0	0	0	1 (0.2)	0
心肺停止	0	0	0	0	0	0
心筋症	0	0	0	0	0	0
心血管障害	0	0	0	0	0	0
冠動脈閉塞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	CA204-004 E-Ld > 24 N = 101	CA204-004 Ld <= 24 N = 317	CA204-004 Ld > 24 N = 54	Pooled E-Ld <= 24 N = 451	Pooled E-Ld > 24 N = 140
心房拡張	0	0	0	0	0	0
左室機能不全	0	0	0	0	0	0
左室肥大	0	0	0	0	0	0
僧帽弁閉鎖不全症	0	0	0	0	0	0
上室性頻脈	1 (0.3)	0	0	0	1 (0.2)	0
頻脈性不整脈	0	0	0	0	0	0
心室不全	1 (0.3)	0	0	0	1 (0.2)	0
急性心筋梗塞	0	0	2 (0.6)	0	0	0
心房頻脈	0	0	0	0	0	0
心臓瘤	0	0	0	0	0	0
左室不全	0	0	1 (0.3)	0	0	0
心筋梗塞	0	0	2 (0.6)	0	0	0
結節性不整脈	0	0	1 (0.3)	0	0	0
心膜炎	0	0	1 (0.3)	0	0	0
洞不全症候群	0	0	0	1 (1.9)	0	0
心室性不整脈	0	0	1 (0.3)	0	0	0
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	21 (6.6)	3 (3.0)	15 (4.7)	0	25 (5.5)	6 (4.3)
基底細胞癌	4 (1.3)	1 (1.0)	3 (0.9)	0	5 (1.1)	1 (0.7)
皮膚有棘細胞癌	4 (1.3)	0	1 (0.3)	0	4 (0.9)	0
悪性新生物進行	2 (0.6)	0	0	0	2 (0.4)	0
形質細胞性骨髄腫	3 (0.9)	0	1 (0.3)	0	3 (0.7)	0
脂肪腫	0	0	0	0	0	0
骨髄異形成症候群	1 (0.3)	1 (1.0)	3 (0.9)	0	2 (0.4)	2 (1.4)
形質細胞腫	2 (0.6)	0	1 (0.3)	0	2 (0.4)	0
皮膚乳頭腫	0	0	0	0	0	0
扁平上皮癌	1 (0.3)	0	0	0	2 (0.4)	1 (0.7)
膀胱移行上皮癌	1 (0.3)	0	0	0	2 (0.4)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
肺の悪性新生物	1 (0.3)	0	0	0	1 (0.2)	0
結腸腺癌	1 (0.3)	0	1 (0.3)	0	1 (0.2)	0
乳癌	1 (0.3)	0	0	0	1 (0.2)	0
乳腺線維腫	0	0	0	0	0	0
慢性リンパ性白血病	1 (0.3)	0	0	0	1 (0.2)	0
赤白血病	0	1 (1.0)	0	0	0	1 (0.7)
消化器新生物	0	0	0	0	0	0
乳房脂肪腫	0	0	0	0	0	0
乳腺上皮内小葉癌	0	0	0	0	0	1 (0.7)
悪性黒色腫	0	0	0	0	0	1 (0.7)
悪性胸水	0	0	0	0	0	0
髄膜腫	1 (0.3)	0	0	0	1 (0.2)	0
中皮腫	1 (0.3)	0	0	0	1 (0.2)	0
乳頭腫	0	0	0	0	0	0
前立腺癌	0	0	1 (0.3)	0	1 (0.2)	0
前立腺腺腫	0	0	0	0	0	0
脂漏性角化症	0	0	0	0	0	0
皮膚癌	0	0	0	0	0	0
甲状腺新生物	0	0	0	0	0	0
子宮平滑筋腫	0	0	0	0	0	0
子宮内膜癌	0	0	1 (0.3)	0	0	0
血管腫	0	0	0	0	0	0
骨血管腫	0	0	1 (0.3)	0	0	0
遠隔転移を伴う肺癌	0	0	1 (0.3)	0	0	0
表皮内悪性黒色腫	0	0	0	0	0	0
原発巣不明の悪性新生物	0	0	0	0	0	0
扁桃癌	0	0	1 (0.3)	0	0	0
腫瘍熱	0	0	1 (0.3)	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
耳および迷路障害	5 (1.6)	0	1 (0.3)	0	5 (1.1)	0
回転性めまい	3 (0.9)	0	0	0	3 (0.7)	0
耳痛	0	0	0	0	0	0
聴力低下	0	0	0	0	0	0
耳鳴	0	0	0	0	0	0
難聴	0	0	0	0	0	0
耳不快感	0	0	0	0	0	0
両耳難聴	1 (0.3)	0	0	0	1 (0.2)	0
耳垢栓塞	0	0	0	0	0	0
片耳難聴	0	0	0	0	0	0
聴覚障害	1 (0.3)	0	0	0	1 (0.2)	0
中耳の炎症	0	0	0	0	0	0
耳漏	0	0	0	0	0	0
耳の障害	0	0	0	0	0	0
耳そう痒症	0	0	0	0	0	0
老人性難聴	0	0	0	0	0	0
頭位性回転性めまい	0	0	1 (0.3)	0	0	0
肝胆道系障害	8 (2.5)	1 (1.0)	0	0	9 (2.0)	1 (0.7)
高ビリルビン血症	2 (0.6)	0	0	0	2 (0.4)	0
胆嚢炎	1 (0.3)	1 (1.0)	0	0	2 (0.4)	1 (0.7)
胆石症	1 (0.3)	0	0	0	1 (0.2)	0
肝機能異常	0	0	0	0	0	0
肝炎	1 (0.3)	0	0	0	1 (0.2)	0
肝腫大	0	0	0	0	0	0
胆管炎	1 (0.3)	0	0	0	1 (0.2)	0
急性胆嚢炎	0	0	0	0	0	0
慢性胆嚢炎	1 (0.3)	0	0	0	1 (0.2)	0
胆汁うっ滞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
薬物性肝障害	0	0	0	0	0	0
肝不全	1 (0.3)	0	0	0	1 (0.2)	0
肝細胞損傷	1 (0.3)	0	0	0	1 (0.2)	0
肝毒性	1 (0.3)	0	0	0	1 (0.2)	0
肝障害	0	0	0	0	0	0
肝損傷	1 (0.3)	0	0	0	1 (0.2)	0
アルコール性肝疾患	0	0	0	0	0	0
生殖系および乳房障害	0	0	2 (0.6)	0	2 (0.4)	0
良性前立腺肥大症	0	0	1 (0.3)	0	1 (0.2)	0
骨盤痛	0	0	1 (0.3)	0	1 (0.2)	0
乳房痛	0	0	0	0	0	0
勃起不全	0	0	0	0	0	0
生殖器病変	0	0	0	0	0	0
前立腺炎	0	0	0	0	0	0
外陰腟不快感	0	0	0	0	0	0
外陰腟そう痒症	0	0	0	0	0	0
乳房石灰化	0	0	0	0	0	0
乳房腫瘤	0	0	0	0	0	0
乳房圧痛	0	0	0	0	0	0
性器びらん	0	0	0	0	0	0
女性化乳房	0	0	0	0	0	0
陰部そう痒症	0	0	0	0	0	0
精巣痛	0	0	0	0	0	0
腟びらん	0	0	0	0	0	0
腟出血	0	0	0	0	0	0
腟の炎症	0	0	0	0	0	0
膀胱瘤	0	0	0	0	0	0
卵巣嚢胞	0	0	0	0	0	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
陰茎浮腫	0	0	0	0	0	0
陰嚢血瘤	0	0	0	0	0	0
陰嚢浮腫	0	0	0	0	0	0
子宮痛	0	0	0	0	0	0
腟分泌物	0	0	0	0	0	0
外陰腟痛	0	0	0	0	0	0
内分泌障害	2 (0.6)	0	0	0	4 (0.9)	0
クッシング様症状	1 (0.3)	0	0	0	1 (0.2)	0
甲状腺機能低下症	0	0	0	0	1 (0.2)	0
副腎機能不全	1 (0.3)	0	0	0	1 (0.2)	0
副甲状腺機能亢進症	0	0	0	0	0	0
甲状腺機能亢進症	0	0	0	0	1 (0.2)	0
自己免疫性甲状腺炎	0	0	0	0	0	0
クッシング症候群	0	0	0	0	0	0
続発性副甲状腺機能亢進症	0	0	0	0	0	0
ステロイド離脱症候群	0	0	0	0	0	0
免疫系障害	1 (0.3)	0	1 (0.3)	0	2 (0.4)	0
過敏症	0	0	1 (0.3)	0	0	0
季節性アレルギー	0	0	0	0	0	0
薬物過敏症	0	0	0	0	0	0
アナフィラキシー反応	0	0	0	0	1 (0.2)	0
節足動物咬傷アレルギー	0	0	0	0	0	0
免疫グロブリン療法アレルギー	0	0	0	0	0	0
自己免疫障害	1 (0.3)	0	0	0	1 (0.2)	0
低γグロブリン血症	0	0	0	0	0	0
外科および内科処置	2 (0.6)	0	0	0	2 (0.4)	0
歯根端切除	1 (0.3)	0	0	0	1 (0.2)	0

SYSTEM ORGAN CLASS (%) PREFERRED TERM (%)	CA204-004 E-Ld <= 24 N = 318	 > 24 N = 101	CA204-004 Ld <= 24 N = 317	 > 24 N = 54	Pooled E-Ld <= 24 N = 451	 > 24 N = 140
中心静脈カテーテル留置	0	0	0	0	0	0
病変部切除	0	0	0	0	0	0
皮膚新生物切除	1 (0.3)	0	0	0	1 (0.2)	0
縫合	0	0	0	0	0	0
腱手術	0	0	0	0	0	0
抜歯	0	0	0	0	0	0
四肢手術	0	0	0	0	0	0
先天性、家族性および遺伝性障害	0	0	1 (0.3)	0	0	0
包茎	0	0	0	0	0	0
心房中隔欠損症	0	0	1 (0.3)	0	0	0
歯原性嚢胞	0	0	0	0	0	0
腓骨部筋萎縮症	0	0	0	0	0	0
社会環境	0	0	0	0	0	0
日常生活動作障害者	0	0	0	0	0	0
歩行障害者	0	0	0	0	0	0

Includes AE and SAE with onset on or after the first dosing date and on or prior to the last dosing date +60 days.
AE onset occurring on or within 24 months after the first dose of any study drug will be summarized in the <=24 months column.
AE onset occurring after 24 months of the first dose of any study drug will be summarized in the > 24 months column.
A subject who reported multiple events mapped to the same SOC/preferred term is counted once within the time category (<= 24, or >24 months).
All treated subjects are included in the <= 24 months category. Only treated subjects who are followed for AE beyond 24 months are included in the > 24 months category.
Sorting is done by decreasing order based on the 'any grade' column of the pooled E-Ld arm.
Pooled E-Ld: HuLuc63-1703, CA204-004 (E-Ld), CA204-005, and CA204-007.
MedDRA 17.0
CTC Version 3.0
Program Source: /projects/bms211263/stats/primary/prog/tables/rt-ae-longterm.sas 13FEB2015:00:56:14

APPENDIX 60　　死亡例の一覧（010 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
TdE/TdEC	1000-00005	WHITE	10 mg/kg	FEMALE	4[redacted]	貧血	8	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						出血性素因	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	8	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	8	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	38.8H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	17		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	17		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症性ショック	17	4D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						血小板減少症	17	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
TdE/TdEC	1001-00029	WHITE	10 mg/kg	FEMALE	5[redacted]	血中クレアチニン増加	-1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	4	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	14	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	21	0S	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						急性腎不全	21	49D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						傾眠	21		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	23	3D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	26	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	26	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1001-00030	WHITE	10 mg/kg	MALE	6[redacted]	不安	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						咳嗽	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	30		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺臓炎	38	7D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						貧血	39	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	44		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪性新生物進行	55	16D	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
TdE/TdEC	1002-00007	WHITE	10 mg/kg	MALE	6[redacted]	高血圧	1	34.1H	MULTIPLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						錯乱状態	2	48.0H	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	3	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	15	13.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嚥下障害	30	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	38	12.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	45	6.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	52		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	59		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	59	12.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心臓死	64	5M	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1004-00034	WHITE	10 mg/kg	MALE	7[redacted]	注入に伴う反応	1	2.2H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔感染	15	27D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	22	21D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						気管支吸引	42	24.0H	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
TdE/TdEC	1004-00036	WHITE	10 mg/kg	MALE	5[redacted]	貧血	5	269D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	29	245D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低ナトリウム血症	29	245D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	57	217D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						傾眠	71	203D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下障害	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	152	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	155	119D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	169	104D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	169	104D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	197	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	225	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	225	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊柱損傷	225	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	253	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心肺停止	273	24.0H	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1005-00023	WHITE	10 mg/kg	MALE	7[redacted]	突然死	3	23M	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
TdE/TdEC	1005-00032	WHITE	10 mg/kg	MALE	5[redacted]	帯状疱疹	-13	13D	MULTIPLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-13	67D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	19		RELATED	GRADE 4	AE	DRUG INTERRUPTED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻出血	22	7D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口腔内痛	24	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						医療機器関連感染	25		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支肺アスペルギルス症	29		MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						錯乱状態	53	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						敗血症性ショック	53	2D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1008-00011	WHITE	10 mg/kg	FEMALE	6[redacted]	疼痛	1	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	2		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						洞性頻脈	2	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺水腫	3	3D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						発熱	5	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1008-00049	WHITE	10 mg/kg	MALE	6[redacted]	疲労	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	9	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	22	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊椎骨折	56	10D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						骨折	61	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	92		RELATED	GRADE 2	AE	DOSE REDUCED	
						脊椎痛	94		MULTIPLE	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						疾患進行	116	4.7H	MULTIPLE	GRADE 5	SAE	DRUG INTERRUPTED	FATAL
NOT TREATED	1002-00018	WHITE		FEMALE	[redacted]	全身健康状態低下		35D	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL

APPENDIX 61　　重篤な有害事象を発現した被験者の一覧（010 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
TdE/TdEC	1000-00005	WHITE	10 mg/kg	FEMALE	4[redacted]	貧血	8	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						出血性素因	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	8	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	8	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	15	38.8H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	17		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						好中球減少症	17		NOT RELATED	GRADE 4	AE	DOSE NOT CHANGED	
						敗血症性ショック	17	4D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						血小板減少症	17	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
TdE/TdEC	1000-00015	WHITE	10 mg/kg	FEMALE	6[redacted]	骨痛	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						期外収縮	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	15	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	22	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						発熱	22	15D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						貧血	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血小板減少症	36	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	42		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						捻髪音	42	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋肉痛	43		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						無力症	51		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	51		RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	51	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	51		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	51		NOT RELATED	GRADE 3	AE	DOSE REDUCED	
						気道感染	60	11D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
TdE/TdEC	1000-00045	WHITE	10 mg/kg	MALE	5[redacted]	骨痛	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						捻髪音	84	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						臨床検査異常	84	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						湿性咳嗽	84	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不安	112		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	126		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鉄欠乏	145		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	168		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	205	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	205	20D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						深部静脈血栓症	234		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	360		MULTIPLE	GRADE 2	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
TdE/TdEC	1000-00046	WHITE	10 mg/kg	FEMALE	7[redacted]	骨痛	6		RELATED	GRADE 1	AE	DOSE REDUCED	
						貧血	13		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						傾眠	16	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪心	20		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	20	34D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						腎不全	20	34D	MULTIPLE	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
TdE/TdEC	1001-00029	WHITE	10 mg/kg	FEMALE	5[redacted]	血中クレアチニン増加	-1		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	4	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						貧血	14	6D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						貧血	21	0S	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						急性腎不全	21	49D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						傾眠	21		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	23	3D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						貧血	26	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血小板減少症	26	10D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						貧血	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1001-00030	WHITE	10 mg/kg	MALE	6[redacted]	不安	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	30		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	30		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺臓炎	38	7D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						貧血	39	10D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	44		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪性新生物進行	55	16D	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
TdE/TdEC	1001-00044	WHITE	10 mg/kg	MALE	8[redacted]	低血圧	8	7D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						平衡障害	15	169D	RELATED	GRADE 1	AE	DOSE REDUCED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						浮動性めまい	15	168D	RELATED	GRADE 1	AE	DOSE REDUCED	
						便秘	28	22D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	49	77D	RELATED	GRADE 1	AE	DOSE REDUCED	
						末梢性浮腫	70	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	84	14D	RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性ニューロパチー	126	14D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	140	71D	RELATED	GRADE 1	AE	DOSE INCREASED	
						貧血	155	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	210	36D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	239	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						貧血	245	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						気道感染	265	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺炎	278	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						ラ音	287		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						肺臓炎	321	9D	MULTIPLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
TdE/TdEC	1002-00007	WHITE	10 mg/kg	MALE	6[redacted]	高血圧	1	34.1H	MULTIPLE	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						錯乱状態	2	48.0H	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	3	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	15	13.0H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						嚥下障害	30	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	38	12.2H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	45	6.1H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	52		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						呼吸困難	59		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血圧	59	12.5H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心臓死	64	5M	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1002-00050	WHITE	10 mg/kg	FEMALE	[redacted]	不安	8	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	8	8.7H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	8	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						口内乾燥	36	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						気道感染	37	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	45	12D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						腹痛	71	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球数減少	96	58D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道分泌増加	113	72D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アレルギー性皮膚炎	157	13D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	157	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスペルギルス感染	185	2D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						アスペルギルス感染	187	14D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						便秘	187	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						静脈炎	193	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中カリウム減少	197	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アスペルギルス感染	202		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						帯状疱疹	209	31D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	213	13D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						肝機能検査異常	239		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	284		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
TdE/TdEC	1004-00028	WHITE	10 mg/kg	MALE	6[redacted]	発熱	25	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	31	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	85	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	99		RELATED	GRADE 2	AE	DOSE REDUCED	
						末梢性浮腫	113		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						血栓症	113	14D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腫瘍フレア	113		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						大腿骨骨折	144	58D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
TdE/TdEC	1004-00034	WHITE	10 mg/kg	MALE	7[redacted]	注入に伴う反応	1	2.2H	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						口腔感染	15	27D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	22	21D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						気管支吸引	42	24.0H	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
TdE/TdEC	1004-00036	WHITE	10 mg/kg	MALE	5[redacted]	貧血	5	269D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻咽頭炎	8	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低カルシウム血症	29	245D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						低ナトリウム血症	29	245D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						無力症	57	217D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						傾眠	71	203D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						嚥下障害	127	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						嘔吐	152	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	155	119D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	169	104D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	169	104D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	197	76D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胃腸炎	225	48D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						好中球減少症	225	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊柱損傷	225	48D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	253	21D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心肺停止	273	24.0H	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1004-00037	WHITE	10 mg/kg	MALE	6[redacted]	無力症	-1		NOT APPLICABLE	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	-1		NOT APPLICABLE	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	7		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	7		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						形質細胞腫	28		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						肺感染	48	21D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						骨溶解	182		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
TdE/TdEC	1005-00023	WHITE	10 mg/kg	MALE	7[redacted]	突然死	3	23M	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
TdE/TdEC	1005-00025	WHITE	10 mg/kg	MALE	6[redacted]	高血圧	2		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						ウイルス性消化管感染	22	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						ウイルス性上気道感染	22	3D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						咳嗽	24	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						鼻漏	24	7D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						腹痛	48	43.3H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						錯乱状態	48	25D	MULTIPLE	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						帯状疱疹	48	18D	MULTIPLE	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						膵炎	48	18D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						急性膵炎	48	5D	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						錯乱状態	49	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高ナトリウム血症	49	10D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						骨痛	79		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1005-00026	WHITE	10 mg/kg	MALE	6[redacted]	不安	28		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	44		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	155	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺塞栓症	180		MULTIPLE	GRADE 2	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						上気道感染	310		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
TdE/TdEC	1005-00027	WHITE	10 mg/kg	FEMALE	6[redacted]	咳嗽	14	12D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						神経毒性	43		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	78		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						悪性新生物進行	88	21D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
TdE/TdEC	1005-00032	WHITE	10 mg/kg	MALE	5[redacted]	帯状疱疹	-13	13D	MULTIPLE	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腎不全	-13	67D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						血小板減少症	19		RELATED	GRADE 4	AE	DRUG INTERRUPTED	
						鼻出血	22	7D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						口腔内痛	24	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						医療機器関連感染	25		NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						気管支肺アスペルギルス症	29		MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	NOT RECOVERED/ NOT RESOLVED
						錯乱状態	53	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						敗血症性ショック	53	2D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
TdE/TdEC	1008-00011	WHITE	10 mg/kg	FEMALE	6[redacted]	疼痛	1	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						背部痛	2		NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						ヘモグロビン減少	2		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発熱	2	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						洞性頻脈	2	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						肺水腫	3	3D	MULTIPLE	GRADE 5	SAE	DRUG WITHDRAWN	FATAL
						発熱	5	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1008-00012	WHITE	10 mg/kg	FEMALE	7[redacted]	末梢性浮腫	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鉄欠乏	50		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						脱毛症	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						発熱	98	8D	NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						気道感染	98	15D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						振戦	141		RELATED	GRADE 2	AE	DOSE REDUCED	
						錯感覚	197		RELATED	GRADE 3	AE	DOSE REDUCED	
						肺炎	203	9D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						疲労	225	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						鉄欠乏	225	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						関節痛	253		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	253	28D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	253	56D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
TdE/TdEC	1008-00038	WHITE	10 mg/kg	FEMALE	6[redacted]	発熱	23	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺臓炎	355	9D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
TdE/TdEC	1008-00049	WHITE	10 mg/kg	MALE	6[redacted]	疲労	1		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						失神	9	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						高血糖	22	24.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						背部痛	29		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						脊椎骨折	56	10D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						骨折	61	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性ニューロパチー	92		RELATED	GRADE 2	AE	DOSE REDUCED	
						脊椎痛	94		MULTIPLE	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						疾患進行	116	4.7H	MULTIPLE	GRADE 5	SAE	DRUG INTERRUPTED	FATAL

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
TdE/TdEC	1010-00020	WHITE	10 mg/kg	MALE	6[redacted]	振戦	1	15M	RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						肋骨骨折	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	21	22D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						気道感染	91	3D	MULTIPLE	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						末梢性ニューロパチー	104	86D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						胸痛	111	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						便失禁	132	86D	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						無力症	148	28D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						無力症	176	14D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	190		RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性ニューロパチー	190	28D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						蜂巣炎	204	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						蜂巣炎	207	7D	MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						末梢性ニューロパチー	218		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧性心疾患	224		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						皮下組織膿瘍	316	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
TdE/TdEC	1010-00039	WHITE	10 mg/kg	MALE	5[redacted]	気道感染	28	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	57	7D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						有害事象	72	49D	RELATED	GRADE 2	AE	DOSE REDUCED	
						高血糖	78	15D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						無力症	93		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						高血糖	93	71D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心筋炎	93	28D	MULTIPLE	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
						有害事象	121		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	164	42D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	206		RELATED	GRADE 1	AE	DRUG INTERRUPTED	
NOT TREATED	1002-00018	WHITE		FEMALE	6[redacted]	全身健康状態低下		35D	MULTIPLE	GRADE 5	SAE	DOSE NOT CHANGED	FATAL
NOT TREATED	1005-00043	WHITE		FEMALE	6[redacted]	脳浮腫			MULTIPLE	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED

APPENDIX 62　　死亡例の一覧（1701 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	AE Preferred Term	AE Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
5.0 mg/kg	1507	White	5.0 mg/kg	Female	[redacted]	悪寒	1	1 D	RELATED	GRADE 2	AE	Meds reqd	
						発熱	1	2 D	NOT RELATED	GRADE 1	SAE	New/Prolong Hosp	Resolved or returned to baseline
						頻脈	1	2 D	NOT RELATED	GRADE 1	SAE	New/Prolong Hosp	Resolved or returned to baseline
						貧血	8	28 D	NOT RELATED	GRADE 3	SAE	New/Prolong Hosp	Resolved or returned to baseline
						末梢性浮腫	16	CONT.	NOT RELATED	GRADE 2	AE	None	
						食欲不振	31	CONT.	NOT RELATED	GRADE 2	AE	None	
						疲労	31	CONT.	NOT RELATED	GRADE 3	AE	None	
						滑液嚢腫	31	CONT.	NOT RELATED	GRADE 2	AE	None	
						腎不全	36	27 D	NOT RELATED	GRADE 4	SAE	None	Death
						敗血症	36	CONT.	NOT RELATED	GRADE 4	SAE	None	AE Continuing
						尿路感染	36	CONT.	NOT RELATED	GRADE 4	SAE	New/Prolong Hosp	AE Continuing

APPENDIX 63　　重篤な有害事象を発現した被験者の一覧（1701 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
P1 ELOTUZUMAB 2.5 MG/KG	0016-01601	WHITE	2.5 mg/kg	FEMALE	6[redacted]	悪寒	1	12.8H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	1	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	1	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						感覚鈍麻	3		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腫瘤	3		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不安	4		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔うっ血	22	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	29	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	37	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						排尿困難	66	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	119	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	119	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	122		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	122	35D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	122		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	122	9D	NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	122		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						うつ病	136		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上腹部痛	148	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						下痢	148	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋肉痛	151	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	165		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	176	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	184		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	191	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	191	38D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻咽頭炎	194	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻咽頭炎	218	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						湿性咳嗽	232	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 5 MG/KG	0016-01602	WHITE	5 mg/kg	FEMALE	5[redacted]	疲労	5	50D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						うつ病	12		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	12		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	12		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	22	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	26	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中マグネシウム減少	29	57D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顔面浮腫	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						脱水	54	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE DELAYED
						疲労	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋力低下	54		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	54		RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE DELAYED
						敗血症	56	13D	RELATED	GRADE 3	SAE	E:DOSE DELAYED, DRUG WITHDRAWN B:DOSE DELAYED, DRUG WITHDRAWN D:DOSE DELAYED, DRUG WITHDRAWN
						嘔吐	69		NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中マグネシウム減少	85		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0011-01101	WHITE	20 mg/kg	MALE	7[redacted]	肺炎	-12	8D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性心筋梗塞	1	3D	NOT RELATED	GRADE 3	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						胸痛	1		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血管穿刺部位血腫	10		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性心筋梗塞	23	5D	NOT RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0013-01307	BLACK OR AFRICAN AMERICAN	20 mg/kg	MALE	6[redacted]	尺骨骨折	42		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						単純ヘルペス	45	29D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性感覚ニューロパチー	63	8D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	67	22D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						過小食	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						多飲症	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						多尿	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						関節硬直	70		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	70	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中ビリルビン増加	77	7D	NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	77		RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	81	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高カルシウム血症	81	8D	NOT RELATED	GRADE 4	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	81	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						急性腎不全	81	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腎尿細管性アシドーシス	81	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	83		NOT RELATED	GRADE 2	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	83	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0014-01403	WHITE	20 mg/kg	FEMALE	6[redacted]	頭痛	1	30M	RELATED	GRADE 2	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						喘鳴	1	22D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋攣縮	21	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	22	23D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気管支炎	22	23D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	22	23D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口内炎	22	23D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	29		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						呼吸困難	32	4M	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	32	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	44		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頚部痛	44		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	53	3D	NOT RELATED	GRADE 2	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						靱帯捻挫	53		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						靱帯捻挫	53		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0015-01506	WHITE	20 mg/kg	MALE	4[redacted]	冷汗	4	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	4		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	4	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	4		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	4		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	5	3D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	11	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カルシウム血症	11	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						神経痛	11	54D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	20	34D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	20		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	20	48.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻漏	20	13D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						γ－グルタミルトランスフェラーゼ増加	22	21D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	22	21D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	22	21D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	30	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						そう痒性皮疹	42	12D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	43		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胸痛	53	48.0H	RELATED	GRADE 3	SAE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						呼吸困難	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顔面浮腫	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カルシウム血症	53	18D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						局所腫脹	53	48.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	53	18D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	54	16D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	54	24.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中重炭酸塩減少	64	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						紅斑	64	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						局所腫脹	64	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪寒	66	4D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胃腸炎	66	4D	RELATED	GRADE 3	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						蕁麻疹	66		RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						不眠症	81		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0015-01509	BLACK OR AFRICAN AMERICAN	20 mg/kg	FEMALE	[redacted]	神経痛	-13	77D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	6	24D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	11	74D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	11	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	15	98D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高コレステロール血症	15		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	22	52D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	22	10D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	32	32D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	32	42D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	32	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						便秘	50	4D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球形態異常	53	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						カテーテル留置部位疼痛	56	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						カテーテル留置部位紅斑	64	21D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	74	14D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	84	24.3H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	85	32D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						高血糖	85	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	88	5D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	95	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	95	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	95	21D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	95	11D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中乳酸脱水素酵素増加	106	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	106	10D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	106	21D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	106	162D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						骨痛	109	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	113	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						高血糖	116	15D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中トロンボプラスチン増加	127	151D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	127	141D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	127	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	134	134D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性ニューロパチー	134	3D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						好中球減少症	134	4D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DRUG INTERRUPTED D:DOSE NOT CHANGED
						副鼻腔うっ血	134	15D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						末梢性ニューロパチー	136		RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋骨格系胸痛	144	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	148	51D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	155	24.0H	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	169	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	176	36D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	176	24D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	190	120D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	199	13D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						アフタ性口内炎	232		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中クレアチニン増加	235	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血中アルブミン減少	253	15D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	253	7D	NOT RELATED	GRADE 3	SAE	E:DOSE DELAYED B:DOSE DELAYED D:DOSE NOT CHANGED
						血中リン増加	267	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	274	36D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	277	33D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肉離れ	277	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	288	21D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	288	11D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	298	46D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						好中球減少症	298	12D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	309	8D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	309	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	316	87D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔炎	316	14D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	343	9D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	351	52D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低ナトリウム血症	351	52D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	351	32D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	351	32D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						顎骨壊死	351		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	382	12D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球減少症	382	12D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	382	18D	RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	387	11D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球減少症	399	4D	RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0018-01803	WHITE	20 mg/kg	MALE	4[redacted]	体重減少	1		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	5		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	5	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発疹	7	16D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						呼吸困難	11		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	43	4D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						流涙増加	46		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	53	40D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						胃食道逆流性疾患	63		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球減少症	71	32D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	85		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	120		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	126	12D	NOT RELATED	GRADE 2	SAE	E:DOSE DELAYED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発疹	144	33D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	193	29D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						霧視	197		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	212	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼡径部痛	220	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	240	52D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	296	28D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	323		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	358	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低血圧	365	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	401		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						上気道感染	403	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	407	32D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	431	20D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						インフルエンザ	431	5D	NOT RELATED	GRADE 3	SAE	E:DOSE DELAYED B:DOSE DELAYED D:DOSE NOT CHANGED
						低カリウム血症	442	4D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	449		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	545	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口唇潰瘍	577	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	631	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	633	6D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE DELAYED D:DOSE NOT CHANGED
						結膜炎	634	12D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	634	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						脱水	662	8D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気管支炎	749	5D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						上気道感染	771	13D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						肺炎	783	10D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						背部痛	813		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0019-01901	WHITE	20 mg/kg	MALE	6[redacted]	貧血	-10	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						貧血	1	28D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪寒	1	11.1H	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						呼吸困難	1	11.1H	NOT RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	1	11.1H	RELATED	GRADE 1	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	1	4.1H	NOT RELATED	GRADE 2	AE	E:DRUG INTERRUPTED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻呼吸	1	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口唇水疱	2	26D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	2	48.0H	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	6	31D	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	8	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	8	5D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	8	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						無力症	9	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	9	28D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						労作性呼吸困難	9	11D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						非心臓性胸痛	9	5D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻呼吸	10	24.0H	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	11	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						イレウス	11	3D	RELATED	GRADE 1	SAE	E:DOSE DELAYED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	11	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	29	12D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	36	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						疲労	36	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	36	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	36	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	37	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻出血	38	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	40	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						好中球数減少	40	9D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頻脈	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	40	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						咳嗽	45	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻閉	45	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	48	14D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	54	6D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹痛	57	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	57		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						放屁	58	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	58	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	58	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						霧視	59		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	61	9D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						末梢性感覚ニューロパチー	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	69	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						浮動性めまい	69		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						鼻閉	69	13D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	69	8D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						リンパ球数減少	71		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						白血球数減少	71		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						腹部膨満	72		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	72	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	72		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	82	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						食欲減退	90		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	90		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性感覚ニューロパチー	90		RELATED	GRADE 2	AE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						活動性低下	103	16D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						気道うっ血	111		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						活動性低下	118		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
P1 ELOTUZUMAB 20 MG/KG	0019-01902	WHITE	20 mg/kg	MALE	5[redacted]	多汗症	1	30M	RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						湿性咳嗽	1	19D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						口腔咽頭痛	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						気道うっ血	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						副鼻腔炎に伴う頭痛	3	17D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	7	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	8	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						消化不良	10		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						季節性アレルギー	10	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	11	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	22	4D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	22	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						頭痛	25		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疲労	32		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						帯状疱疹	32	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						悪心	32	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						神経痛	32	26D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						末梢性浮腫	32	26D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						そう痒症	32	29D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						嘔吐	32	3D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						しゃっくり	34	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						眼乾燥	40		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						四肢痛	46		NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action
						不眠症	64		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						血小板減少症	64	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	67	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						高血糖	67		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						激越	77	5D	NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						アンモニア増加	77	11D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						低カリウム血症	77	11D	NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	77	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						尿失禁	77	11D	NOT RELATED	GRADE 2	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						代謝性脳症	78	10D	NOT RELATED	GRADE 4	SAE	E:DRUG WITHDRAWN B:DRUG WITHDRAWN D:DOSE NOT CHANGED
						末梢性浮腫	78	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						自殺念慮	78		NOT RELATED	GRADE 4	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						トロポニンＩ増加	78	10D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	79	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						発熱	80	24.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						疼痛	81	7D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						下痢	82	48.0H	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						筋力低下	85	3D	NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						ほてり	88		NOT RELATED	GRADE 1	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED
						四肢痛	99		NOT RELATED	GRADE 3	AE	E:DOSE NOT CHANGED B:DOSE NOT CHANGED D:DOSE NOT CHANGED

APPENDIX 64　重篤な有害事象を発現した被験者の一覧（011 試験、治験薬投与例）

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
Elo-20mg/kg	1102-00053	WHITE	20 mg/kg	FEMALE	7[redacted]	疲労	1	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	9	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						手首関節骨折	9	49D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						痔核	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						膣感染	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	106	127D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						アフタ性口内炎	169		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						注入に伴う反応	206	48.0H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						腹部膨満	281	113D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						クッシング様症状	281	113D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						局所腫脹	281	29D	NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						末梢性浮腫	281	113D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						悪寒	309	3D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						倦怠感	309	3D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						末梢性浮腫	309	85D	NOT RELATED	GRADE 2	AE	DRUG WITHDRAWN	
						脱毛症	365		NOT RELATED	GRADE 1	AE	DRUG WITHDRAWN	
						憩室炎	374	6D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
Elo-20mg/kg	1102-00056	WHITE	20 mg/kg	FEMALE	5[redacted]	不眠症	1	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頻脈	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						味覚異常	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	11	19D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉炎	11	19D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						上気道感染	57	16D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						関節腫脹	113		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
Elo-20mg/kg	1102-00057	WHITE	20 mg/kg	FEMALE	7[redacted]	消化不良	1	10M	RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						尿路感染	1	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						消化不良	9	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血圧	29		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	87	19D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						上気道感染	134	36D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						尿路感染	134		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血腫	141		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻出血	196	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						冠動脈ステント挿入	416	24.0H	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						虚血性視神経症	493	24.0H	NOT RELATED	GRADE 3	AE	DRUG INTERRUPTED	
						尿路性敗血症	542	8D	NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED
Elo-20mg/kg	1107-00061	WHITE	20 mg/kg	MALE	7[redacted]	カテーテル留置部位疼痛	36	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						変形性関節症	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	141	61D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						転倒	176		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	201		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						筋力低下	201	56D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	201	56D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						無力症	256	5D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
Elo-20mg/kg	1107-00062	WHITE	20 mg/kg	MALE	6[redacted]	末梢性ニューロパチー	8		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						食欲減退	57	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						一過性脳虚血発作	72	3D	NOT RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED
						疲労	85		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	141	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						錯感覚	169		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	225		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						ウイルス性胃腸炎	600		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						季節性アレルギー	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚剥脱	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯の障害	645		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
Elo-20mg/kg	1109-00084	WHITE	20 mg/kg	MALE	6[redacted]	四肢痛	142		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						病的骨折	151	3D	NOT RELATED	GRADE 3	SAE	DRUG WITHDRAWN	RECOVERED/ RESOLVED WITH SEQUELAE
Elo-10mg/kg	1102-00059	WHITE	10 mg/kg	FEMALE	6[redacted]	疲労	1	6D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	1		RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	36		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						消化不良	36	163D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						回転性めまい	41	48.0H	NOT RELATED	GRADE 2	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						副鼻腔炎	60		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎に伴う頭痛	169		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						網膜剥離	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
Elo-10mg/kg	1102-00060	WHITE	10 mg/kg	FEMALE	6[redacted]	筋骨格硬直	1	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	336		NOT RELATED	GRADE 1	AE	DRUG INTERRUPTED	
						脱水	401		NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						急性腎不全	401	53D	NOT RELATED	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/RESOLVED
						不眠症	402		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸不全	414		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
Elo-10mg/kg	1102-00122	WHITE	10 mg/kg	MALE	6[redacted]	そう痒性皮疹	8	22D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						眼感染	141	30D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						副鼻腔炎	197	15D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						副鼻腔炎	391	8D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						低リン酸血症	407	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腎細胞癌	479		NOT RELATED	GRADE 4	SAE	DRUG WITHDRAWN	NOT RECOVERED/ NOT RESOLVED
Elo-10mg/kg	1109-00085	WHITE	10 mg/kg	FEMALE	6[redacted]	頭痛	9		RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	22		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	253	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状丘疹状皮疹	312	9D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						上気道感染	352	10D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						肺炎	356	6D	RELATED	GRADE 3	SAE	DOSE NOT CHANGED	UNKNOWN
Elo-10mg/kg	1113-00101	WHITE	10 mg/kg	MALE	6[redacted]	冷感	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	2	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						不眠症	8	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	9	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頻尿	29	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	36	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	36	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	43	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	43	48.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	92	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	92	2D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	109	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	120	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	136	20D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋痙縮	155	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						咳嗽	166		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	190	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中カリウム増加	197	0S	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	198		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	243	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔咽頭痛	243		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						四肢痛	254	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						末梢性浮腫	281	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						呼吸困難	285	32.5H	RELATED	GRADE 2	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						呼吸困難	287	66D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						口腔カンジダ症	309	29D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	316	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						処置後出血	316	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						前立腺癌	316		NOT RELATED	GRADE 4	SAE	DOSE NOT CHANGED	NOT RECOVERED/ NOT RESOLVED
						貧血	324	14D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心嚢液貯留	324		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						胸水	324		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心房細動	326		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						冠動脈疾患	330		RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						鼻出血	335	17D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	351	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	352	7D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						末梢性浮腫	352	11D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						呼吸困難	358	4D	RELATED	GRADE 4	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED WITH SEQUELAE
						うっ血性心不全	359	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						うっ血性心不全	360		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						呼吸困難	361		NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						末梢性浮腫	365		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
Elo-10mg/kg	1113-00102	WHITE	10 mg/kg	MALE	5[redacted]	下痢	1	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						冷感	1	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	4	3D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						悪心	4	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	8	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						冷感	8	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	9	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	9	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	9	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	12	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	15		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	15	8D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	16	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下腹部痛	19	4D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	19	4D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						副鼻腔炎	24	20D	RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高血糖	29	0S	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						多汗症	29	48.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						筋骨格系胸痛	43	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						便秘	50	8D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						浮動性めまい	50	6.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						筋骨格系胸痛	50	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	50	6.8H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	57	15D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	57	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	57		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						背部痛	71	43D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	71	42D	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						錯感覚	71	15D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	71	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						腹痛	84	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	84	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	87	27D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						直腸膿瘍	95	6D	NOT RELATED	GRADE 3	SAE	DRUG INTERRUPTED	RECOVERED/ RESOLVED
						悪心	98	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	112	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下腹部痛	113	15D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	123	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	126	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	127	1.7H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	133	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	139	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						不眠症	148	23D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	154	0S	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	164	48.0H	NOT RELATED	GRADE 3	AE	DOSE NOT CHANGED	
						疲労	170	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						頭痛	178	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	178	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高血糖	182	0S	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	184	24.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						腹痛	195	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	195	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						痔出血	205	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						低ナトリウム血症	210	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						高血糖	211	0S	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中副甲状腺ホルモン増加	224		NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	224	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						浮動性めまい	225	6.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	225	6.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	226	48.0H	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	227	27D	RELATED	GRADE 3	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						頭痛	231	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	251	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	252	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	253	1.4H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	254	70D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	259	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	259	3D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						高尿酸血症	266	43D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						斑状出血	280	16D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	281	2.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						心拍数減少	281	1.1H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪寒	292	48.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	292	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	293	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						便秘	298	3D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	308	24.0H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						歯肉炎	309	7D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	329	7D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						食欲減退	330	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						疲労	330	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						振戦	334	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
						鼻出血	337	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						皮膚亀裂	337	71D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						鼻咽頭炎	346	13D	NOT RELATED	GRADE 2	AE	DRUG INTERRUPTED	
						高尿酸血症	350	29D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						悪心	365	11.3H	RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						疲労	371	8D	RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						下痢	372	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	375	25D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						発疹	375	5D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						血中クレアチニン増加	378	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						下痢	386	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						多汗症	386	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						不眠症	386	8D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	391	24.0H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						関節痛	399	9D	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						悪心	407	8.6H	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	422	6D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	435	26D	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						振戦	461	24.0H	NOT RELATED	GRADE 2	AE	DOSE NOT CHANGED	
						心拍数減少	463	11M	NOT RELATED	GRADE 1	AE	DOSE NOT CHANGED	
						頭痛	480	3D	RELATED	GRADE 1	AE	DOSE NOT CHANGED	

Treatment Group	Subject ID	Race	Dose	Sex	Age	Adverse Event (PT)	Onset Study Day	AE Duration	AE Relationship	AE Intensity	AE Type	AE Action	SAE Outcome
NOT TREATED	1107-00065	WHITE		MALE	6[redacted]	脱水		48.0H	NOT APPLICABLE	GRADE 2	AE	DOSE NOT CHANGED	
						切開部位蜂巣炎		6D	NOT APPLICABLE	GRADE 3	SAE	DOSE NOT CHANGED	RECOVERED/ RESOLVED

APPENDIX 65　　VISITごとのリンパ球絶対数の平均変化量の要約統計量（004 試験、治験薬投与例）

Visit	E-Ld N = 318								Ld N = 317							
					Percent Change from Baseline								Percent Change from Baseline			
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max		N#	Mean	SD	Min, Max	Mean	SD	Min, Max	
BASELINE	318	1.4547	0.79171	0.270, 5.989					317	1.4671	0.73872	0.272, 6.300				
CYCLE 1 DAY 1	116	1.0579	0.67759	0.136, 3.848	-23.52	32.711	-83.8,	92.7	23	1.5508	0.94144	0.100, 3.450	-4.99	39.186	-88.9,	121.7
CYCLE 1 DAY 8	303	0.7178	0.49465	0.100, 4.117	-49.49	22.897	-91.9,	47.3	304	1.1345	0.63361	0.155, 6.100	-16.56	38.194	-90.9,	232.2
CYCLE 1 DAY 15	304	0.7352	0.57412	0.000, 6.001	-46.33	34.188	-100.0,	183.2	301	1.1236	0.61612	0.114, 5.200	-19.39	32.969	-86.3,	190.4
CYCLE 1 DAY 22	301	0.6847	0.58677	0.057, 6.682	-49.80	37.613	-94.5,	416.0	297	1.0203	0.54426	0.099, 4.400	-26.15	36.579	-86.9,	279.8
CYCLE 2 DAY 1	305	0.9063	0.58489	0.128, 4.732	-31.60	40.775	-91.1,	265.4	298	1.3053	0.63904	0.260, 3.900	-5.69	40.102	-75.1,	341.3
CYCLE 2 DAY 8	305	0.8007	0.58665	0.048, 4.776	-41.55	34.412	-94.9,	224.4	294	1.0924	0.57258	0.000, 3.300	-19.51	40.102	-100.0,	296.5
CYCLE 2 DAY 15	302	0.9391	0.70476	0.099, 5.724	-30.03	49.753	-89.0,	418.5	295	1.1683	0.62923	0.100, 4.104	-13.74	44.416	-88.9,	327.3
CYCLE 2 DAY 22	302	0.9442	0.72032	0.100, 5.202	-30.90	46.669	-92.3,	280.5	289	1.0966	0.55214	0.100, 4.144	-18.01	42.424	-88.9,	239.2
CYCLE 3 DAY 1	305	1.0557	0.72724	0.175, 6.804	-21.12	52.569	-91.9,	425.4	298	1.2995	0.63333	0.154, 3.700	-3.80	45.272	-84.9,	280.0
CYCLE 3 DAY 15	302	0.9128	0.60934	0.100, 6.007	-31.50	44.736	-88.2,	334.6	286	1.1875	0.61599	0.060, 4.557	-10.69	48.305	-91.0,	384.6
CYCLE 4 DAY 1	302	0.9732	0.69529	0.053, 7.580	-28.42	39.686	-94.1,	227.1	285	1.2970	0.63172	0.069, 3.610	-3.01	45.559	-93.2,	271.3
CYCLE 4 DAY 15	296	0.8658	0.61968	0.130, 6.965	-35.64	38.258	-86.3,	266.7	273	1.1467	0.58922	0.200, 3.602	-14.39	49.068	-80.6,	416.1
CYCLE 5 DAY 1	291	0.8757	0.60029	0.057, 6.670	-34.68	34.226	-95.2,	109.9	267	1.2625	0.60895	0.200, 3.400	-4.62	50.532	-77.9,	407.7
CYCLE 5 DAY 15	278	0.8288	0.59714	0.072, 6.883	-36.58	36.491	-93.0,	128.6	256	1.1505	0.57626	0.180, 3.540	-14.18	45.052	-82.9,	369.9

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas　　11MAR2015:05:32:50

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Ld N = 318							Ld N = 317						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 6 DAY 1	280	0.8759	0.58013	0.156, 3.971	-35.74	36.100	-86.0, 128.2	251	1.2185	0.59355	0.169, 3.720	-7.96	47.551	-91.8, 430.1
CYCLE 6 DAY 15	268	0.8398	0.65598	0.126, 8.618	-35.39	39.411	-87.7, 163.0	230	1.1366	0.53146	0.100, 2.891	-13.62	44.941	-88.9, 272.4
CYCLE 7 DAY 1	270	0.8926	0.59160	0.106, 4.910	-33.36	36.528	-91.0, 117.1	239	1.2586	0.59986	0.200, 3.385	-5.62	47.928	-80.2, 281.5
CYCLE 7 DAY 15	267	0.8626	0.58550	0.130, 5.998	-34.61	35.824	-86.3, 129.3	223	1.1597	0.58533	0.100, 3.368	-14.91	48.931	-83.3, 458.0
CYCLE 8 DAY 1	260	0.8674	0.50844	0.000, 3.340	-33.51	37.557	-100.0, 204.9	220	1.2488	0.57894	0.180, 3.180	-8.24	42.655	-80.5, 242.7
CYCLE 8 DAY 15	248	0.8586	0.54815	0.136, 4.764	-33.56	37.041	-86.7, 181.5	205	1.1558	0.55883	0.200, 3.434	-14.11	43.804	-89.5, 221.1
CYCLE 9 DAY 1	244	0.8729	0.51506	0.117, 3.690	-31.47	42.104	-88.8, 213.9	206	1.2469	0.56243	0.180, 3.199	-7.56	40.992	-79.1, 235.3
CYCLE 9 DAY 15	243	0.8854	0.63827	0.085, 6.275	-32.48	43.449	-88.4, 291.4	193	1.1302	0.52020	0.230, 2.500	-13.42	48.170	-83.1, 309.1
CYCLE 10 DAY 1	235	0.8778	0.49268	0.100, 2.700	-33.01	37.831	-84.8, 159.3	200	1.2357	0.56774	0.170, 3.540	-6.31	50.784	-81.9, 371.1
CYCLE 10 DAY 15	229	0.8506	0.48826	0.189, 3.446	-34.60	36.020	-85.2, 104.0	179	1.1232	0.50103	0.187, 2.520	-13.30	45.646	-80.2, 195.8
CYCLE 11 DAY 1	225	0.8721	0.48265	0.072, 3.250	-32.74	37.573	-93.0, 149.0	184	1.2388	0.63207	0.224, 4.600	-3.93	61.998	-79.0, 519.1
CYCLE 11 DAY 15	222	0.8344	0.52206	0.100, 3.380	-37.13	33.376	-88.2, 97.2	178	1.1167	0.54501	0.160, 3.135	-13.67	48.934	-89.9, 271.3
CYCLE 12 DAY 1	216	0.8594	0.53201	0.120, 3.420	-34.89	39.683	-86.8, 136.3	173	1.2414	0.93227	0.190,11.271	-5.35	71.107	-86.3, 597.0
CYCLE 12 DAY 15	216	0.8184	0.47271	0.110, 2.714	-37.34	36.714	-85.5, 135.9	168	1.1215	0.55668	0.190, 3.442	-10.57	62.026	-84.6, 434.3
CYCLE 13 DAY 1	211	0.8614	0.50010	0.090, 3.100	-34.72	40.110	-89.3, 135.1	164	1.1940	0.54097	0.300, 3.231	-7.72	64.214	-82.1, 623.4

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas 11MAR2015:05:32:50

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Ld N = 318							Ld N = 317						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 13 DAY 15	206	0.8409	0.46399	0.095, 2.904	-35.56	36.887	-87.7, 132.5	158	1.1006	0.57008	0.170, 4.067	-12.67	60.611	-84.9, 440.6
CYCLE 14 DAY 1	205	0.8537	0.48747	0.086, 2.920	-35.39	38.447	-94.6, 125.9	159	1.1931	0.57524	0.112, 4.048	-10.07	48.866	-80.9, 323.1
CYCLE 14 DAY 15	195	0.8352	0.45590	0.038, 2.200	-35.65	40.454	-95.0, 135.4	148	1.0936	0.53221	0.200, 2.997	-16.75	52.359	-81.2, 313.3
CYCLE 15 DAY 1	200	0.8699	0.54806	0.135, 3.062	-35.22	41.215	-92.3, 229.2	147	1.1400	0.56050	0.130, 3.050	-14.20	55.116	-90.2, 428.7
CYCLE 15 DAY 15	188	0.8556	0.47045	0.000, 2.788	-34.27	38.257	-100.0, 188.4	140	1.1163	0.54482	0.280, 3.589	-14.02	48.723	-86.5, 302.4
CYCLE 16 DAY 1	184	0.8561	0.48846	0.087, 2.417	-35.21	39.723	-88.5, 191.1	141	1.1890	0.59708	0.200, 3.319	-8.59	51.460	-78.9, 268.2
CYCLE 16 DAY 15	179	0.8540	0.50837	0.156, 2.992	-35.27	37.965	-86.8, 157.3	129	1.1048	0.56065	0.248, 3.069	-11.87	49.841	-92.5, 262.9
CYCLE 17 DAY 1	179	0.8328	0.49616	0.156, 2.822	-36.34	41.220	-92.4, 184.5	137	1.1928	0.56309	0.230, 3.179	-9.13	49.929	-78.4, 290.9
CYCLE 17 DAY 15	178	0.8473	0.48349	0.100, 2.993	-34.93	40.318	-90.0, 211.8	128	1.1301	0.55836	0.270, 3.217	-13.93	49.333	-78.8, 261.9
CYCLE 18 DAY 1	173	0.8358	0.49313	0.050, 2.908	-36.41	39.802	-96.6, 155.7	135	1.1754	0.58914	0.200, 3.771	-11.06	44.821	-79.5, 228.3
CYCLE 18 DAY 15	169	0.8350	0.47799	0.100, 2.499	-35.66	37.228	-90.5, 110.8	125	1.1569	0.55825	0.210, 3.029	-7.45	62.182	-89.0, 323.8
CYCLE 19 DAY 1	166	0.8491	0.49638	0.141, 3.537	-35.13	39.164	-86.3, 145.5	131	1.2070	0.59188	0.180, 4.051	-7.13	47.602	-87.6, 243.4
CYCLE 19 DAY 15	155	0.8163	0.45075	0.200, 2.512	-34.96	40.568	-86.2, 183.2	102	1.1472	0.59971	0.111, 3.130	-14.06	48.284	-87.7, 155.2
CYCLE 20 DAY 1	160	0.8675	0.51861	0.130, 3.122	-34.06	41.674	-86.2, 215.9	115	1.1602	0.60764	0.210, 4.511	-11.10	56.246	-84.1, 388.8
CYCLE 20 DAY 15	146	0.8493	0.48158	0.100, 2.583	-31.80	41.325	-83.3, 175.6	100	1.1643	0.50688	0.440, 2.688	-9.83	60.083	-85.1, 447.2

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas 11MAR2015:05:32:50

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Ld N = 318							Ld N = 317						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 21 DAY 1	153	0.8583	0.51572	0.160, 2.868	-32.37	40.436	-91.9, 133.7	106	1.2399	0.62643	0.230, 3.932	-6.00	52.651	-86.3, 285.3
CYCLE 21 DAY 15	144	0.8272	0.48036	0.164, 2.785	-34.97	38.404	-86.3, 162.5	94	1.1632	0.64464	0.240, 3.549	-15.02	47.884	-84.0, 227.3
CYCLE 22 DAY 1	144	0.8254	0.45066	0.160, 2.756	-34.62	40.324	-84.5, 172.5	102	1.1963	0.60632	0.170, 3.804	-10.35	64.505	-83.4, 470.3
CYCLE 22 DAY 15	142	0.8235	0.47646	0.228, 2.401	-34.58	44.305	-86.1, 260.0	93	1.2012	0.58181	0.102, 3.096	-9.66	49.889	-87.7, 217.8
CYCLE 23 DAY 1	141	0.8444	0.50475	0.145, 2.666	-32.13	44.663	-85.9, 193.6	99	1.2800	0.67037	0.270, 4.263	-7.87	47.420	-81.4, 183.9
CYCLE 23 DAY 15	139	0.8174	0.47792	0.186, 2.688	-32.97	41.163	-82.4, 159.2	86	1.1362	0.64141	0.250, 3.691	-20.30	50.062	-86.7, 269.2
CYCLE 24 DAY 1	139	0.8584	0.51882	0.181, 3.389	-30.72	45.195	-86.2, 213.5	91	1.2898	0.68112	0.270, 3.921	-6.23	52.564	-75.6, 264.3
CYCLE 24 DAY 15	134	0.8396	0.47874	0.180, 2.458	-34.37	36.150	-82.8, 151.8	82	1.1676	0.65486	0.200, 3.515	-15.41	44.944	-81.2, 177.6
CYCLE 25 DAY 1	131	0.8095	0.50946	0.059, 3.191	-35.68	42.896	-96.0, 171.4	82	1.2245	0.63449	0.220, 3.807	-7.92	49.248	-86.9, 179.5
CYCLE 25 DAY 15	121	0.7954	0.47375	0.050, 3.092	-36.06	43.612	-96.2, 234.0	72	1.2181	0.99703	0.130, 7.989	-8.12	72.856	-81.2, 457.5
CYCLE 26 DAY 1	129	0.8261	0.49412	0.190, 3.168	-31.85	52.186	-91.0, 336.6	73	1.2213	0.63688	0.170, 4.082	-5.30	53.776	-82.8, 260.8
CYCLE 26 DAY 15	112	0.8017	0.44714	0.200, 2.246	-33.25	47.700	-86.2, 288.4	60	1.2192	0.51023	0.380, 2.730	-1.62	68.303	-78.2, 392.3
CYCLE 27 DAY 1	108	0.8257	0.46132	0.062, 2.303	-31.13	56.010	-97.1, 367.5	63	1.2532	0.72389	0.400, 5.081	-1.47	49.432	-73.0, 157.0
CYCLE 27 DAY 15	99	0.8216	0.47257	0.118, 2.726	-32.07	49.282	-93.2, 229.4	42	1.0783	0.61920	0.295, 2.857	-17.50	45.532	-85.0, 88.9
CYCLE 28 DAY 1	85	0.8182	0.43989	0.100, 1.992	-31.40	49.528	-86.3, 172.5	46	1.3275	0.72135	0.300, 3.820	-3.99	53.527	-81.3, 181.1

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas 11MAR2015:05:32:50

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Ld N = 318							Ld N = 317						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 28 DAY 15	80	0.8581	0.46480	0.200, 2.200	-28.96	59.074	-81.4, 299.8	37	1.1083	0.53513	0.200, 3.000	-13.02	41.021	-77.4, 97.1
CYCLE 29 DAY 1	76	0.8529	0.49690	0.150, 2.335	-30.44	51.125	-93.0, 242.7	41	1.2217	0.67635	0.440, 3.772	-7.68	41.856	-76.1, 80.5
CYCLE 29 DAY 15	68	0.8480	0.46680	0.200, 2.472	-28.08	55.866	-80.1, 280.1	29	1.1159	0.52034	0.471, 2.353	-11.72	37.685	-66.0, 84.0
CYCLE 30 DAY 1	65	0.8715	0.40992	0.200, 2.100	-30.95	41.478	-81.8, 137.5	34	1.1612	0.54864	0.400, 2.200	-6.89	40.050	-74.5, 105.4
CYCLE 30 DAY 15	58	0.8807	0.50383	0.250, 2.629	-32.73	46.535	-85.3, 155.4	24	1.1173	0.44050	0.400, 1.936	-5.65	36.416	-50.0, 60.5
CYCLE 31 DAY 1	55	0.8716	0.50937	0.150, 2.303	-30.11	49.380	-86.4, 153.1	27	1.1797	0.44118	0.270, 2.061	2.32	40.790	-70.8, 97.0
CYCLE 31 DAY 15	53	0.8713	0.42587	0.200, 2.302	-31.00	45.382	-81.7, 175.0	21	1.0683	0.45788	0.400, 2.352	-9.46	34.511	-66.7, 71.1
CYCLE 32 DAY 1	48	0.8619	0.44043	0.207, 2.424	-33.80	42.069	-87.4, 146.4	22	1.0973	0.46237	0.339, 1.970	-3.25	42.465	-76.9, 85.4
CYCLE 32 DAY 15	39	0.8448	0.51327	0.248, 2.300	-27.74	68.140	-82.4, 279.9	14	0.9498	0.39539	0.429, 1.790	-8.11	54.344	-77.7, 92.5
CYCLE 33 DAY 1	41	0.8826	0.49674	0.200, 2.200	-28.82	60.636	-85.1, 232.1	19	1.1494	0.47247	0.320, 1.760	-3.97	40.441	-74.8, 82.9
CYCLE 33 DAY 15	38	0.8873	0.57277	0.172, 2.527	-32.93	45.373	-88.2, 135.7	12	1.1627	0.44565	0.580, 2.060	-14.08	36.922	-70.1, 62.7
CYCLE 34 DAY 1	34	0.8854	0.47668	0.200, 2.249	-30.14	51.350	-86.9, 140.0	14	1.2019	0.53963	0.400, 2.262	-2.96	51.006	-82.4, 104.9
CYCLE 34 DAY 15	28	0.8381	0.39722	0.160, 1.869	-30.22	56.153	-89.6, 194.6	7	1.2180	0.66026	0.500, 2.344	-14.13	40.833	-55.3, 58.2
CYCLE 35 DAY 1	22	0.9665	0.47369	0.170, 2.120	-21.95	43.279	-88.9, 98.3	8	1.1366	0.52756	0.507, 2.110	-13.13	34.088	-45.5, 65.9
CYCLE 35 DAY 15	16	0.8373	0.45242	0.120, 2.166	-23.72	43.882	-92.2, 106.2	4	0.6755	0.05903	0.610, 0.753	-10.46	40.697	-41.7, 48.8

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas 11MAR2015:05:32:50

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Ld N = 318							Ld N = 317						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 36 DAY 1	14	0.7273	0.42752	0.131, 1.984	-36.75	28.511	-91.5, 23.9	7	1.1326	0.36143	0.670, 1.750	15.12	49.139	-45.6, 88.2
CYCLE 36 DAY 15	10	0.7125	0.36743	0.196, 1.200	-22.27	50.630	-85.6, 95.6	3	0.6527	0.18847	0.440, 0.799	-9.28	22.035	-34.3, 7.3
CYCLE 37 DAY 1	9	0.6307	0.22599	0.360, 1.000	-37.53	27.081	-66.9, 27.9	4	0.9213	0.20690	0.700, 1.200	15.82	38.741	-19.1, 70.7
CYCLE 37 DAY 15	9	0.6670	0.27765	0.220, 1.119	-30.07	49.929	-85.7, 79.6	3	0.6220	0.13908	0.462, 0.714	-0.30	63.762	-57.8, 68.3
CYCLE 38 DAY 1	5	0.6462	0.35964	0.352, 1.200	-41.85	22.056	-74.2, -17.6	3	0.8883	0.11680	0.767, 1.000	-11.71	21.093	-29.9, 11.4
CYCLE 38 DAY 15	6	0.7310	0.40173	0.181, 1.300	-35.93	27.824	-69.5, 0.0	1	0.7560		0.756, 0.756	-6.20		-6.2, -6.2
CYCLE 39 DAY 1	2	1.0000	0.56569	0.600, 1.400	-1.96	2.766	-3.9, 0.0	2	1.1745	0.81247	0.600, 1.749	-28.02	3.484	-30.5, -25.6
CYCLE 39 DAY 15	1	1.0000		1.000, 1.000	66.67		66.7, 66.7	2	1.0605	0.83509	0.470, 1.651	-38.03	5.167	-41.7, -34.4
CYCLE 40 DAY 1	2	0.4190	0.09758	0.350, 0.488	-29.76	16.844	-41.7, -17.8	2	1.0045	0.82661	0.420, 1.589	-42.37	7.811	-47.9, -36.8
CYCLE 40 DAY 15	1	0.8400		0.840, 0.840	40.00		40.0, 40.0	1	0.6380		0.638, 0.638	-20.84		-20.8, -20.8
CYCLE 41 DAY 1	1	0.5700		0.570, 0.570	-5.00		-5.0, -5.0	0						
CYCLE 41 DAY 15	1	0.6500		0.650, 0.650	8.33		8.3, 8.3	0						
CYCLE 42 DAY 1	1	0.5000		0.500, 0.500	-16.67		-16.7, -16.7	0						

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb-lympa.sas 11MAR2015:05:32:50

APPENDIX 66　　VISITごとのリンパ球絶対数の平均変化量の要約統計量（004 試験、日本人部分集団、治験薬投与例）

Visit	E-Ld N = 31							Ld N = 29						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
BASELINE	31	1.3167	0.54167	0.609, 2.668				29	1.4898	0.75969	0.472, 3.321			
CYCLE 1 DAY 1	7	0.8734	0.57341	0.232, 1.848	-51.56	24.404	-77.9, -20.6	1	2.4570		2.457, 2.457	-26.02		-26.0, -26.0
CYCLE 1 DAY 8	30	0.5956	0.26695	0.153, 1.248	-52.20	17.643	-83.7, -11.3	29	1.0969	0.57924	0.155, 2.808	-20.97	34.977	-73.2, 74.7
CYCLE 1 DAY 15	31	0.7281	0.26106	0.229, 1.380	-39.79	23.389	-72.9, 16.0	29	1.0797	0.57639	0.480, 2.646	-21.22	29.387	-77.1, 53.4
CYCLE 1 DAY 22	29	0.5630	0.23766	0.057, 1.012	-52.41	20.244	-94.5, -13.3	29	0.9789	0.50267	0.099, 1.976	-30.98	25.246	-86.9, 16.4
CYCLE 2 DAY 1	31	0.7845	0.31775	0.324, 1.478	-34.54	33.048	-68.3, 69.1	29	1.3235	0.48015	0.262, 2.199	-1.21	38.200	-55.6, 76.5
CYCLE 2 DAY 8	31	0.7267	0.30038	0.279, 1.469	-41.12	21.569	-80.3, 10.0	29	1.1327	0.46732	0.514, 2.040	-12.02	40.785	-71.5, 87.5
CYCLE 2 DAY 15	31	0.9744	0.53633	0.180, 2.653	-18.59	52.253	-87.5, 162.2	29	1.2415	0.59242	0.329, 2.575	-7.20	45.614	-59.1, 117.9
CYCLE 2 DAY 22	31	0.9133	0.53127	0.160, 2.520	-24.61	49.079	-80.2, 149.0	29	1.2141	0.55125	0.455, 2.652	-6.01	49.627	-68.4, 128.7
CYCLE 3 DAY 1	31	0.9904	0.41679	0.248, 1.836	-15.84	45.556	-76.2, 101.4	29	1.4820	0.54529	0.482, 2.464	15.10	48.785	-69.4, 127.9
CYCLE 3 DAY 15	30	0.8779	0.35731	0.128, 1.851	-28.10	30.318	-87.7, 52.0	29	1.4297	0.59069	0.510, 3.240	12.77	52.534	-61.8, 125.2
CYCLE 4 DAY 1	30	0.9096	0.38794	0.368, 1.862	-23.05	39.516	-73.4, 91.5	28	1.4395	0.54362	0.609, 2.580	9.17	48.122	-65.5, 126.7
CYCLE 4 DAY 15	29	0.8777	0.43029	0.153, 1.863	-28.32	37.620	-85.3, 53.6	28	1.2807	0.58016	0.315, 2.277	-4.22	46.779	-72.7, 70.2
CYCLE 5 DAY 1	28	0.7073	0.34196	0.057, 1.408	-44.29	29.957	-95.2, 62.9	28	1.4386	0.46490	0.780, 2.622	11.60	50.087	-72.3, 142.2
CYCLE 5 DAY 15	28	0.6783	0.26892	0.299, 1.225	-45.92	21.030	-75.6, 0.5	28	1.3189	0.53101	0.489, 2.331	-2.34	37.206	-74.1, 79.9

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas　　19JUN2015:07:24:27

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Japanese Subjects

Visit	E-Ld N = 31								Ld N = 29							
					Percent Change from Baseline								Percent Change from Baseline			
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max		N#	Mean	SD	Min, Max	Mean	SD	Min, Max	
CYCLE 6 DAY 1	28	0.8441	0.51728	0.217, 2.166	-33.44	40.666	-83.6,	61.0	27	1.2212	0.45322	0.386, 2.412	-7.24	41.471	-83.6,	84.9
CYCLE 6 DAY 15	28	0.7975	0.38366	0.264, 1.785	-36.30	31.417	-73.8,	39.6	26	1.3051	0.50059	0.378, 2.385	-4.09	45.073	-73.7,	84.0
CYCLE 7 DAY 1	28	0.7239	0.35266	0.106, 1.365	-42.18	29.441	-91.0,	9.9	26	1.4317	0.42971	0.643, 2.652	8.31	48.977	-73.9,	106.7
CYCLE 7 DAY 15	28	0.8931	0.50444	0.281, 2.310	-30.64	33.285	-78.6,	34.7	25	1.3527	0.59659	0.346, 2.592	-6.06	48.179	-72.3,	108.7
CYCLE 8 DAY 1	27	0.7975	0.39146	0.255, 1.643	-37.41	29.442	-79.5,	33.5	24	1.3977	0.51363	0.616, 2.600	4.97	52.524	-79.6,	109.8
CYCLE 8 DAY 15	27	0.8912	0.38616	0.189, 1.887	-28.60	32.333	-85.7,	34.0	24	1.4995	0.65983	0.349, 2.750	6.70	44.590	-89.5,	101.5
CYCLE 9 DAY 1	27	0.8463	0.49060	0.117, 2.250	-31.32	44.259	-88.8,	92.0	24	1.4334	0.47048	0.660, 2.288	7.25	50.503	-63.1,	96.0
CYCLE 9 DAY 15	26	0.8795	0.45342	0.315, 2.088	-26.34	42.279	-76.9,	98.8	23	1.2882	0.57389	0.353, 2.500	-6.09	49.442	-83.1,	92.8
CYCLE 10 DAY 1	27	0.8211	0.40971	0.195, 1.562	-35.94	30.917	-81.3,	17.5	22	1.4004	0.51702	0.624, 2.574	7.42	50.709	-81.2,	88.1
CYCLE 10 DAY 15	26	0.9332	0.51913	0.241, 2.530	-23.69	44.847	-76.9,	104.0	21	1.1771	0.52673	0.187, 2.115	-10.60	53.288	-75.3,	99.4
CYCLE 11 DAY 1	25	0.8362	0.43683	0.234, 1.710	-30.95	38.150	-79.5,	79.0	21	1.4445	0.59661	0.520, 2.715	13.95	63.217	-70.5,	157.1
CYCLE 11 DAY 15	26	0.9057	0.53970	0.171, 2.555	-28.14	40.776	-83.6,	77.1	21	1.3569	0.71686	0.336, 3.135	3.83	60.665	-89.9,	164.7
CYCLE 12 DAY 1	26	0.8525	0.48098	0.205, 1.782	-32.73	36.578	-82.6,	56.2	21	1.2780	0.44525	0.483, 2.195	1.26	52.631	-84.6,	121.9
CYCLE 12 DAY 15	25	0.8851	0.43042	0.285, 2.047	-27.20	38.523	-80.7,	46.4	21	1.1746	0.55465	0.319, 2.556	-10.79	48.487	-82.3,	98.1
CYCLE 13 DAY 1	23	0.8043	0.37752	0.200, 1.676	-35.39	36.386	-78.0,	76.9	21	1.2068	0.49003	0.315, 2.332	-2.62	58.171	-82.1,	135.8

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas 19JUN2015:07:24:27

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Japanese Subjects

Visit	E-Ld N = 31							Ld N = 29						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 13 DAY 15	22	0.9065	0.42608	0.234, 1.650	-23.49	42.534	-73.5, 52.9	20	1.3653	0.87636	0.342, 4.067	3.91	66.603	-80.6, 133.0
CYCLE 14 DAY 1	22	0.8429	0.35115	0.272, 1.469	-29.51	37.627	-68.5, 80.3	19	1.3640	0.46854	0.490, 2.475	7.37	57.043	-75.8, 150.3
CYCLE 14 DAY 15	21	0.7642	0.38067	0.297, 1.581	-34.37	41.407	-78.6, 70.8	19	1.2195	0.65158	0.318, 2.781	-7.51	53.839	-81.2, 109.0
CYCLE 15 DAY 1	21	0.8451	0.38664	0.144, 1.535	-28.99	43.202	-76.4, 92.6	16	1.2522	0.64978	0.380, 2.662	-3.86	68.440	-74.2, 169.2
CYCLE 15 DAY 15	21	0.8120	0.35655	0.282, 1.351	-30.90	44.085	-78.8, 116.9	15	1.2847	0.48969	0.448, 1.975	0.72	56.612	-86.5, 99.7
CYCLE 16 DAY 1	20	0.8206	0.42147	0.150, 1.674	-31.68	44.997	-87.3, 122.5	16	1.5288	0.58873	0.552, 2.867	22.02	71.196	-76.9, 189.9
CYCLE 16 DAY 15	20	0.8865	0.47561	0.156, 1.992	-24.65	44.989	-86.8, 79.6	16	1.3528	0.76593	0.248, 3.069	5.07	65.640	-92.5, 122.9
CYCLE 17 DAY 1	20	0.7520	0.45055	0.208, 1.552	-40.60	33.852	-84.0, 40.1	15	1.3053	0.66634	0.395, 2.801	-1.96	69.118	-73.4, 183.2
CYCLE 17 DAY 15	20	0.8251	0.36165	0.288, 1.728	-31.18	37.007	-75.6, 72.9	14	1.3630	0.80416	0.328, 2.948	1.52	76.980	-75.3, 198.1
CYCLE 18 DAY 1	20	0.7511	0.41236	0.168, 1.700	-40.87	30.922	-83.4, 29.4	14	1.4971	0.73107	0.440, 3.247	20.06	86.381	-79.5, 228.3
CYCLE 18 DAY 15	20	0.9169	0.44022	0.360, 2.204	-22.49	42.073	-75.8, 69.0	14	1.3662	0.54262	0.644, 2.546	5.40	68.235	-63.1, 141.1
CYCLE 19 DAY 1	19	0.8743	0.45262	0.287, 1.995	-27.33	42.596	-79.0, 78.7	14	1.2613	0.43302	0.480, 1.869	-2.22	56.781	-74.9, 82.0
CYCLE 19 DAY 15	19	0.9468	0.51090	0.391, 2.512	-22.99	38.536	-73.6, 64.2	14	1.4019	0.73116	0.111, 2.508	3.29	72.671	-85.3, 146.9
CYCLE 20 DAY 1	18	0.7826	0.33820	0.130, 1.440	-32.34	43.741	-78.7, 78.7	14	1.1872	0.36275	0.480, 1.711	-5.07	52.189	-84.1, 63.8
CYCLE 20 DAY 15	17	1.0095	0.53321	0.338, 2.054	-12.21	49.073	-79.2, 77.2	13	1.2745	0.64309	0.494, 2.688	-2.66	61.669	-85.1, 114.0

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas 19JUN2015:07:24:27

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Japanese Subjects

Visit	E-Ld N = 31							Ld N = 29						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 21 DAY 1	18	0.8416	0.36808	0.397, 1.974	-27.07	44.702	-67.9, 107.8	13	1.2666	0.58886	0.378, 2.116	2.39	69.779	-86.3, 103.7
CYCLE 21 DAY 15	18	0.9005	0.43426	0.376, 1.890	-23.59	43.404	-74.8, 62.7	12	1.1928	0.66854	0.453, 2.684	-11.66	69.594	-84.0, 171.4
CYCLE 22 DAY 1	16	0.7746	0.37323	0.247, 1.760	-32.96	37.964	-71.0, 60.7	12	1.2347	0.55294	0.429, 2.328	-2.33	70.538	-75.7, 135.4
CYCLE 22 DAY 15	15	0.7399	0.33416	0.300, 1.554	-36.77	32.855	-78.3, 41.9	12	1.1773	0.65101	0.481, 2.295	-10.73	69.274	-85.5, 109.0
CYCLE 23 DAY 1	14	0.7399	0.21566	0.462, 1.155	-35.52	27.609	-73.8, 23.1	11	1.2647	0.67329	0.520, 2.847	-10.95	57.223	-72.0, 112.9
CYCLE 23 DAY 15	15	0.9532	0.46543	0.544, 1.989	-20.32	40.217	-75.4, 81.6	10	1.3408	1.06084	0.304, 3.691	-17.15	73.300	-75.5, 160.5
CYCLE 24 DAY 1	13	0.8623	0.30884	0.429, 1.512	-20.22	36.490	-68.5, 51.7	11	1.2580	0.84812	0.624, 3.449	-11.35	61.279	-75.6, 126.9
CYCLE 24 DAY 15	14	0.8699	0.31626	0.480, 1.458	-21.63	35.912	-82.0, 32.6	11	1.3263	0.95546	0.621, 3.515	-5.59	75.079	-81.2, 177.6
CYCLE 25 DAY 1	14	0.7470	0.32526	0.276, 1.363	-32.85	35.825	-87.3, 24.5	9	1.2071	0.53577	0.784, 2.453	3.05	76.059	-75.5, 148.0
CYCLE 25 DAY 15	11	0.8921	0.37325	0.442, 1.670	-20.18	38.151	-80.3, 52.5	8	1.0705	0.76163	0.336, 2.778	-16.27	85.847	-75.4, 180.9
CYCLE 26 DAY 1	12	0.8513	0.40179	0.449, 1.610	-18.62	41.650	-66.6, 47.0	7	1.3431	0.39024	0.758, 1.833	16.52	65.232	-57.2, 85.3
CYCLE 26 DAY 15	13	0.9400	0.43901	0.381, 1.824	-13.92	44.099	-73.6, 62.8	7	1.3046	0.74179	0.697, 2.730	15.87	91.854	-59.1, 176.0
CYCLE 27 DAY 1	13	0.8541	0.34532	0.436, 1.596	-19.80	45.129	-68.3, 63.2	6	1.3632	0.47638	0.940, 2.181	33.76	72.900	-67.2, 120.5
CYCLE 27 DAY 15	12	0.9462	0.65714	0.361, 2.726	-17.65	59.616	-69.7, 148.9	6	1.0533	0.54198	0.385, 1.868	-0.23	66.213	-67.3, 88.9
CYCLE 28 DAY 1	11	0.8233	0.33540	0.462, 1.404	-23.07	36.149	-66.1, 50.7	5	1.2508	0.51454	0.616, 1.728	24.50	75.185	-78.5, 94.6

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas 19JUN2015:07:24:27

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Japanese Subjects

Visit	E-Ld N = 31								Ld N = 29							
					Percent Change from Baseline								Percent Change from Baseline			
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max		N#	Mean	SD	Min, Max	Mean	SD	Min, Max	
CYCLE 28 DAY 15	11	0.9878	0.46675	0.486, 2.045	-12.27	47.637	-67.6,	86.8	5	1.0532	0.43135	0.700, 1.750	-0.62	62.714	-70.6,	97.1
CYCLE 29 DAY 1	11	0.7903	0.31592	0.360, 1.276	-26.99	32.376	-66.5,	30.9	5	1.0048	0.26395	0.684, 1.351	-2.29	55.353	-76.1,	78.5
CYCLE 29 DAY 15	11	0.9236	0.46068	0.468, 1.944	-17.51	43.396	-68.6,	77.5	5	1.1202	0.31876	0.818, 1.634	7.14	62.380	-66.0,	84.0
CYCLE 30 DAY 1	10	0.8436	0.32580	0.480, 1.577	-22.78	40.319	-71.7,	44.0	5	0.8794	0.29095	0.554, 1.332	-20.75	35.074	-74.5,	14.8
CYCLE 30 DAY 15	9	0.9067	0.35636	0.461, 1.404	-18.73	40.406	-61.3,	44.0	5	1.0902	0.33668	0.640, 1.431	-1.83	52.099	-50.0,	56.1
CYCLE 31 DAY 1	7	0.7640	0.35250	0.408, 1.406	-24.14	48.991	-69.6,	44.5	5	1.1832	0.34441	0.836, 1.749	14.87	65.100	-70.8,	97.0
CYCLE 31 DAY 15	6	0.8103	0.31109	0.486, 1.204	-24.69	42.049	-68.0,	21.6	5	0.9316	0.37323	0.544, 1.519	-11.92	58.555	-66.7,	71.1
CYCLE 32 DAY 1	5	0.6062	0.11086	0.465, 0.720	-47.45	18.813	-76.9,	-25.4	5	0.9926	0.19515	0.660, 1.178	-5.01	43.569	-76.9,	38.7
CYCLE 32 DAY 15	5	0.7692	0.13419	0.600, 0.914	-29.29	43.844	-66.3,	46.7	5	0.9154	0.39863	0.429, 1.419	-7.43	68.380	-77.7,	87.5
CYCLE 33 DAY 1	5	0.7628	0.19340	0.504, 0.925	-29.68	45.164	-65.3,	45.7	4	1.0325	0.26172	0.720, 1.332	-3.71	61.938	-74.8,	76.0
CYCLE 33 DAY 15	5	0.7698	0.14497	0.592, 0.921	-25.61	47.155	-77.8,	47.8	4	0.9418	0.19462	0.816, 1.232	-14.51	55.778	-70.1,	62.7
CYCLE 34 DAY 1	5	0.7680	0.26766	0.420, 1.030	-28.05	54.343	-69.2,	65.3	3	0.9047	0.35016	0.504, 1.152	-28.79	46.437	-82.4,	-0.7
CYCLE 34 DAY 15	4	0.7948	0.08903	0.684, 0.888	-17.07	30.394	-42.7,	23.1	2	0.6765	0.22415	0.518, 0.835	-39.51	22.394	-55.3,	-23.7
CYCLE 35 DAY 1	4	0.7273	0.09708	0.604, 0.840	-25.74	20.229	-47.2,	-3.0	2	0.8920	0.10465	0.818, 0.966	-20.98	6.014	-25.2,	-16.7
CYCLE 35 DAY 15	4	0.7193	0.10997	0.640, 0.880	-26.66	21.701	-41.4,	5.6	2	0.7145	0.05445	0.676, 0.753	-36.45	7.463	-41.7,	-31.2

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas 19JUN2015:07:24:27

Protocol: CA204004

Summary Statistics for Lymphocytes (Absolute)
All Treated Japanese Subjects

Visit	E-Ld N = 31							Ld N = 29						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 36 DAY 1	4	0.6858	0.17796	0.518, 0.894	-26.96	36.737	-59.0, 23.9	2	0.9295	0.20718	0.783, 1.076	-17.07	21.818	-32.5, -1.6
CYCLE 36 DAY 15	2	0.4680	0.38467	0.196, 0.740	-33.43	73.829	-85.6, 18.8	1	0.7190		0.719, 0.719	-34.28		-34.3, -34.3
CYCLE 37 DAY 1	2	0.6240	0.24466	0.451, 0.797	-19.50	67.080	-66.9, 27.9	1	0.8850		0.885, 0.885	-19.10		-19.1, -19.1
CYCLE 37 DAY 15	2	0.7740	0.48790	0.429, 1.119	5.53	104.767	-68.5, 79.6	1	0.4620		0.462, 0.462	-57.77		-57.8, -57.8
CYCLE 38 DAY 1	1	0.3520		0.352, 0.352	-74.19		-74.2, -74.2	1	0.7670		0.767, 0.767	-29.89		-29.9, -29.9
CYCLE 38 DAY 15	1	0.5300		0.530, 0.530	-61.14		-61.1, -61.1	0						

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms111382/stats/Japan/prog/tables/rt-lb-lympa.sas 19JUN2015:07:24:27

APPENDIX 67　　VISITごとのリンパ球絶対数の平均変化量の要約統計量（009 試験、治験薬投与例）

Visit	E-Bd N = 75							Bd N = 75						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
BASELINE	72	1.5554	0.73833	0.200, 4.230				75	1.4443	0.58000	0.420, 2.800			
CYCLE 1 DAY 1	29	1.2535	0.78715	0.320, 3.744	-24.71	25.800	-74.2, 38.0	14	1.3329	0.55686	0.671, 2.310	-18.66	26.180	-60.6, 35.0
CYCLE 1 DAY 4	70	0.9539	0.68517	0.194, 3.932	-32.54	47.981	-79.7, 224.0	67	1.5584	0.86805	0.400, 4.090	12.96	48.121	-76.5, 161.8
CYCLE 1 DAY 8	68	0.9730	0.63809	0.092, 2.790	-33.95	38.986	-86.2, 113.5	67	1.4644	0.84935	0.330, 4.081	3.90	43.757	-67.8, 131.9
CYCLE 1 DAY 11	69	1.1358	0.88759	0.080, 5.547	-20.68	69.995	-93.7, 442.0	69	1.4401	0.81480	0.300, 3.898	1.69	43.935	-68.6, 122.8
CYCLE 2 DAY 1	62	0.7206	0.55062	0.066, 3.142	-51.59	36.530	-90.1, 172.3	50	1.0357	0.51791	0.184, 2.115	-26.33	20.500	-75.5, 19.6
CYCLE 2 DAY 4	67	0.9529	0.57142	0.184, 2.740	-34.46	29.900	-82.8, 55.1	59	1.3551	0.80977	0.223, 4.715	0.16	66.878	-74.2, 399.5
CYCLE 2 DAY 8	67	0.8400	0.45654	0.180, 2.645	-39.83	34.895	-85.1, 128.0	56	1.3004	0.65566	0.312, 2.880	-6.13	36.848	-68.2, 86.7
CYCLE 2 DAY 11	69	0.9976	0.81957	0.203, 5.676	-33.42	36.673	-85.0, 111.1	60	1.2885	0.89225	0.246, 5.553	-2.54	62.618	-74.0, 342.1
CYCLE 3 DAY 1	57	0.8744	0.57681	0.116, 2.720	-39.03	39.467	-87.0, 114.2	37	0.8716	0.37189	0.218, 1.875	-30.20	23.056	-82.1, 32.1
CYCLE 3 DAY 4	57	1.2332	0.74799	0.136, 4.384	-10.00	81.721	-83.8, 535.0	50	1.2135	0.64790	0.178, 3.317	-9.15	42.837	-82.9, 100.0
CYCLE 3 DAY 8	59	1.0931	0.62666	0.180, 3.200	-18.41	58.837	-81.0, 320.0	53	1.2315	0.63034	0.265, 2.981	-6.76	42.280	-80.6, 108.6
CYCLE 3 DAY 11	62	1.2291	0.72870	0.252, 3.462	-17.14	40.516	-79.3, 103.1	54	1.2487	0.59969	0.180, 2.776	-4.10	46.350	-70.2, 115.7
CYCLE 4 DAY 1	51	0.8883	0.52732	0.185, 3.000	-38.28	33.556	-84.5, 76.6	38	1.0429	0.50365	0.231, 2.270	-24.44	24.147	-69.1, 33.4
CYCLE 4 DAY 4	56	1.3452	0.74820	0.316, 4.064	-9.56	40.991	-82.8, 119.5	43	1.0609	0.54905	0.150, 2.590	-18.22	40.630	-82.9, 78.3

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas　　29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75							Bd N = 75						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 4 DAY 8	58	1.1732	0.59145	0.167, 2.639	-7.88	105.168	-83.1, 720.0	47	1.0606	0.55233	0.253, 2.600	-19.42	36.691	-79.5, 88.3
CYCLE 4 DAY 11	61	1.1711	0.72626	0.202, 3.131	-19.53	43.708	-81.1, 140.8	49	1.0747	0.56718	0.252, 2.396	-13.88	41.690	-86.4, 107.5
CYCLE 5 DAY 1	43	0.9694	0.54048	0.172, 2.336	-30.06	39.149	-92.2, 95.0	31	1.0128	0.64887	0.194, 2.680	-26.58	34.182	-83.3, 49.1
CYCLE 5 DAY 4	45	1.2730	0.88643	0.262, 4.715	1.56	143.338	-75.3, 905.0	40	1.0402	0.53834	0.189, 2.800	-18.81	36.786	-80.6, 60.4
CYCLE 5 DAY 8	54	1.1510	0.66661	0.250, 3.520	-6.72	117.540	-80.3, 795.0	40	1.1617	0.63536	0.243, 3.104	-7.10	44.025	-77.5, 149.1
CYCLE 5 DAY 11	52	1.2143	0.74908	0.143, 3.990	-15.29	49.651	-85.5, 203.5	45	1.1323	0.54766	0.168, 2.660	-8.13	43.989	-74.6, 96.2
CYCLE 6 DAY 1	43	0.9419	0.49308	0.199, 2.220	-26.58	87.174	-78.0, 500.0	25	0.8448	0.54123	0.153, 2.050	-29.33	42.620	-86.1, 109.9
CYCLE 6 DAY 4	36	1.1624	0.82763	0.210, 4.602	-17.62	36.743	-85.6, 55.6	34	1.1644	0.64937	0.173, 2.700	-10.69	39.183	-75.6, 70.2
CYCLE 6 DAY 8	51	1.0671	0.64372	0.210, 3.040	-10.27	127.538	-79.9, 850.0	36	1.1002	0.63113	0.226, 2.964	-12.25	36.552	-85.3, 54.7
CYCLE 6 DAY 11	47	1.0668	0.64233	0.297, 3.757	-20.24	48.251	-79.9, 200.0	38	1.1662	0.54905	0.197, 2.250	-5.68	45.984	-79.5, 128.3
CYCLE 7 DAY 1	43	0.9916	0.45759	0.262, 2.175	-32.59	38.628	-80.6, 152.0	22	0.7927	0.46166	0.147, 2.006	-29.00	39.933	-87.7, 70.4
CYCLE 7 DAY 4	36	1.1392	0.84038	0.291, 4.788	-7.18	103.854	-85.6, 555.0	26	1.0620	0.53741	0.261, 2.100	-15.60	44.020	-86.1, 100.0
CYCLE 7 DAY 8	44	1.0755	0.56512	0.291, 2.805	-22.68	41.004	-74.0, 132.3	31	1.0321	0.45541	0.281, 1.870	-7.89	41.573	-83.7, 69.4
CYCLE 7 DAY 11	43	1.1052	0.73481	0.193, 4.558	-16.42	43.769	-80.4, 156.0	31	1.1330	0.51475	0.226, 2.560	-12.28	40.424	-81.7, 66.6
CYCLE 8 DAY 1	34	1.0930	0.65471	0.327, 3.774	-24.91	42.559	-80.8, 116.0	21	0.8291	0.40973	0.243, 1.782	-29.89	31.086	-80.2, 47.2

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75						Bd N = 75					
					Percent Change from Baseline						Percent Change from Baseline	
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 8 DAY 4	22	1.0185	0.72409	0.249, 2.808	-4.16	128.517	-80.6, 540.0	20	1.0737	0.52313	0.283, 1.798	-22.41	33.232	-82.5, 37.3
CYCLE 8 DAY 8	36	1.0438	0.62240	0.248, 3.404	-14.83	99.573	-82.5, 495.0	24	1.1107	0.48336	0.248, 1.960	-19.69	36.284	-72.6, 62.8
CYCLE 8 DAY 11	38	1.1601	0.83708	0.332, 4.884	-17.68	54.308	-74.2, 192.4	28	1.1855	0.51262	0.410, 2.100	-14.18	40.882	-81.7, 84.5
CYCLE 9 DAY 1	36	0.9799	0.59924	0.275, 3.162	-36.38	31.387	-75.3, 83.5	17	0.8075	0.29989	0.179, 1.340	-37.57	19.575	-80.0, -8.3
CYCLE 9 DAY 8	35	1.0995	0.63414	0.227, 2.784	-23.46	52.297	-85.5, 231.0	26	1.1062	0.54817	0.277, 2.200	-22.05	29.970	-82.5, 22.9
CYCLE 9 DAY 15	41	1.1804	0.69648	0.249, 4.046	-17.66	48.175	-79.0, 226.5	27	1.0580	0.49974	0.216, 2.000	-22.46	32.724	-71.1, 40.0
CYCLE 10 DAY 1	30	1.1547	0.66418	0.323, 3.040	-24.03	45.987	-80.5, 177.0	15	0.9885	0.50140	0.396, 1.806	-30.20	25.702	-75.4, 0.0
CYCLE 10 DAY 8	31	1.1402	0.75760	0.270, 3.800	-23.03	56.484	-83.0, 240.0	23	1.1635	0.49638	0.328, 2.100	-12.68	26.823	-67.1, 26.7
CYCLE 10 DAY 15	40	1.0484	0.59558	0.075, 2.517	-24.63	53.716	-92.4, 260.5	25	1.1122	0.54093	0.292, 2.538	-16.30	31.231	-70.4, 50.3
CYCLE 11 DAY 1	28	1.0143	0.65495	0.289, 2.898	-33.87	34.019	-80.3, 85.0	13	0.8527	0.46994	0.150, 1.650	-39.36	27.156	-82.1, -1.8
CYCLE 11 DAY 8	32	0.9508	0.59538	0.296, 3.201	-25.96	67.969	-87.9, 310.0	20	1.2085	0.48683	0.372, 1.980	-9.06	25.442	-64.0, 33.7
CYCLE 11 DAY 15	36	1.0248	0.58851	0.210, 3.388	-18.32	66.852	-88.2, 335.0	20	1.1597	0.51514	0.334, 2.133	-13.82	27.543	-66.5, 27.3
CYCLE 12 DAY 1	29	1.0342	0.48318	0.301, 2.310	-27.69	35.081	-70.7, 101.5	12	0.9803	0.43559	0.320, 1.725	-30.65	19.911	-67.6, -1.4
CYCLE 12 DAY 8	25	0.9524	0.62533	0.301, 3.051	-24.87	70.824	-72.5, 300.0	15	0.9614	0.38538	0.318, 1.500	-17.11	41.973	-79.2, 60.0
CYCLE 12 DAY 15	33	1.0272	0.57297	0.369, 3.080	-21.38	47.468	-80.3, 185.0	19	1.0286	0.49727	0.317, 1.900	-14.82	33.628	-67.9, 40.0

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75							Bd N = 75						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 13 DAY 1	23	1.0028	0.59039	0.331, 2.686	-25.69	38.512	-82.8, 101.5	10	0.8885	0.55764	0.289, 2.150	-27.80	25.096	-76.0, 6.7
CYCLE 13 DAY 8	22	1.0270	0.71506	0.215, 3.360	-22.55	60.391	-81.1, 215.0	16	1.2499	0.63011	0.392, 2.590	-6.87	33.070	-75.5, 52.4
CYCLE 13 DAY 15	27	1.0311	0.60984	0.318, 3.198	-17.94	51.685	-67.7, 215.0	18	1.0589	0.45786	0.253, 1.850	-13.16	33.476	-59.2, 65.7
CYCLE 14 DAY 1	17	0.9829	0.46813	0.250, 1.729	-21.44	31.379	-69.1, 57.0	12	0.7835	0.44208	0.221, 1.578	-40.65	26.097	-75.6, -2.6
CYCLE 14 DAY 8	18	1.0523	0.58823	0.226, 2.424	-15.71	56.593	-72.0, 170.0	13	1.3129	0.49217	0.706, 2.500	-2.40	35.095	-55.9, 47.1
CYCLE 14 DAY 15	22	1.1666	0.74387	0.359, 3.900	-4.30	62.624	-55.8, 245.0	15	1.1909	0.60605	0.267, 2.250	-16.12	27.706	-67.5, 15.7
CYCLE 15 DAY 1	17	1.1165	0.75231	0.288, 3.360	-13.32	58.043	-64.4, 179.5	9	0.7924	0.56249	0.305, 2.062	-40.20	26.471	-73.4, 2.3
CYCLE 15 DAY 8	15	0.9167	0.55171	0.220, 1.869	-11.16	104.947	-82.7, 355.0	10	1.3492	0.63975	0.531, 2.520	-7.55	32.955	-66.8, 48.2
CYCLE 15 DAY 15	18	1.0707	0.67810	0.319, 3.328	-8.11	64.776	-64.2, 235.0	11	1.0974	0.64535	0.363, 2.105	-14.32	44.064	-65.1, 77.1
CYCLE 16 DAY 1	14	0.9821	0.78974	0.242, 3.375	-24.19	33.684	-75.5, 66.5	10	0.8586	0.59861	0.302, 2.190	-27.21	44.848	-73.9, 69.6
CYCLE 16 DAY 8	11	1.0102	0.62893	0.156, 2.223	-30.72	36.277	-84.2, 55.6	10	1.3150	0.53353	0.615, 2.300	-7.81	32.384	-57.2, 45.7
CYCLE 16 DAY 15	15	0.9896	0.57473	0.337, 2.688	-27.18	21.611	-65.8, 6.1	13	1.2191	0.52968	0.350, 2.065	-6.37	39.746	-56.0, 77.1
CYCLE 17 DAY 1	15	1.1306	0.67835	0.377, 3.162	-25.23	20.263	-61.8, 0.7	7	0.9121	0.72968	0.113, 2.359	-34.43	34.058	-90.6, 17.1
CYCLE 17 DAY 8	12	0.9188	0.73549	0.195, 3.016	-36.50	24.601	-80.2, -6.1	10	1.2908	0.59345	0.600, 2.331	-12.29	26.926	-60.6, 37.1
CYCLE 17 DAY 15	17	1.0495	0.50651	0.247, 2.160	-22.45	25.679	-74.9, 27.9	12	1.0712	0.59884	0.354, 2.196	-17.87	36.306	-68.3, 37.1

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75								Bd N = 75							
					Percent Change from Baseline								Percent Change from Baseline			
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max		N#	Mean	SD	Min, Max	Mean	SD	Min, Max	
CYCLE 18 DAY 1	13	0.9538	0.47570	0.362, 1.957	-30.56	20.399	-62.1,	1.3	8	0.8086	0.59700	0.300, 2.107	-35.55	27.424	-75.1,	4.6
CYCLE 18 DAY 8	10	1.0030	0.54744	0.250, 2.184	-31.86	32.776	-74.6,	46.1	8	1.4286	0.52871	0.787, 2.280	0.94	26.525	-36.0,	34.1
CYCLE 18 DAY 15	15	1.2434	0.71434	0.324, 3.484	-9.99	26.887	-67.1,	40.2	11	1.2849	0.59221	0.309, 2.132	2.34	44.782	-44.2,	102.9
CYCLE 19 DAY 1	11	1.0339	0.67595	0.279, 2.759	-24.45	21.060	-71.7,	13.4	6	0.8548	0.56316	0.378, 1.739	-28.02	21.952	-60.7,	-5.1
CYCLE 19 DAY 8	13	0.9468	0.61071	0.240, 2.465	-29.48	34.517	-81.1,	28.4	7	1.2976	0.52215	0.602, 2.109	-2.67	32.665	-42.6,	36.7
CYCLE 19 DAY 15	13	0.9407	0.40442	0.381, 1.660	-25.88	20.840	-61.4,	11.9	9	1.1641	0.56526	0.334, 2.167	-3.24	43.396	-44.0,	78.6
CYCLE 20 DAY 1	10	0.9646	0.52600	0.249, 2.047	-24.55	28.698	-74.7,	17.9	4	0.7605	0.30531	0.353, 1.009	-29.48	29.765	-70.7,	0.0
CYCLE 20 DAY 8	9	0.8281	0.28796	0.409, 1.331	-22.61	23.958	-60.9,	13.4	5	1.4028	0.22180	1.042, 1.590	25.90	60.291	-24.6,	125.7
CYCLE 20 DAY 15	13	0.9115	0.39038	0.236, 1.463	-22.28	27.479	-76.1,	29.9	9	1.1923	0.57088	0.346, 2.320	-2.62	35.086	-42.0,	54.3
CYCLE 21 DAY 1	9	0.7369	0.31844	0.268, 1.320	-31.23	27.812	-67.8,	10.8	6	0.7070	0.33868	0.291, 1.005	-31.20	20.602	-71.1,	-14.4
CYCLE 21 DAY 8	10	0.9000	0.42673	0.202, 1.484	-27.62	30.799	-75.0,	32.5	7	1.2179	0.35293	0.673, 1.800	-6.61	29.025	-35.8,	45.7
CYCLE 21 DAY 15	11	0.9991	0.47299	0.254, 1.739	-13.15	30.608	-74.2,	32.4	8	1.2886	0.55691	0.349, 2.133	5.14	39.071	-42.0,	62.9
CYCLE 22 DAY 1	8	0.7404	0.31518	0.277, 1.140	-22.28	32.970	-65.7,	37.3	5	0.7166	0.23868	0.376, 1.030	-25.07	14.434	-43.2,	-8.9
CYCLE 22 DAY 8	5	0.6054	0.36283	0.226, 1.052	-26.02	47.898	-77.1,	27.9	5	1.0418	0.31767	0.549, 1.400	-10.49	36.749	-54.4,	38.6
CYCLE 22 DAY 15	10	0.8697	0.53744	0.245, 1.940	-20.03	38.634	-70.2,	64.2	7	1.0620	0.43980	0.367, 1.800	-9.73	24.141	-34.7,	35.7

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75							Bd N = 75						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 23 DAY 1	7	0.5311	0.21599	0.259, 0.910	-36.90	36.240	-73.7, 35.8	6	1.2328	1.01110	0.292, 3.200	1.77	46.906	-34.9, 88.2
CYCLE 23 DAY 8	4	0.6170	0.27611	0.220, 0.860	-15.93	48.050	-77.7, 28.4	4	1.4553	0.38358	1.111, 2.000	24.62	44.103	-19.6, 85.7
CYCLE 23 DAY 15	5	0.7104	0.18168	0.392, 0.830	-24.91	30.536	-60.2, 23.9	6	1.2288	0.74496	0.378, 2.625	8.72	38.438	-25.3, 60.0
CYCLE 24 DAY 1	6	0.7802	0.20756	0.451, 0.996	-11.35	29.536	-54.3, 25.4	5	0.7248	0.29379	0.350, 1.034	-25.94	13.536	-49.0, -15.9
CYCLE 24 DAY 8	4	0.5793	0.21219	0.326, 0.830	-22.89	38.237	-66.9, 23.9	3	1.2510	0.13173	1.128, 1.390	23.72	48.287	-18.4, 76.4
CYCLE 24 DAY 15	6	0.7488	0.20864	0.366, 0.920	-13.73	34.153	-62.9, 32.8	4	0.9885	0.48010	0.346, 1.421	-10.79	17.025	-30.2, 4.1
CYCLE 25 DAY 1	6	0.6585	0.22775	0.375, 0.988	-24.50	32.025	-62.0, 19.4	2	0.9270	0.86267	0.317, 1.537	-4.19	31.715	-26.6, 18.2
CYCLE 25 DAY 8	3	0.4907	0.14644	0.328, 0.612	-36.82	35.927	-66.7, 3.0	1	1.1300		1.130, 1.130	61.43		61.4, 61.4
CYCLE 25 DAY 15	5	0.6720	0.26426	0.335, 0.950	-29.42	26.397	-66.0, -4.9	1	0.2200		0.220, 0.220	-49.07		-49.1, -49.1
CYCLE 26 DAY 1	4	0.6518	0.31309	0.281, 1.035	-25.95	39.723	-71.5, 20.4	2	0.6615	0.33729	0.423, 0.900	-14.43	17.456	-26.8, -2.1
CYCLE 26 DAY 8	4	0.5775	0.17643	0.314, 0.688	-33.20	32.719	-68.2, 10.8	1	1.5000		1.500, 1.500	22.05		22.1, 22.1
CYCLE 26 DAY 15	5	0.7290	0.26675	0.434, 1.069	-24.23	23.271	-56.0, -6.4	2	0.7650	0.60104	0.340, 1.190	-12.23	12.815	-21.3, -3.2
CYCLE 27 DAY 1	4	0.7960	0.35544	0.346, 1.203	-9.10	48.257	-64.9, 49.5	2	0.6730	0.38184	0.403, 0.943	-14.99	11.708	-23.3, -6.7
CYCLE 27 DAY 8	4	0.4918	0.17752	0.320, 0.672	-47.29	12.595	-63.5, -32.7	1	1.3300		1.330, 1.330	8.22		8.2, 8.2
CYCLE 27 DAY 15	5	0.8292	0.26571	0.615, 1.239	-13.66	22.106	-39.6, 7.4	2	0.6650	0.51619	0.300, 1.030	-23.37	10.157	-30.6, -16.2

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75							Bd N = 75						
					Percent Change from Baseline							Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 28 DAY 1	4	0.6923	0.38517	0.389, 1.232	-22.71	41.145	-60.5, 18.5	3	0.8043	0.41833	0.425, 1.253	-14.38	25.252	-43.5, 2.0
CYCLE 28 DAY 8	4	0.4623	0.14787	0.296, 0.599	-49.18	14.727	-70.0, -36.0	1	1.4450		1.445, 1.445	17.58		17.6, 17.6
CYCLE 28 DAY 15	4	0.8043	0.12557	0.688, 0.954	-8.45	46.494	-40.5, 60.6	1	0.3510		0.351, 0.351	-18.75		-18.8, -18.8
CYCLE 29 DAY 1	3	0.7040	0.34263	0.374, 1.058	-25.76	15.321	-37.0, -8.3	2	0.5675	0.31042	0.348, 0.787	-27.70	11.681	-36.0, -19.4
CYCLE 29 DAY 8	2	0.5335	0.04738	0.500, 0.567	-29.53	19.388	-43.2, -15.8	1	1.3500		1.350, 1.350	9.85		9.8, 9.8
CYCLE 29 DAY 15	3	0.8423	0.32116	0.500, 1.137	-9.40	7.294	-15.8, -1.5	2	0.8570	0.75378	0.324, 1.390	-5.95	26.941	-25.0, 13.1
CYCLE 30 DAY 1	3	0.9177	0.32686	0.600, 1.253	-0.11	9.295	-9.9, 8.6	2	0.5930	0.36487	0.335, 0.851	-26.61	5.871	-30.8, -22.5
CYCLE 30 DAY 8	2	0.6010	0.14284	0.500, 0.702	-22.78	9.832	-29.7, -15.8	1	0.3400		0.340, 0.340	-72.34		-72.3, -72.3
CYCLE 30 DAY 15	3	0.9090	0.33023	0.600, 1.257	-0.99	11.056	-12.9, 8.9	2	0.8995	0.82095	0.319, 1.480	-2.87	32.937	-26.2, 20.4
CYCLE 31 DAY 1	3	0.8873	0.29692	0.600, 1.193	-2.87	8.860	-13.0, 3.4	0						
CYCLE 31 DAY 8	2	0.6690	0.09758	0.600, 0.738	-12.56	19.188	-26.1, 1.0	0						
CYCLE 31 DAY 15	2	0.6780	0.11031	0.600, 0.756	-11.66	17.914	-24.3, 1.0	0						
CYCLE 32 DAY 1	2	0.6785	0.41507	0.385, 0.972	-18.94	22.969	-35.2, -2.7	0						
CYCLE 32 DAY 8	1	0.7920		0.792, 0.792	-20.72		-20.7, -20.7	0						
CYCLE 32 DAY 15	1	0.8580		0.858, 0.858	-14.11		-14.1, -14.1	0						

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas 29APR2[redacted]:05:52:02

Protocol: CA204009

Summary Statistics for Lymphocytes (Absolute)
All Treated Subjects

Visit	E-Bd N = 75						Bd N = 75					
				Percent Change from Baseline						Percent Change from Baseline		
	N#	Mean	SD	Min, Max	Mean	SD	Min, Max	N#	Mean	SD	Min, Max	Mean	SD	Min, Max
CYCLE 33 DAY 1	1	0.7560		0.756, 0.756	-24.32		-24.3, -24.3	0						
CYCLE 33 DAY 8	1	0.6750		0.675, 0.675	-32.43		-32.4, -32.4	0						
CYCLE 33 DAY 15	1	0.8200		0.820, 0.820	-17.92		-17.9, -17.9	0						
CYCLE 34 DAY 1	1	0.7370		0.737, 0.737	-26.23		-26.2, -26.2	0						
CYCLE 34 DAY 8	1	0.7110		0.711, 0.711	-28.83		-28.8, -28.8	0						
CYCLE 34 DAY 15	1	0.8010		0.801, 0.801	-19.82		-19.8, -19.8	0						

Number of subjects with baseline value and cycle X.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb-lympa.sas

29APR2[redacted]:05:52:02

APPENDIX 68　肝機能及び腎機能検査値の最異常GRADE（004 試験、治験薬投与例）

Lab Test Description Toxicity Grade	E-Ld N = 318	Ld N = 317	Total N = 635
ALKALINE PHOSPHATASE (ALP)			
GRADE 0	195 (61.3)	221 (70.2)	416 (65.7)
GRADE 1	101 (31.8)	85 (27.0)	186 (29.4)
GRADE 2	18 (5.7)	9 (2.9)	27 (4.3)
GRADE 3	4 (1.3)	0	4 (0.6)
GRADE 4	0	0	0
NOT REPORTED	0	2	2
ANY GRADE	123 (38.7)	94 (29.8)	217 (34.3)
GRADE 3-4	4 (1.3)	0	4 (0.6)
ASPARTATE AMINOTRANSFERASE (AST)			
GRADE 0	166 (52.4)	180 (57.3)	346 (54.8)
GRADE 1	126 (39.7)	109 (34.7)	235 (37.2)
GRADE 2	16 (5.0)	17 (5.4)	33 (5.2)
GRADE 3	9 (2.8)	8 (2.5)	17 (2.7)
GRADE 4	0	0	0
NOT REPORTED	1	3	4
ANY GRADE	151 (47.6)	134 (42.7)	285 (45.2)
GRADE 3-4	9 (2.8)	8 (2.5)	17 (2.7)
ALANINE AMINOTRANSFERASE (ALT)			
GRADE 0	139 (43.7)	150 (47.8)	289 (45.7)
GRADE 1	130 (40.9)	115 (36.6)	245 (38.8)
GRADE 2	33 (10.4)	36 (11.5)	69 (10.9)
GRADE 3	16 (5.0)	12 (3.8)	28 (4.4)
GRADE 4	0	1 (0.3)	1 (0.2)
NOT REPORTED	0	3	3
ANY GRADE	179 (56.3)	164 (52.2)	343 (54.3)
GRADE 3-4	16 (5.0)	13 (4.1)	29 (4.6)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb.sas　10MAR2015:13:33:46

Protocol: CA204004

Renal and Liver Laboratory Test Results Summary of Worst Toxicity Grade - SI Units
All Treated Subjects

Lab Test Description Toxicity Grade	E-Ld N = 318	Ld N = 317	Total N = 635
BILIRUBIN, TOTAL			
GRADE 0	238 (74.8)	225 (71.7)	463 (73.3)
GRADE 1	47 (14.8)	53 (16.9)	100 (15.8)
GRADE 2	25 (7.9)	34 (10.8)	59 (9.3)
GRADE 3	8 (2.5)	2 (0.6)	10 (1.6)
GRADE 4	0	0	0
NOT REPORTED	0	3	3
ANY GRADE	80 (25.2)	89 (28.3)	169 (26.7)
GRADE 3-4	8 (2.5)	2 (0.6)	10 (1.6)
CREATININE			
GRADE 0	157 (49.4)	173 (54.6)	330 (52.0)
GRADE 1	100 (31.4)	93 (29.3)	193 (30.4)
GRADE 2	53 (16.7)	42 (13.2)	95 (15.0)
GRADE 3	5 (1.6)	7 (2.2)	12 (1.9)
GRADE 4	3 (0.9)	2 (0.6)	5 (0.8)
ANY GRADE	161 (50.6)	144 (45.4)	305 (48.0)
GRADE 3-4	8 (2.5)	9 (2.8)	17 (2.7)
ALBUMIN			
GRADE 0	82 (26.7)	104 (34.4)	186 (30.5)
GRADE 1	105 (34.2)	120 (39.7)	225 (36.9)
GRADE 2	108 (35.2)	71 (23.5)	179 (29.4)
GRADE 3	12 (3.9)	7 (2.3)	19 (3.1)
GRADE 4	0	0	0
NOT REPORTED	11	15	26
ANY GRADE	225 (73.3)	198 (65.6)	423 (69.5)
GRADE 3-4	12 (3.9)	7 (2.3)	19 (3.1)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb.sas 10MAR2015:13:33:46

APPENDIX 69　　ベースラインにおける肝機能及び腎機能検査値の最異常GRADE（004 試験、治験薬投与例）

Lab Test Description Toxicity Grade	E-Ld N = 318	Ld N = 317	Total N = 635
ALKALINE PHOSPHATASE (ALP)			
GRADE 0	195 (61.3)	221 (70.2)	416 (65.7)
GRADE 1	101 (31.8)	85 (27.0)	186 (29.4)
GRADE 2	18 (5.7)	9 (2.9)	27 (4.3)
GRADE 3	4 (1.3)	0	4 (0.6)
GRADE 4	0	0	0
NOT REPORTED	0	2	2
ANY GRADE	123 (38.7)	94 (29.8)	217 (34.3)
GRADE 3-4	4 (1.3)	0	4 (0.6)
ASPARTATE AMINOTRANSFERASE (AST)			
GRADE 0	166 (52.4)	180 (57.3)	346 (54.8)
GRADE 1	126 (39.7)	109 (34.7)	235 (37.2)
GRADE 2	16 (5.0)	17 (5.4)	33 (5.2)
GRADE 3	9 (2.8)	8 (2.5)	17 (2.7)
GRADE 4	0	0	0
NOT REPORTED	1	3	4
ANY GRADE	151 (47.6)	134 (42.7)	285 (45.2)
GRADE 3-4	9 (2.8)	8 (2.5)	17 (2.7)
ALANINE AMINOTRANSFERASE (ALT)			
GRADE 0	139 (43.7)	150 (47.8)	289 (45.7)
GRADE 1	130 (40.9)	115 (36.6)	245 (38.8)
GRADE 2	33 (10.4)	36 (11.5)	69 (10.9)
GRADE 3	16 (5.0)	12 (3.8)	28 (4.4)
GRADE 4	0	1 (0.3)	1 (0.2)
NOT REPORTED	0	3	3
ANY GRADE	179 (56.3)	164 (52.2)	343 (54.3)
GRADE 3-4	16 (5.0)	13 (4.1)	29 (4.6)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb.sas　　10MAR2015:13:33:46

Protocol: CA204004

Renal and Liver Laboratory Test Results Summary of Worst Toxicity Grade - SI Units
All Treated Subjects

Lab Test Description Toxicity Grade	E-Ld N = 318	Ld N = 317	Total N = 635
BILIRUBIN, TOTAL			
GRADE 0	238 (74.8)	225 (71.7)	463 (73.3)
GRADE 1	47 (14.8)	53 (16.9)	100 (15.8)
GRADE 2	25 (7.9)	34 (10.8)	59 (9.3)
GRADE 3	8 (2.5)	2 (0.6)	10 (1.6)
GRADE 4	0	0	0
NOT REPORTED	0	3	3
ANY GRADE	80 (25.2)	89 (28.3)	169 (26.7)
GRADE 3-4	8 (2.5)	2 (0.6)	10 (1.6)
CREATININE			
GRADE 0	157 (49.4)	173 (54.6)	330 (52.0)
GRADE 1	100 (31.4)	93 (29.3)	193 (30.4)
GRADE 2	53 (16.7)	42 (13.2)	95 (15.0)
GRADE 3	5 (1.6)	7 (2.2)	12 (1.9)
GRADE 4	3 (0.9)	2 (0.6)	5 (0.8)
ANY GRADE	161 (50.6)	144 (45.4)	305 (48.0)
GRADE 3-4	8 (2.5)	9 (2.8)	17 (2.7)
ALBUMIN			
GRADE 0	82 (26.7)	104 (34.4)	186 (30.5)
GRADE 1	105 (34.2)	120 (39.7)	225 (36.9)
GRADE 2	108 (35.2)	71 (23.5)	179 (29.4)
GRADE 3	12 (3.9)	7 (2.3)	19 (3.1)
GRADE 4	0	0	0
NOT REPORTED	11	15	26
ANY GRADE	225 (73.3)	198 (65.6)	423 (69.5)
GRADE 3-4	12 (3.9)	7 (2.3)	19 (3.1)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms111382/stats/primary/prog/tables/rt-lb.sas 10MAR2015:13:33:46

APPENDIX 70　肝機能及び腎機能検査値の最異常GRADE（009 試験、治験薬投与例）

Lab Test Description Toxicity Grade	E-Bd N = 75	Bd N = 75	Total N = 150
ALKALINE PHOSPHATASE (ALP)			
GRADE 0	51 (69.9)	64 (86.5)	115 (78.2)
GRADE 1	20 (27.4)	10 (13.5)	30 (20.4)
GRADE 2	1 (1.4)	0	1 (0.7)
GRADE 3	1 (1.4)	0	1 (0.7)
GRADE 4	0	0	0
NOT REPORTED	2	1	3
ANY GRADE	22 (30.1)	10 (13.5)	32 (21.8)
GRADE 3-4	1 (1.4)	0	1 (0.7)
ASPARTATE AMINOTRANSFERASE (AST)			
GRADE 0	43 (60.6)	46 (63.9)	89 (62.2)
GRADE 1	22 (31.0)	24 (33.3)	46 (32.2)
GRADE 2	4 (5.6)	2 (2.8)	6 (4.2)
GRADE 3	1 (1.4)	0	1 (0.7)
GRADE 4	1 (1.4)	0	1 (0.7)
NOT REPORTED	4	3	7
ANY GRADE	28 (39.4)	26 (36.1)	54 (37.8)
GRADE 3-4	2 (2.8)	0	2 (1.4)
ALANINE AMINOTRANSFERASE (ALT)			
GRADE 0	48 (65.8)	47 (63.5)	95 (64.6)
GRADE 1	20 (27.4)	21 (28.4)	41 (27.9)
GRADE 2	2 (2.7)	6 (8.1)	8 (5.4)
GRADE 3	2 (2.7)	0	2 (1.4)
GRADE 4	1 (1.4)	0	1 (0.7)
NOT REPORTED	2	1	3
ANY GRADE	25 (34.2)	27 (36.5)	52 (35.4)
GRADE 3-4	3 (4.1)	0	3 (2.0)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb.sas　29APR2[redacted]:04:11:17

Protocol: CA204009

Renal and Liver Laboratory Test Results Summary of Worst Toxicity Grade - SI Units
All Treated Subjects

Lab Test Description Toxicity Grade	E-Bd N = 75	Bd N = 75	Total N = 150
BILIRUBIN, TOTAL			
GRADE 0	59 (80.8)	64 (86.5)	123 (83.7)
GRADE 1	10 (13.7)	8 (10.8)	18 (12.2)
GRADE 2	4 (5.5)	2 (2.7)	6 (4.1)
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	2	1	3
ANY GRADE	14 (19.2)	10 (13.5)	24 (16.3)
GRADE 3-4	0	0	0
CREATININE			
GRADE 0	49 (67.1)	42 (56.8)	91 (61.9)
GRADE 1	14 (19.2)	25 (33.8)	39 (26.5)
GRADE 2	6 (8.2)	7 (9.5)	13 (8.8)
GRADE 3	4 (5.5)	0	4 (2.7)
GRADE 4	0	0	0
NOT REPORTED	2	1	3
ANY GRADE	24 (32.9)	32 (43.2)	56 (38.1)
GRADE 3-4	4 (5.5)	0	4 (2.7)
ALBUMIN			
GRADE 0	15 (21.7)	27 (40.9)	42 (31.1)
GRADE 1	34 (49.3)	27 (40.9)	61 (45.2)
GRADE 2	20 (29.0)	8 (12.1)	28 (20.7)
GRADE 3	0	4 (6.1)	4 (3.0)
GRADE 4	0	0	0
NOT REPORTED	6	9	15
ANY GRADE	54 (78.3)	39 (59.1)	93 (68.9)
GRADE 3-4	0	4 (6.1)	4 (3.0)

Toxicity Scale: CTC version 3.0
Includes laboratory test results with date after the first dosing date and on or prior to the last dosing date +60 days.
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb.sas 29APR2[redacted]:04:11:17

APPENDIX 71　　ベースラインにおける肝機能及び腎機能検査値の最異常GRADE（009 試験、治験薬投与例）

Lab Test Description Toxicity Grade	E-Bd N = 77	Bd N = 75	Total N = 152
ALKALINE PHOSPHATASE (ALP)			
GRADE 0	69 (94.5)	71 (94.7)	140 (94.6)
GRADE 1	4 (5.5)	4 (5.3)	8 (5.4)
GRADE 2	0	0	0
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	4	0	4
ANY GRADE	4 (5.5)	4 (5.3)	8 (5.4)
GRADE 3-4	0	0	0
ASPARTATE AMINOTRANSFERASE (AST)			
GRADE 0	66 (90.4)	67 (90.5)	133 (90.5)
GRADE 1	7 (9.6)	6 (8.1)	13 (8.8)
GRADE 2	0	1 (1.4)	1 (0.7)
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	4	1	5
ANY GRADE	7 (9.6)	7 (9.5)	14 (9.5)
GRADE 3-4	0	0	0
ALANINE AMINOTRANSFERASE (ALT)			
GRADE 0	70 (95.9)	69 (92.0)	139 (93.9)
GRADE 1	3 (4.1)	6 (8.0)	9 (6.1)
GRADE 2	0	0	0
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	4	0	4
ANY GRADE	3 (4.1)	6 (8.0)	9 (6.1)
GRADE 3-4	0	0	0

Toxicity Scale: CTC version 3.0
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb.sas　　29APR2[redacted]:04:12:30

Protocol: CA204009

Baseline Renal and Liver Laboratory Test Results Summary - SI Units
All Randomized Subjects

Lab Test Description Toxicity Grade	E-Bd N = 77	Bd N = 75	Total N = 152
BILIRUBIN, TOTAL			
GRADE 0	66 (91.7)	72 (97.3)	138 (94.5)
GRADE 1	5 (6.9)	2 (2.7)	7 (4.8)
GRADE 2	1 (1.4)	0	1 (0.7)
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	5	1	6
ANY GRADE	6 (8.3)	2 (2.7)	8 (5.5)
GRADE 3-4	0	0	0
CREATININE			
GRADE 0	60 (82.2)	61 (81.3)	121 (81.8)
GRADE 1	9 (12.3)	13 (17.3)	22 (14.9)
GRADE 2	4 (5.5)	1 (1.3)	5 (3.4)
GRADE 3	0	0	0
GRADE 4	0	0	0
NOT REPORTED	4	0	4
ANY GRADE	13 (17.8)	14 (18.7)	27 (18.2)
GRADE 3-4	0	0	0
ALBUMIN			
GRADE 0	41 (65.1)	41 (71.9)	82 (68.3)
GRADE 1	17 (27.0)	14 (24.6)	31 (25.8)
GRADE 2	5 (7.9)	1 (1.8)	6 (5.0)
GRADE 3	0	1 (1.8)	1 (0.8)
GRADE 4	0	0	0
NOT REPORTED	14	18	32
ANY GRADE	22 (34.9)	16 (28.1)	38 (31.7)
GRADE 3-4	0	1 (1.8)	1 (0.8)

Toxicity Scale: CTC version 3.0
Percentages for each lab test are out of the number of treated subjects with labs recorded in the period.
Program Source: /projects/bms209459/stats/primary/prog/tables/rt-lb.sas 29APR2[redacted]:04:12:30

1 2.7.1 で引用した参考文献

【モジュール 2.7.1、5 項】を参照のこと。

2 2.7.2 で引用した参考文献

【モジュール 2.7.2、6 項】を参照のこと。

3 2.7.3 で引用した参考文献

該当なし

4 2.7.4 で引用した参考文献

【モジュール 2.7.4、7 項】を参照のこと。