3. 付録

3.1 有害事象の発現例数

3.1.1 EMR200095-007 試験

表 62 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-007 試験

Part: A

	Treatment Y (N=6)					
SYSTEM ORGAN CLASS/ Preferred term	Related			Unrelated		
	e	n	(%)	e	n	(%)
TOTAL SUBJECTS	4	2	33.3	4	2	33.3
胃腸障害	3	1	16.7			
腹部不快感	1	1	16.7			
下痢	1	1	16.7			
鼓腸	1	1	16.7			
一般・全身障害および投与部位の状態				1	1	16.7
血管穿刺部位疼痛				1	1	16.7
筋骨格系および結合組織障害				2	2	33.3
筋痙縮				1	1	16.7
筋肉痛				1	1	16.7
神経系障害	1	1	16.7			
傾眠	1	1	16.7			
腎および尿路障害				1	1	16.7
排尿困難				1	1	16.7

N = number of subjects exposed per treatment; n = number of subjects that experienced the adverse event per treatment.
e = number of times the adverse event occurred.
The percentage represents the number of subjects as a % of the total number of subjects per treatment.
Adverse events are classified according to MedDRA Version 16.1
Treatment Y=500 mg MSC2156119J + 2.5 MBq ^{14}C-MSC2156119J.
Treatment Z=500 mg MSC2156119J + IV tracer dose of ^{14}C-MSC2156119J after 4 hours.
Treatment A=100 mg MSC2156119J oral solution; B=100 mg MSC2156119J Tablet 1; C=100 mg MSC2156119J Tablet 2.

表 62　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-007 試験（続き）

Part: B

SYSTEM ORGAN CLASS/ Preferred term	Treatment Z (N=6) Related e	Related n	Related (%)	Unrelated e	Unrelated n	Unrelated (%)
TOTAL SUBJECTS	4	2	33.3	7	4	66.7
耳および迷路障害				1	1	16.7
耳痛				1	1	16.7
胃腸障害	3	2	33.3	3	3	50.0
腹部不快感				1	1	16.7
腹痛	1	1	16.7	1	1	16.7
下痢	1	1	16.7			
口唇乾燥				1	1	16.7
悪心	1	1	16.7			
筋骨格系および結合組織障害				1	1	16.7
関節痛				1	1	16.7
神経系障害	1	1	16.7	2	1	16.7
頭痛				1	1	16.7
失神寸前の状態	1	1	16.7	1	1	16.7

N = number of subjects exposed per treatment; n = number of subjects that experienced the adverse event per treatment.
e = number of times the adverse event occurred.
The percentage represents the number of subjects as a % of the total number of subjects per treatment.
Adverse events are classified according to MedDRA Version 16.1
Treatment Y=500 mg MSC2156119J + 2.5 MBq ^{14}C-MSC2156119J.
Treatment Z=500 mg MSC2156119J + IV tracer dose of ^{14}C-MSC2156119J after 4 hours.
Treatment A=100 mg MSC2156119J oral solution; B=100 mg MSC2156119J Tablet 1; C=100 mg MSC2156119J Tablet 2.

表 62　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-007 試験（続き）

Part: C

SYSTEM ORGAN CLASS/ Preferred term	Treatment A (N=15)						Treatment B (N=14)						Treatment C (N=15)					
	Related			Unrelated			Related			Unrelated			Related			Unrelated		
	e	n	(%)	e	n	(%)	e	n	(%)	e	n	(%)	e	n	(%)	e	n	(%)
TOTAL SUBJECTS	1	1	6.7	18	10	66.7	3	2	14.3	15	9	64.3	2	2	13.3	8	8	53.3
胃腸障害				1	1	6.7	3	2	14.3	7	5	35.7				1	1	6.7
腹部膨満							2	2	14.3	1	1	7.1						
腹痛							1	1	7.1	2	2	14.3				1	1	6.7
アフタ性口内炎				1	1	6.7												
下痢										2	2	14.3						
変色便										1	1	7.1						
歯肉痛										1	1	7.1						
一般・全身障害および投与部位の状態										1	1	7.1				2	2	13.3
無力症																1	1	6.7
血管穿刺部位内出血										1	1	7.1						
血管穿刺部位疼痛																1	1	6.7
感染症および寄生虫症				2	2	13.3				2	2	14.3						
鼻咽頭炎										2	2	14.3						
鼻炎				2	2	13.3												
臨床検査				1	1	6.7				1	1	7.1						

N = number of subjects exposed per treatment; n = number of subjects that experienced the adverse event per treatment.
e = number of times the adverse event occurred.
The percentage represents the number of subjects as a % of the total number of subjects per treatment.
Adverse events are classified according to MedDRA Version 16.1
Treatment Y=500 mg MSC2156119J + 2.5 MBq ^{14}C-MSC2156119J.
Treatment Z=500 mg MSC2156119J + IV tracer dose of ^{14}C-MSC2156119J after 4 hours.
Treatment A=100 mg MSC2156119J oral solution; B=100 mg MSC2156119J Tablet 1; C=100 mg MSC2156119J Tablet 2.

表 62　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-007 試験（続き）

Part: C

SYSTEM ORGAN CLASS/ Preferred term	Treatment A (N=15) Related e	Related n	Related (%)	Unrelated e	Unrelated n	Unrelated (%)	Treatment B (N=14) Related e	Related n	Related (%)	Unrelated e	Unrelated n	Unrelated (%)	Treatment C (N=15) Related e	Related n	Related (%)	Unrelated e	Unrelated n	Unrelated (%)
リパーゼ増加				1	1	6.7				1	1	7.1						
筋骨格系および結合組織障害				3	3	20.0										2	2	13.3
背部痛				1	1	6.7												
筋痙縮				1	1	6.7												
筋肉痛				1	1	6.7										1	1	6.7
四肢痛																1	1	6.7
神経系障害	1	1	6.7	7	4	26.7				2	2	14.3	2	2	13.3	3	3	20.0
頭痛				5	3	20.0				2	2	14.3	2	2	13.3	3	3	20.0
傾眠	1	1	6.7	2	1	6.7												
精神障害										1	1	7.1						
異常な夢										1	1	7.1						
腎および尿路障害				1	1	6.7												
排尿困難				1	1	6.7												
呼吸器、胸郭および縦隔障害				2	2	13.3												

N = number of subjects exposed per treatment; n = number of subjects that experienced the adverse event per treatment.
e = number of times the adverse event occurred.
The percentage represents the number of subjects as a % of the total number of subjects per treatment.
Adverse events are classified according to MedDRA Version 16.1
Treatment Y=500 mg MSC2156119J + 2.5 MBq ^{14}C-MSC2156119J.
Treatment Z=500 mg MSC2156119J + IV tracer dose of ^{14}C-MSC2156119J after 4 hours.
Treatment A=100 mg MSC2156119J oral solution; B=100 mg MSC2156119J Tablet 1; C=100 mg MSC2156119J Tablet 2.

表 62 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-007 試験（続き）

Part: C

SYSTEM ORGAN CLASS/ Preferred term	Treatment A (N=15) Related e	n (%)	Unrelated e	n (%)	Treatment B (N=14) Related e	n (%)	Unrelated e	n (%)	Treatment C (N=15) Related e	n (%)	Unrelated e	n (%)
咽喉乾燥			1	1 6.7								
口腔咽頭痛			1	1 6.7								
皮膚および皮下組織障害			1	1 6.7			1	1 7.1				
多汗症			1	1 6.7								
皮膚疼痛							1	1 7.1				

N = number of subjects exposed per treatment; n = number of subjects that experienced the adverse event per treatment.
e = number of times the adverse event occurred.
The percentage represents the number of subjects as a % of the total number of subjects per treatment.
Adverse events are classified according to MedDRA Version 16.1
Treatment Y=500 mg MSC2156119J + 2.5 MBq ^{14}C-MSC2156119J.
Treatment Z=500 mg MSC2156119J + IV tracer dose of ^{14}C-MSC2156119J after 4 hours.
Treatment A=100 mg MSC2156119J oral solution; B=100 mg MSC2156119J Tablet 1; C=100 mg MSC2156119J Tablet 2.

3.1.2 MS200095-0044 試験

表 63 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験

Part A

Primary System Organ Class Preferred Term	Overall N=40 (100%) Not related N=40 (100%) n (%) e	 Related N=40 (100%) n (%) e
Subjects with at least one event	16 (40.0) 22	17 (42.5) 29
眼障害	2 (5.0) 2	0 (0.0) 0
眼痛	1 (2.5) 1	0 (0.0) 0
視力障害	1 (2.5) 1	0 (0.0) 0
胃腸障害	3 (7.5) 3	13 (32.5) 21
腹痛	0 (0.0) 0	3 (7.5) 3
下腹部痛	1 (2.5) 1	0 (0.0) 0
上腹部痛	0 (0.0) 0	1 (2.5) 1
異常便	0 (0.0) 0	1 (2.5) 1
下痢	0 (0.0) 0	6 (15.0) 7
軟便	0 (0.0) 0	3 (7.5) 4
鼓腸	0 (0.0) 0	2 (5.0) 4
悪心	1 (2.5) 1	1 (2.5) 1
歯痛	1 (2.5) 1	0 (0.0) 0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part A

Primary System Organ Class Preferred Term	Overall N=40 (100%) Not related N=40 (100%) n (%) e			Related N=40 (100%) n (%) e		
一般・全身障害および投与部位の状態	2	(5.0)	2	0	(0.0)	0
無力症	1	(2.5)	1	0	(0.0)	0
血管穿刺部位疼痛	1	(2.5)	1	0	(0.0)	0
感染症および寄生虫症	5	(12.5)	5	0	(0.0)	0
インフルエンザ	1	(2.5)	1	0	(0.0)	0
上咽頭炎	3	(7.5)	3	0	(0.0)	0
ウイルス性上気道感染	1	(2.5)	1	0	(0.0)	0
傷害、中毒および処置合併症	1	(2.5)	1	0	(0.0)	0
創傷	1	(2.5)	1	0	(0.0)	0
筋骨格系および結合組織障害	2	(5.0)	2	2	(5.0)	2
関節痛	0	(0.0)	0	1	(2.5)	1
背部痛	2	(5.0)	2	0	(0.0)	0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part A

Primary System Organ Class Preferred Term	Overall N=40 (100%) Not related N=40 (100%) n (%) e	 Related N=40 (100%) n (%) e
筋力低下	0 (0.0) 0	1 (2.5) 1
神経系障害	6 (15.0) 7	6 (15.0) 6
頭痛	6 (15.0) 7	6 (15.0) 6

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part B

Primary System Organ Class Preferred Term	Overall N=14 (100%) Not related N=14 (100%) n (%) e	 Related N=14 (100%) n (%) e
Subjects with at least one event	8 (57.1) 14	6 (42.9) 10
胃腸障害	0 (0.0) 0	4 (28.6) 5
腹痛	0 (0.0) 0	3 (21.4) 3
下痢	0 (0.0) 0	2 (14.3) 2
傷害、中毒および処置合併症	2 (14.3) 2	0 (0.0) 0
胸部損傷	1 (7.1) 1	0 (0.0) 0
大腿骨頚部骨折	1 (7.1) 1	0 (0.0) 0
筋骨格系および結合組織障害	1 (7.1) 1	0 (0.0) 0
背部痛	1 (7.1) 1	0 (0.0) 0
神経系障害	3 (21.4) 4	3 (21.4) 5
浮動性めまい	1 (7.1) 2	1 (7.1) 1
味覚異常	0 (0.0) 0	1 (7.1) 1

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part B

Primary System Organ Class Preferred Term	Overall N=14 (100%) Not related N=14 (100%) n (%) e	 Related N=14 (100%) n (%) e
頭痛	2 (14.3) 2	2 (14.3) 2
傾眠	0 (0.0) 0	1 (7.1) 1
腎および尿路障害	2 (14.3) 4	0 (0.0) 0
尿意切迫	2 (14.3) 3	0 (0.0) 0
頻尿	1 (7.1) 1	0 (0.0) 0
呼吸器、胸郭および縦隔障害	2 (14.3) 2	0 (0.0) 0
口腔咽頭痛	2 (14.3) 2	0 (0.0) 0
外科および内科処置	1 (7.1) 1	0 (0.0) 0
歯根切除	1 (7.1) 1	0 (0.0) 0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part C

Primary System Organ Class Preferred Term	Overall N=12 (100%) Not related N=12 (100%) n (%) e	 Related N=12 (100%) n (%) e
Subjects with at least one event	6 (50.0) 28	7 (58.3) 11
耳および迷路障害	1 (8.3) 3	1 (8.3) 1
耳鳴	0 (0.0) 0	1 (8.3) 1
回転性めまい	1 (8.3) 3	0 (0.0) 0
胃腸障害	0 (0.0) 0	3 (25.0) 4
上腹部痛	0 (0.0) 0	3 (25.0) 3
下痢	0 (0.0) 0	1 (8.3) 1
一般・全身障害および投与部位の状態	3 (25.0) 4	0 (0.0) 0
カテーテル留置部位疼痛	1 (8.3) 1	0 (0.0) 0
カテーテル留置部位関連反応	1 (8.3) 1	0 (0.0) 0
カテーテル留置部位腫脹	1 (8.3) 1	0 (0.0) 0
疲労	1 (8.3) 1	0 (0.0) 0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part C

Primary System Organ Class Preferred Term	Overall N=12 (100%) Not related N=12 (100%) n (%) e	 Related N=12 (100%) n (%) e
感染症および寄生虫症	2 (16.7) 2	0 (0.0) 0
上咽頭炎	2 (16.7) 2	0 (0.0) 0
傷害、中毒および処置合併症	1 (8.3) 1	0 (0.0) 0
靭帯捻挫	1 (8.3) 1	0 (0.0) 0
臨床検査	1 (8.3) 1	0 (0.0) 0
体温上昇	1 (8.3) 1	0 (0.0) 0
筋骨格系および結合組織障害	3 (25.0) 3	0 (0.0) 0
四肢痛	3 (25.0) 3	0 (0.0) 0
神経系障害	4 (33.3) 6	3 (25.0) 4
浮動性めまい	1 (8.3) 1	0 (0.0) 0
味覚異常	0 (0.0) 0	1 (8.3) 2
頭痛	4 (33.3) 4	2 (16.7) 2

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 63 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0044 試験（続き）

Part C

Primary System Organ Class Preferred Term	Overall N=12 (100%) Not related N=12 (100%) n (%) e	 Related N=12 (100%) n (%) e
感覚鈍麻	1 (8.3) 1	0 (0.0) 0
呼吸器、胸郭および縦隔障害	3 (25.0) 7	0 (0.0) 0
咳嗽	2 (16.7) 2	0 (0.0) 0
口腔咽頭痛	2 (16.7) 5	0 (0.0) 0
皮膚および皮下組織障害	1 (8.3) 1	1 (8.3) 2
多汗症	0 (0.0) 0	1 (8.3) 2
発疹	1 (8.3) 1	0 (0.0) 0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

3.1.3 EMR200095-002 試験

表 64 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-002 試験

	Total Subjects (n=28) - Events (n=37)			
	Unrelated		Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	16 (57.1)	23	6 (21.4)	14
臨床検査	4 (14.3)	6	2 (7.1)	6
アミラーゼ増加	2 (7.1)	3	2 (7.1)	4
リパーゼ増加	2 (7.1)	3	1 (3.6)	1
血小板数減少	0 (0.0)	0	1 (3.6)	1
感染症および寄生虫症	7 (25.0)	8	0 (0.0)	0
上気道感染	5 (17.9)	5	0 (0.0)	0
気管支炎	1 (3.6)	1	0 (0.0)	0
消化管感染	1 (3.6)	1	0 (0.0)	0
インフルエンザ	1 (3.6)	1	0 (0.0)	0
筋骨格系および結合組織障害	4 (14.3)	5	1 (3.6)	1
背部痛	4 (14.3)	5	0 (0.0)	0
筋肉痛	0 (0.0)	0	1 (3.6)	1

表 64　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、EMR200095-002 試験（続き）

	Total Subjects (n=28) - Events (n=37)			
	Unrelated		Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n
胃腸障害	2 (7.1)	2	2 (7.1)	3
嘔吐	0 (0.0)	0	2 (7.1)	2
消化不良	0 (0.0)	0	1 (3.6)	1
悪心	1 (3.6)	1	0 (0.0)	0
歯痛	1 (3.6)	1	0 (0.0)	0
神経系障害	1 (3.6)	1	2 (7.1)	2
頭痛	1 (3.6)	1	2 (7.1)	2
一般・全身障害および投与部位の状態	1 (3.6)	1	1 (3.6)	1
疲労	0 (0.0)	0	1 (3.6)	1
インフルエンザ様疾患	1 (3.6)	1	0 (0.0)	0
代謝および栄養障害	0 (0.0)	0	1 (3.6)	1
食欲減退	0 (0.0)	0	1 (3.6)	1

3.1.4 MS200095-0012 試験

表 65 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0012 試験

System Organ Class Preferred Term	Test Treatment N = 23 (100%)				Reference Treatment N = 23 (100%)			
	Related		Unrelated		Related		Unrelated	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects with at least one event and number of events	4	(17.4)	8	(34.8)	3	(13.0)	8	(34.8)
胃腸障害	1	(4.3)	3	(13.0)	1	(4.3)	2	(8.7)
腹痛	1	(4.3)	0	(0.0)	0	(0.0)	0	(0.0)
下痢	0	(0.0)	1	(4.3)	1	(4.3)	1	(4.3)
消化不良	0	(0.0)	1	(4.3)	0	(0.0)	0	(0.0)
口腔内潰瘍形成	0	(0.0)	1	(4.3)	0	(0.0)	0	(0.0)
悪心	1	(4.3)	0	(0.0)	0	(0.0)	0	(0.0)
歯痛	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.3)
嘔吐	0	(0.0)	0	(0.0)	1	(4.3)	0	(0.0)
一般・全身障害および投与部位の状態	0	(0.0)	1	(4.3)	0	(0.0)	3	(13.0)
カテーテル留置部位炎症	0	(0.0)	1	(4.3)	0	(0.0)	0	(0.0)
カテーテル留置部位関連反応	0	(0.0)	0	(0.0)	0	(0.0)	2	(8.7)
悪寒	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.3)
インフルエンザ様疾患	0	(0.0)	0	(0.0)	0	(0.0)	1	(4.3)

e = number of events; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment-emergent adverse event.
Test (T): 1 x 500 mg tepotinib tablet; Reference (R): 5 x 100 mg tepotinib tablets
System organ class and preferred term are from the MedDRA Version 18.1. The numbers of subjects in each column cannot be added because a subject may have had more than 1 adverse event. A subject experiencing multiple occurrences of an adverse event was counted, at most, once per preferred term for each treatment. Any TEAE that occurred during a washout between treatment periods was attributed to the treatment given in the preceding period.

表 65 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0012 試験（続き）

System Organ Class Preferred Term	Test Treatment N = 23 (100%)				Reference Treatment N = 23 (100%)			
	Related		Unrelated		Related		Unrelated	
	n (%)	e	n (%)	e	n (%)	e	n (%)	e
肝胆道系障害	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
肝機能異常	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
感染症および寄生虫症	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0
インフルエンザ	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0
傷害、中毒および処置合併症	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	1 (4.3)	1
節足動物咬傷	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0
眼内異物	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	1 (4.3)	1
臨床検査	1 (4.3)	2	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
アミラーゼ増加	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
リパーゼ増加	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
神経系障害	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0
頭痛	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0

e = number of events; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment-emergent adverse event.
Test (T): 1 x 500 mg tepotinib tablet; Reference (R): 5 x 100 mg tepotinib tablets
System organ class and preferred term are from the MedDRA Version 18.1. The numbers of subjects in each column cannot be added because a subject may have had more than 1 adverse event. A subject experiencing multiple occurrences of an adverse event was counted, at most, once per preferred term for each treatment. Any TEAE that occurred during a washout between treatment periods was attributed to the treatment given in the preceding period.

表 65 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0012 試験（続き）

System Organ Class Preferred Term	Test Treatment N = 23 (100%)				Reference Treatment N = 23 (100%)			
	Related n (%)	e	Unrelated n (%)	e	Related n (%)	e	Unrelated n (%)	e
呼吸器、胸郭および縦隔障害	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
咽喉乾燥	1 (4.3)	1	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0
皮膚および皮下組織障害	0 (0.0)	0	2 (8.7)	2	2 (8.7)	2	2 (8.7)	2
接触性皮膚炎	0 (0.0)	0	2 (8.7)	2	0 (0.0)	0	0 (0.0)	0
皮膚乾燥	0 (0.0)	0	0 (0.0)	0	0 (0.0)	0	1 (4.3)	1
湿疹	0 (0.0)	0	0 (0.0)	0	1 (4.3)	1	0 (0.0)	0
斑状丘疹状皮疹	0 (0.0)	0	0 (0.0)	0	1 (4.3)	1	1 (4.3)	1

e = number of events; MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment-emergent adverse event.
Test (T): 1 x 500 mg tepotinib tablet; Reference (R): 5 x 100 mg tepotinib tablets
System organ class and preferred term are from the MedDRA Version 18.1. The numbers of subjects in each column cannot be added because a subject may have had more than 1 adverse event. A subject experiencing multiple occurrences of an adverse event was counted, at most, once per preferred term for each treatment. Any TEAE that occurred during a washout between treatment periods was attributed to the treatment given in the preceding period.

3.1.5 EMR200095-001 試験

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
Any Adverse Events	41 (97.6%)	45 (100.0%)	59 (95.2%)	145 (97.3%)
胃腸障害	27 (64.3%)	31 (68.9%)	45 (72.6%)	103 (69.1%)
便秘	13 (31.0%)	11 (24.4%)	18 (29.0%)	42 (28.2%)
悪心	11 (26.2%)	10 (22.2%)	15 (24.2%)	36 (24.2%)
嘔吐	11 (26.2%)	8 (17.8%)	13 (21.0%)	32 (21.5%)
腹痛	5 (11.9%)	8 (17.8%)	11 (17.7%)	24 (16.1%)
下痢	7 (16.7%)	6 (13.3%)	6 (9.7%)	19 (12.8%)
腹水	1 (2.4%)	7 (15.6%)	10 (16.1%)	18 (12.1%)
腹部膨満	2 (4.8%)	5 (11.1%)	6 (9.7%)	13 (8.7%)
口内乾燥	2 (4.8%)	2 (4.4%)	5 (8.1%)	9 (6.0%)
小腸閉塞	1 (2.4%)	4 (8.9%)	1 (1.6%)	6 (4.0%)
上腹部痛	0 (0.0%)	3 (6.7%)	2 (3.2%)	5 (3.4%)
嚥下障害	1 (2.4%)	1 (2.2%)	3 (4.8%)	5 (3.4%)
胃食道逆流性疾患	4 (9.5%)	1 (2.2%)	0 (0.0%)	5 (3.4%)
下腹部痛	1 (2.4%)	0 (0.0%)	2 (3.2%)	3 (2.0%)
痔核	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
消化不良	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
胃腸出血	2 (4.8%)	0 (0.0%)	0 (0.0%)	2 (1.3%)
メレナ	2 (4.8%)	0 (0.0%)	0 (0.0%)	2 (1.3%)
口内炎	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
腹部不快感	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
腹部腫瘤	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
便習慣変化	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
おくび	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
便失禁	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
糞塊	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
変色便	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
放屁	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
消化管運動障害	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
胃腸音異常	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
歯肉痛	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
血便排泄	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
胃排出不全	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
大腸閉塞	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
口唇腫脹	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
腸間膜静脈血栓症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
神経因性腸	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
嚥下痛	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
レッチング	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
歯痛	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
一般・全身障害および投与部位の状態	19 (45.2%)	32 (71.1%)	43 (69.4%)	94 (63.1%)
疲労	12 (28.6%)	17 (37.8%)	20 (32.3%)	49 (32.9%)
末梢性浮腫	6 (14.3%)	10 (22.2%)	24 (38.7%)	40 (26.8%)
発熱	5 (11.9%)	2 (4.4%)	6 (9.7%)	13 (8.7%)
悪寒	2 (4.8%)	1 (2.2%)	4 (6.5%)	7 (4.7%)
非心臓性胸痛	1 (2.4%)	4 (8.9%)	1 (1.6%)	6 (4.0%)
末梢腫脹	4 (9.5%)	0 (0.0%)	1 (1.6%)	5 (3.4%)
倦怠感	0 (0.0%)	3 (6.7%)	1 (1.6%)	4 (2.7%)
無力症	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
疼痛	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
腋窩痛	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
早期満腹	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
歩行障害	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
局所腫脹	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
浮腫	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
カテーテル留置部位紅斑	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
医療機器閉塞	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
疾患進行	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
冷感	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
全身健康状態低下	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
全身性浮腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
限局性浮腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
異物感	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
代謝および栄養障害	27 (64.3%)	23 (51.1%)	40 (64.5%)	90 (60.4%)
食欲減退	12 (28.6%)	5 (11.1%)	27 (43.5%)	44 (29.5%)
低アルブミン血症	8 (19.0%)	6 (13.3%)	11 (17.7%)	25 (16.8%)
脱水	2 (4.8%)	6 (13.3%)	10 (16.1%)	18 (12.1%)
低ナトリウム血症	3 (7.1%)	2 (4.4%)	8 (12.9%)	13 (8.7%)
高カリウム血症	1 (2.4%)	5 (11.1%)	5 (8.1%)	11 (7.4%)
低マグネシウム血症	4 (9.5%)	3 (6.7%)	4 (6.5%)	11 (7.4%)
低カリウム血症	3 (7.1%)	3 (6.7%)	2 (3.2%)	8 (5.4%)
低カルシウム血症	1 (2.4%)	3 (6.7%)	3 (4.8%)	7 (4.7%)
悪液質	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
高リン酸塩血症	1 (2.4%)	2 (4.4%)	0 (0.0%)	3 (2.0%)
高血糖	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
高尿酸血症	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
栄養障害	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
脂質異常症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
成長障害	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
高カルシウム血症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
低コレステロール血症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
低血糖症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
低リン酸血症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
血液量減少症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
臨床検査	16 (38.1%)	19 (42.2%)	29 (46.8%)	64 (43.0%)
アスパラギン酸アミノトランスフェラーゼ増加	7 (16.7%)	5 (11.1%)	8 (12.9%)	20 (13.4%)
トランスアミナーゼ上昇	1 (2.4%)	2 (4.4%)	7 (11.3%)	10 (6.7%)
リパーゼ増加	3 (7.1%)	4 (8.9%)	2 (3.2%)	9 (6.0%)
アラニンアミノトランスフェラーゼ増加	1 (2.4%)	1 (2.2%)	6 (9.7%)	8 (5.4%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
血中クレアチニン増加	3 (7.1%)	0 (0.0%)	5 (8.1%)	8 (5.4%)
血中ビリルビン増加	1 (2.4%)	3 (6.7%)	2 (3.2%)	6 (4.0%)
呼吸音異常	2 (4.8%)	1 (2.2%)	3 (4.8%)	6 (4.0%)
体重減少	0 (0.0%)	1 (2.2%)	3 (4.8%)	4 (2.7%)
アミラーゼ増加	2 (4.8%)	1 (2.2%)	0 (0.0%)	3 (2.0%)
血中アルカリホスファターゼ増加	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
γ－グルタミルトランスフェラーゼ増加	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
ヘモグロビン増加	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
国際標準比増加	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
前立腺特異性抗原増加	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
ウエスト周囲径増加	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
体重増加	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
抗凝固薬濃度治療量以下	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
血中クレアチン増加	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血中ブドウ糖減少	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
血中ブドウ糖増加	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
血中乳酸脱水素酵素増加	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
拡張期血圧異常	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血中尿素増加	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
心電図ＰＲ短縮	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
心電図ＱＴ延長	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
心電図ＳＴ部分上昇	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
ヘマトクリット増加	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
好中球数増加	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
足脈拍異常	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血小板数減少	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
白血球数増加	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
呼吸器、胸郭および縦隔障害	13 (31.0%)	16 (35.6%)	24 (38.7%)	53 (35.6%)
呼吸困難	2 (4.8%)	6 (13.3%)	13 (21.0%)	21 (14.1%)
胸水	5 (11.9%)	2 (4.4%)	7 (11.3%)	14 (9.4%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
咳嗽	4 (9.5%)	2 (4.4%)	2 (3.2%)	8 (5.4%)
肺塞栓症	2 (4.8%)	4 (8.9%)	2 (3.2%)	8 (5.4%)
労作性呼吸困難	3 (7.1%)	1 (2.2%)	1 (1.6%)	5 (3.4%)
しゃっくり	1 (2.4%)	2 (4.4%)	2 (3.2%)	5 (3.4%)
口腔咽頭痛	2 (4.8%)	1 (2.2%)	2 (3.2%)	5 (3.4%)
鼻閉	0 (0.0%)	2 (4.4%)	1 (1.6%)	3 (2.0%)
湿性咳嗽	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
鼻漏	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
副鼻腔うっ血	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
誤嚥	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
無気肺	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
慢性閉塞性肺疾患	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
喀血	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
低酸素症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
誤嚥性肺炎	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
気胸	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
肺水腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
気道うっ血	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
頻呼吸	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
喘鳴	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
筋骨格系および結合組織障害	18 (42.9%)	12 (26.7%)	22 (35.5%)	52 (34.9%)
筋肉痛	4 (9.5%)	4 (8.9%)	6 (9.7%)	14 (9.4%)
四肢痛	6 (14.3%)	2 (4.4%)	4 (6.5%)	12 (8.1%)
関節痛	6 (14.3%)	1 (2.2%)	3 (4.8%)	10 (6.7%)
背部痛	4 (9.5%)	3 (6.7%)	1 (1.6%)	8 (5.4%)
筋痙縮	2 (4.8%)	3 (6.7%)	2 (3.2%)	7 (4.7%)
筋骨格痛	2 (4.8%)	4 (8.9%)	1 (1.6%)	7 (4.7%)
筋力低下	2 (4.8%)	2 (4.4%)	1 (1.6%)	5 (3.4%)
筋骨格系胸痛	1 (2.4%)	1 (2.2%)	2 (3.2%)	4 (2.7%)
頚部痛	1 (2.4%)	0 (0.0%)	2 (3.2%)	3 (2.0%)

Note: MedDRA Version 18.0.

表 66　全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
顎痛	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
骨痛	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
単径部痛	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
関節強直	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
ミオパチー	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
変形性関節症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
骨壊死	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
神経系障害	7 (16.7%)	18 (40.0%)	22 (35.5%)	47 (31.5%)
浮動性めまい	3 (7.1%)	5 (11.1%)	7 (11.3%)	15 (10.1%)
末梢性ニューロパチー	2 (4.8%)	4 (8.9%)	4 (6.5%)	10 (6.7%)
頭痛	1 (2.4%)	2 (4.4%)	5 (8.1%)	8 (5.4%)
記憶障害	1 (2.4%)	2 (4.4%)	1 (1.6%)	4 (2.7%)
味覚異常	0 (0.0%)	3 (6.7%)	0 (0.0%)	3 (2.0%)
傾眠	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
脊髄圧迫	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
失神	0 (0.0%)	1 (2.2%)	2 (3.2%)	3 (2.0%)
感覚鈍麻	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
錯感覚	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
振戦	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
アカシジア	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
平衡障害	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
体位性めまい	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
ジスキネジア	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
味覚減退	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
嗜眠	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
神経痛	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
迷走神経障害	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
第７脳神経麻痺	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
声帯麻痺	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
感染症および寄生虫症	11 (26.2%)	16 (35.6%)	19 (30.6%)	46 (30.9%)
尿路感染	2 (4.8%)	4 (8.9%)	7 (11.3%)	13 (8.7%)
口腔カンジダ症	1 (2.4%)	4 (8.9%)	2 (3.2%)	7 (4.7%)
肺炎	0 (0.0%)	1 (2.2%)	3 (4.8%)	4 (2.7%)
副鼻腔炎	1 (2.4%)	2 (4.4%)	1 (1.6%)	4 (2.7%)
真菌感染	0 (0.0%)	2 (4.4%)	1 (1.6%)	3 (2.0%)
ブドウ球菌感染	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
上気道感染	2 (4.8%)	0 (0.0%)	1 (1.6%)	3 (2.0%)
蜂巣炎	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
医療機器関連感染	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
敗血症性ショック	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
ブドウ球菌性菌血症	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
腹壁感染	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
気管支炎	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
結膜炎	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
耳感染	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
大腸菌性尿路感染	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
壊疽	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
麦粒腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
感染性瘻孔	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
腎感染	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
大葉性肺炎	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
真菌性爪床感染	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
爪真菌症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
骨髄炎	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
耳下腺炎	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
処置後感染	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
歯膿瘍	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
気管気管支炎	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
細菌性上気道感染	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
ブドウ球菌性尿路感染	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
尿路性敗血症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
創傷感染	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
皮膚および皮下組織障害	14 (33.3%)	9 (20.0%)	16 (25.8%)	39 (26.2%)
発疹	3 (7.1%)	3 (6.7%)	5 (8.1%)	11 (7.4%)
脱毛症	2 (4.8%)	0 (0.0%)	0 (0.0%)	2 (1.3%)
皮膚乾燥	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
紅斑	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
多汗症	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
爪の障害	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
寝汗	2 (4.8%)	0 (0.0%)	0 (0.0%)	2 (1.3%)
光線過敏性反応	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
そう痒症	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
紅斑性皮疹	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
小水疱性皮疹	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
皮膚色素過剰	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
顔面腫脹	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
日光角化症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
水疱	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
ざ瘡様皮膚炎	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
過角化	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
嵌入爪	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
爪破損	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
爪甲離床症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
全身性皮疹	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
斑状丘疹状皮疹	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
そう痒性皮疹	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
皮膚障害	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
皮膚剥脱	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
皮膚病変	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
皮膚腫瘤	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66　全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
皮膚潰瘍	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
うっ滞性皮膚炎	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
蕁麻疹	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血液およびリンパ系障害	11 (26.2%)	13 (28.9%)	14 (22.6%)	38 (25.5%)
貧血	4 (9.5%)	4 (8.9%)	8 (12.9%)	16 (10.7%)
白血球増加症	2 (4.8%)	6 (13.3%)	2 (3.2%)	10 (6.7%)
血小板減少症	4 (9.5%)	2 (4.4%)	2 (3.2%)	8 (5.4%)
好中球減少症	0 (0.0%)	3 (6.7%)	2 (3.2%)	5 (3.4%)
白血球減少症	2 (4.8%)	1 (2.2%)	1 (1.6%)	4 (2.7%)
慢性疾患の貧血	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
溶血性貧血	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
出血性貧血	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
血小板増加症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
腎および尿路障害	8 (19.0%)	9 (20.0%)	9 (14.5%)	26 (17.4%)
腎不全	3 (7.1%)	1 (2.2%)	4 (6.5%)	8 (5.4%)
急性腎不全	1 (2.4%)	4 (8.9%)	0 (0.0%)	5 (3.4%)
蛋白尿	1 (2.4%)	2 (4.4%)	1 (1.6%)	4 (2.7%)
排尿困難	2 (4.8%)	1 (2.2%)	0 (0.0%)	3 (2.0%)
水腎症	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
着色尿	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
糖尿	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血尿	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
神経因性膀胱	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
夜間頻尿	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
頻尿	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
腎萎縮	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
腎肥大	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
腎機能障害	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
尿管閉塞	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
排尿躊躇	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
尿失禁	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
尿閉	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
精神障害	6 (14.3%)	4 (8.9%)	13 (21.0%)	23 (15.4%)
不眠症	4 (9.5%)	1 (2.2%)	6 (9.7%)	11 (7.4%)
不安	1 (2.4%)	0 (0.0%)	3 (4.8%)	4 (2.7%)
激越	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
譫妄	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
精神状態変化	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
うつ病	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
失見当識	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
感情的苦悩	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
感情の平板化	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
落ち着きのなさ	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
心障害	4 (9.5%)	4 (8.9%)	6 (9.7%)	14 (9.4%)
頻脈	2 (4.8%)	3 (6.7%)	5 (8.1%)	10 (6.7%)
心房細動	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
狭心症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
徐脈	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
洞性不整脈	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
傷害、中毒および処置合併症	4 (9.5%)	6 (13.3%)	4 (6.5%)	14 (9.4%)
転倒	0 (0.0%)	3 (6.7%)	1 (1.6%)	4 (2.7%)
脊椎圧迫骨折	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
足関節部骨折	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
挫傷	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
上顎炎	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
栄養補給チューブ合併症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
股関節部骨折	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66　全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
関節損傷	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
裂傷	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
四肢損傷	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
爪損傷	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
処置による出血	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
放射線性肺臓炎	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
ストーマ部出血	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
生殖系および乳房障害	3 (7.1%)	5 (11.1%)	5 (8.1%)	13 (8.7%)
陰嚢浮腫	1 (2.4%)	0 (0.0%)	2 (3.2%)	3 (2.0%)
乳頭痛	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
腟分泌物	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
腟出血	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
乳房腫瘤	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
乳房腫脹	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
乳房圧痛	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
性交困難	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
乳頭障害	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
陰茎浮腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
陰嚢腫脹	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
精巣腫脹	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
血管障害	4 (9.5%)	1 (2.2%)	8 (12.9%)	13 (8.7%)
深部静脈血栓症	1 (2.4%)	0 (0.0%)	3 (4.8%)	4 (2.7%)
低血圧	1 (2.4%)	0 (0.0%)	2 (3.2%)	3 (2.0%)
高血圧	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
ほてり	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
頚静脈血栓症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
鎖骨下静脈血栓症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
上大静脈症候群	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
表在性血栓性静脈炎	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66　全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
血栓症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
静脈血栓症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
眼障害	3 (7.1%)	1 (2.2%)	5 (8.1%)	9 (6.0%)
霧視	2 (4.8%)	0 (0.0%)	4 (6.5%)	6 (4.0%)
眼乾燥	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
流涙増加	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
眼瞼痙攣	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
網膜色素上皮症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
視力低下	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
硝子体浮遊物	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
肝胆道系障害	0 (0.0%)	7 (15.6%)	2 (3.2%)	9 (6.0%)
高ビリルビン血症	0 (0.0%)	5 (11.1%)	0 (0.0%)	5 (3.4%)
黄疸	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
肝不全	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
胆汁うっ滞性黄疸	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
門脈血栓症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
耳および迷路障害	3 (7.1%)	2 (4.4%)	2 (3.2%)	7 (4.7%)
難聴	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
耳不快感	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
耳痛	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
耳部腫脹	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
中耳滲出液	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
回転性めまい	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
頭位性回転性めまい	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
内分泌障害	2 (4.8%)	2 (4.4%)	3 (4.8%)	7 (4.7%)
甲状腺機能低下症	2 (4.8%)	1 (2.2%)	1 (1.6%)	4 (2.7%)
バセドウ病	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 66 全ての有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
抗利尿ホルモン不適合分泌	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
甲状腺障害	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
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 (2.4%)	3 (6.7%)	1 (1.6%)	5 (3.4%)
脂漏性角化症	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
中枢神経系転移	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
遠隔転移を伴う食道癌	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
腫瘍出血	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
腫瘍浸潤	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
免疫系障害	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
節足動物咬傷アレルギー	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 67 治験薬との因果関係が否定できない有害事象（SOC 及び PT）、EMR200095-001 試験

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
Any Adverse Events	14 (33.3%)	23 (51.1%)	39 (62.9%)	76 (51.0%)
一般・全身障害および投与部位の状態	4 (9.5%)	7 (15.6%)	22 (35.5%)	33 (22.1%)
疲労	3 (7.1%)	5 (11.1%)	11 (17.7%)	19 (12.8%)
末梢性浮腫	1 (2.4%)	2 (4.4%)	16 (25.8%)	19 (12.8%)
限局性浮腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
浮腫	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
末梢腫脹	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
胃腸障害	2 (4.8%)	6 (13.3%)	16 (25.8%)	24 (16.1%)
悪心	1 (2.4%)	2 (4.4%)	6 (9.7%)	9 (6.0%)
嘔吐	2 (4.8%)	2 (4.4%)	5 (8.1%)	9 (6.0%)
下痢	0 (0.0%)	1 (2.2%)	3 (4.8%)	4 (2.7%)
便秘	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
腹痛	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
口内乾燥	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
胃食道逆流性疾患	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
レッチング	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
臨床検査	2 (4.8%)	4 (8.9%)	12 (19.4%)	18 (12.1%)
リパーゼ増加	1 (2.4%)	4 (8.9%)	1 (1.6%)	6 (4.0%)
アスパラギン酸アミノトランスフェラーゼ増加	1 (2.4%)	0 (0.0%)	3 (4.8%)	4 (2.7%)
アラニンアミノトランスフェラーゼ増加	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
血中クレアチニン増加	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
トランスアミナーゼ上昇	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
アミラーゼ増加	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
心電図ＳＴ部分上昇	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
代謝および栄養障害	2 (4.8%)	0 (0.0%)	13 (21.0%)	15 (10.1%)
食欲減退	2 (4.8%)	0 (0.0%)	10 (16.1%)	12 (8.1%)
低アルブミン血症	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)

Note: MedDRA Version 18.0.

表 67　治験薬との因果関係が否定できない有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
低マグネシウム血症	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
低ナトリウム血症	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
皮膚および皮下組織障害	4 (9.5%)	3 (6.7%)	4 (6.5%)	11 (7.4%)
発疹	0 (0.0%)	2 (4.4%)	2 (3.2%)	4 (2.7%)
脱毛症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
爪の障害	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
爪甲離床症	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
光線過敏性反応	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
紅斑性皮疹	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
全身性皮疹	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
そう痒性皮疹	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
皮膚剥脱	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
皮膚色素過剰	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
筋骨格系および結合組織障害	1 (2.4%)	4 (8.9%)	5 (8.1%)	10 (6.7%)
関節痛	1 (2.4%)	1 (2.2%)	0 (0.0%)	2 (1.3%)
骨痛	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
筋痙縮	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
四肢痛	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
筋肉痛	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
ミオパチー	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
神経系障害	1 (2.4%)	5 (11.1%)	3 (4.8%)	9 (6.0%)
末梢性ニューロパチー	1 (2.4%)	1 (2.2%)	1 (1.6%)	3 (2.0%)
浮動性めまい	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
味覚異常	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
頭痛	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
錯感覚	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
振戦	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 67　治験薬との因果関係が否定できない有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
血液およびリンパ系障害	0 (0.0%)	3 (6.7%)	3 (4.8%)	6 (4.0%)
貧血	0 (0.0%)	0 (0.0%)	3 (4.8%)	3 (2.0%)
好中球減少症	0 (0.0%)	2 (4.4%)	0 (0.0%)	2 (1.3%)
血小板減少症	0 (0.0%)	1 (2.2%)	1 (1.6%)	2 (1.3%)
白血球減少症	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
腎および尿路障害	2 (4.8%)	0 (0.0%)	2 (3.2%)	4 (2.7%)
腎不全	2 (4.8%)	0 (0.0%)	1 (1.6%)	3 (2.0%)
糖尿	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
腎肥大	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
生殖系および乳房障害	0 (0.0%)	2 (4.4%)	2 (3.2%)	4 (2.7%)
陰嚢浮腫	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
乳頭障害	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
乳頭痛	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
眼障害	1 (2.4%)	0 (0.0%)	2 (3.2%)	3 (2.0%)
流涙増加	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
霧視	1 (2.4%)	0 (0.0%)	1 (1.6%)	2 (1.3%)
硝子体浮遊物	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血管障害	0 (0.0%)	0 (0.0%)	2 (3.2%)	2 (1.3%)
低血圧	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
血栓症	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
耳および迷路障害	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
難聴	0 (0.0%)	0 (0.0%)	1 (1.6%)	1 (0.7%)
精神障害	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)
落ち着きのなさ	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

表 67 治験薬との因果関係が否定できない有害事象（SOC 及び PT）、EMR200095-001 試験（続き）

System Organ Class Preferred Term	Regimen 1 (N=42)	Regimen 2 (N=45)	Regimen 3 (N=62)	Total (N=149)
呼吸器、胸郭および縦隔障害	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)
咳嗽	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (0.7%)

Note: MedDRA Version 18.0.

3.1.6 EMR200095-003 試験

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
Subjects with TEAE(s)			2	3	6	11 (91.7)
		Grade 1 or Mild	0	0	1	1 (8.3)
		Grade 2 or Moderate	2	0	1	3 (25.0)
		Grade 3 or Severe	0	2	1	3 (25.0)
		Grade 4 or life-threatening or disabling	0	1	3	4 (33.3)
一般・全身障害および投与部位の状態			2	3	5	10 (83.3)
		Grade 1 or Mild	2	2	4	8 (66.7)
		Grade 2 or Moderate	0	1	1	2 (16.7)
	疲労		1	2	1	4 (33.3)
		Grade 1 or Mild	1	2	1	4 (33.3)
	末梢性浮腫		0	0	4	4 (33.3)
		Grade 1 or Mild	0	0	4	4 (33.3)
	倦怠感		0	1	1	2 (16.7)
		Grade 2 or Moderate	0	1	1	2 (16.7)
	発熱		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	血管穿刺部位紅斑		1	0	0	1 (8.3)
		Grade 1 or Mild	1	0	0	1 (8.3)
胃腸障害			1	3	5	9 (75.0)
		Grade 1 or Mild	1	1	4	6 (50.0)
		Grade 2 or Moderate	0	1	1	2 (16.7)
		Grade 3 or Severe	0	1	0	1 (8.3)
	便秘		1	2	3	6 (50.0)
		Grade 1 or Mild	1	2	3	6 (50.0)
	悪心		0	2	3	5 (41.7)
		Grade 1 or Mild	0	1	3	4 (33.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	嘔吐		0	1	3	4 (33.3)
		Grade 1 or Mild	0	1	3	4 (33.3)
	腹部不快感		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	腹水		0	1	0	1 (8.3)
		Grade 3 or Severe	0	1	0	1 (8.3)
	齲歯		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	肛門周囲痛		0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	1	1 (8.3)
	口内炎		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
代謝および栄養障害			1	2	4	7 (58.3)
		Grade 1 or Mild	1	0	1	2 (16.7)
		Grade 2 or Moderate	0	1	2	3 (25.0)
		Grade 3 or Severe	0	1	1	2 (16.7)
	食欲減退		1	2	3	6 (50.0)
		Grade 1 or Mild	1	0	2	3 (25.0)
		Grade 2 or Moderate	0	1	1	2 (16.7)
		Grade 3 or Severe	0	1	0	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	低アルブミン血症		0	0	4	4 (33.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	3	3 (25.0)
	低ナトリウム血症		0	0	1	1 (8.3)
		Grade 3 or Severe	0	0	1	1 (8.3)
臨床検査			0	0	4	4 (33.3)
		Grade 2 or Moderate	0	0	2	2 (16.7)
		Grade 4 or life-threatening or disabling	0	0	2	2 (16.7)
	アミラーゼ増加		0	0	2	2 (16.7)
		Grade 2 or Moderate	0	0	2	2 (16.7)
	リパーゼ増加		0	0	2	2 (16.7)
		Grade 4 or life-threatening or disabling	0	0	2	2 (16.7)
	血中クレアチニン増加		0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	1	1 (8.3)
	C－反応性蛋白増加		0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	1	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
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	1	2	4 (33.3)
		Grade 1 or Mild	0	0	2	2 (16.7)
		Grade 2 or Moderate	1	1	0	2 (16.7)
	癌疼痛		1	0	1	2 (16.7)
		Grade 1 or Mild	0	0	1	1 (8.3)
		Grade 2 or Moderate	1	0	0	1 (8.3)
	腫瘍熱		0	1	1	2 (16.7)
		Grade 1 or Mild	0	0	1	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
神経系障害			1	2	1	4 (33.3)
		Grade 2 or Moderate	1	1	1	3 (25.0)
		Grade 4 or life-threatening or disabling	0	1	0	1 (8.3)
	味覚異常		1	1	1	3 (25.0)
		Grade 1 or Mild	1	0	0	1 (8.3)
		Grade 2 or Moderate	0	1	1	2 (16.7)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	意識変容状態		0	1	0	1 (8.3)
		Grade 4 or life-threatening or disabling	0	1	0	1 (8.3)
	浮動性めまい		0	1	0	1 (8.3)
		Grade 1 or Mild	0	1	0	1 (8.3)
	感覚鈍麻		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	末梢性ニューロパチー		1	0	0	1 (8.3)
		Grade 2 or Moderate	1	0	0	1 (8.3)
精神障害			0	1	2	3 (25.0)
		Grade 1 or Mild	0	1	1	2 (16.7)
		Grade 2 or Moderate	0	0	1	1 (8.3)
	不眠症		0	0	2	2 (16.7)
		Grade 1 or Mild	0	0	2	2 (16.7)
	不安		0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	1	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	うつ病		0	1	0	1 (8.3)
		Grade 1 or Mild	0	1	0	1 (8.3)
呼吸器、胸郭および縦隔障害			0	1	1	2 (16.7)
		Grade 3 or Severe	0	1	0	1 (8.3)
		Grade 4 or life-threatening or disabling	0	0	1	1 (8.3)
	呼吸困難		0	1	1	2 (16.7)
		Grade 3 or Severe	0	1	0	1 (8.3)
		Grade 4 or life-threatening or disabling	0	0	1	1 (8.3)
皮膚および皮下組織障害			0	1	1	2 (16.7)
		Grade 1 or Mild	0	0	1	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	ざ瘡様皮膚炎		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	薬疹		0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
	蕁麻疹		0	1	0	1 (8.3)
		Grade 1 or Mild	0	1	0	1 (8.3)
血液およびリンパ系障害			0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	鉄欠乏性貧血		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
眼障害			0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	眼運動障害		0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
感染症および寄生虫症			0	0	1	1 (8.3)
		Grade 2 or Moderate	0	0	1	1 (8.3)
	鼻咽頭炎		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	皮下組織膿瘍		0	0	1	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68　全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
		Grade 2 or Moderate	0	0	1	1 (8.3)
傷害、中毒および処置合併症			0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	創合併症		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
筋骨格系および結合組織障害			0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
	背部痛		0	0	1	1 (8.3)
		Grade 1 or Mild	0	0	1	1 (8.3)
腎および尿路障害			0	1	0	1 (8.3)
		Grade 3 or Severe	0	1	0	1 (8.3)
	尿路閉塞		0	1	0	1 (8.3)
		Grade 3 or Severe	0	1	0	1 (8.3)
血管障害			0	1	0	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 68 全ての有害事象（SOC 及び PT）、EMR200095-003 試験（続き）

System Organ Class	Preferred Term	NCI CTCAE Grade	215mg (N=3) N	300mg (N=3) N	500mg (N=6) N	Total (N=12) N(%)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	深部静脈血栓症		0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	血栓性静脈炎		0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)
	静脈瘤		0	1	0	1 (8.3)
		Grade 2 or Moderate	0	1	0	1 (8.3)

Source : ADAE
A subject experienced multiple episodes was counted once in the worst CTCAE grade.
Note: MedDRA Version 17.1
Path : Z:¥sas¥merck_serono¥c_met200095_003¥jiki_Final2¥prg¥T_ctcae.sas
Output ID: T_ctcae 13MAR2015 19:25

表 69　治験薬との因果関係が否定できない有害事象（SOC 及び PT）、EMR200095-003 試験

MedDRA System Organ Class Preferred Term	Tepotinib p.o. qd			
	215 mg (N=3) n	300 mg (N=3) n	500 mg (N=6) n	Total (N=12) n (%)
Subjects with any Treatment-related TEAEs	1	1	3	5 (41.7)
臨床検査	0	0	3	3 (25.0)
アミラーゼ増加	0	0	2	2 (16.7)
リパーゼ増加	0	0	2	2 (16.7)
血中クレアチニン増加	0	0	1	1 (8.3)
代謝および栄養障害	1	0	2	3 (25.0)
低アルブミン血症	0	0	2	2 (16.7)
食欲減退	1	0	0	1 (8.3)
低ナトリウム血症	0	0	1	1 (8.3)
胃腸障害	0	0	2	2 (16.7)
悪心	0	0	1	1 (8.3)
口内炎	0	0	1	1 (8.3)
嘔吐	0	0	1	1 (8.3)
一般・全身障害および投与部位の状態	1	1	0	2 (16.7)
疲労	1	1	0	2 (16.7)
神経系障害	1	0	1	2 (16.7)
味覚異常	1	0	1	2 (16.7)
皮膚および皮下組織障害	0	0	1	1 (8.3)
ざ瘡様皮膚炎	0	0	1	1 (8.3)

3.1.7 MS200095-0028 試験

表 70 全ての有害事象（SOC 及び PT）、MS200095-0028 試験

System Organ Class Preferred Term	Healthy Control N=6 (100%) n (%)	Mild Hepatic Impairment N=6 (100%) n (%)	Moderate Hepatic Impairment N=6 (100%) n (%)	Overall N=18(100%) n (%)
Subjects with at least one event	1 (16.7)	0 (0.0)	2 (33.3)	3 (16.7)
胃腸障害	1 (16.7)	0 (0.0)	0 (0.0)	1 (5.6)
下痢	1 (16.7)	0 (0.0)	0 (0.0)	1 (5.6)
感染症および寄生虫症	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)
耳感染	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)
皮膚および皮下組織障害	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)
発疹	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)

MedDRA = Medical Dictionary for Regulatory Activities, Version 21.1

表 71 治験薬との因果関係が否定できない有害事象（SOC 及び PT）、MS200095-0028 試験

System Organ Class Preferred Term	Healthy Control N=6 (100%) n (%)	Mild Hepatic Impairment N=6 (100%) n (%)	Moderate Hepatic Impairment N=6 (100%) n (%)	Overall N=18(100%) n (%)
Subjects with at least one event	1 (16.7)	0 (0.0)	1 (16.7)	2 (11.1)
胃腸障害	1 (16.7)	0 (0.0)	0 (0.0)	1 (5.6)
下痢	1 (16.7)	0 (0.0)	0 (0.0)	1 (5.6)
皮膚および皮下組織障害	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)
発疹	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)

MedDRA = Medical Dictionary for Regulatory Activities, Version 21.1
Related are those events with relationship missing or 'related'.

3.1.8 MS200095-0030 試験

表 72 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0030 試験

	Overall N=12 (100%)			
	Not related N=12 (100%)		Related N=12 (100%)	
Primary System Organ Class Preferred Term	n	(%)	n	(%)
Subjects with at least one event	4	(33.3)	8	(66.7)
胃腸障害	3	(25.0)	6	(50.0)
腹部不快感	1	(8.3)	0	(0.0)
腹痛	0	(0.0)	2	(16.7)
下腹部痛	1	(8.3)	0	(0.0)
上腹部痛	0	(0.0)	4	(33.3)
下痢	0	(0.0)	4	(33.3)
歯肉出血	1	(8.3)	0	(0.0)
悪心	0	(0.0)	1	(8.3)
一般・全身障害および投与部位の状態	1	(8.3)	0	(0.0)
医療機器使用部位反応	1	(8.3)	0	(0.0)

	Not related e	Related e
Subjects with at least one event	4	30
胃腸障害	3	25
腹部不快感	1	0
腹痛	0	2
下腹部痛	1	0
上腹部痛	0	14
下痢	0	8
歯肉出血	1	0
悪心	0	1
一般・全身障害および投与部位の状態	1	0
医療機器使用部位反応	1	0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 72　全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0030 試験（続き）

Primary System Organ Class Preferred Term	Overall N=12 (100%) Not related N=12 (100%) n (%) e	 Related N=12 (100%) n (%) e
神経系障害	0 (0.0) 0	5 (41.7) 5
頭痛	0 (0.0) 0	5 (41.7) 5

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

3.1.9 MS200095-0032 試験

表 73 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0032 試験

Primary System Organ Class Preferred Term	Overall N=20 (100%) Not related N=20 (100%) n (%) e	 Related N=20 (100%) n (%) e
Subjects with at least one event	5 (25.0) 8	14 (70.0) 71
胃腸障害	1 (5.0) 1	14 (70.0) 66
腹部不快感	0 (0.0) 0	1 (5.0) 1
腹痛	0 (0.0) 0	2 (10.0) 2
上腹部痛	0 (0.0) 0	7 (35.0) 17
下痢	0 (0.0) 0	11 (55.0) 30
消化不良	0 (0.0) 0	1 (5.0) 2
硬便	0 (0.0) 0	1 (5.0) 1
軟便	0 (0.0) 0	2 (10.0) 2
鼓腸	0 (0.0) 0	3 (15.0) 3
悪心	0 (0.0) 0	6 (30.0) 8
舌潰瘍	1 (5.0) 1	0 (0.0) 0
臨床検査	3 (15.0) 3	0 (0.0) 0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

表 73 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0032 試験（続き）

Primary System Organ Class Preferred Term	Overall N=20 (100%) Not related N=20 (100%) n (%) e	 Related N=20 (100%) n (%) e
血中クレアチンホスホキナーゼ増加	2 (10.0) 2	0 (0.0) 0
心拍数増加	1 (5.0) 1	0 (0.0) 0
筋骨格系および結合組織障害	1 (5.0) 2	0 (0.0) 0
背部痛	1 (5.0) 1	0 (0.0) 0
椎間板突出	1 (5.0) 1	0 (0.0) 0
神経系障害	1 (5.0) 2	3 (15.0) 5
浮動性めまい	1 (5.0) 1	1 (5.0) 1
頭痛	1 (5.0) 1	2 (10.0) 4

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event

3.1.10 MS200095-0039 試験

表 74 全ての有害事象（SOC 及び PT、治験薬との因果関係別）、MS200095-0039 試験

By Relationship to any Trial Treatment

Primary System Organ Class Preferred Term	Overall N=12 (100%) Not related N=12 (100%) n (%) e		 Related N=12 (100%) n (%) e	
Subjects with at least one event	2 (16.7)	2	2 (16.7)	5
眼障害	0 (0.0)	0	1 (8.3)	1
結膜嚢胞	0 (0.0)	0	1 (8.3)	1
胃腸障害	0 (0.0)	0	1 (8.3)	4
上腹部痛	0 (0.0)	0	1 (8.3)	2
悪心	0 (0.0)	0	1 (8.3)	2
傷害、中毒および処置合併症	1 (8.3)	1	0 (0.0)	0
節足動物咬傷	1 (8.3)	1	0 (0.0)	0
呼吸器、胸郭および縦隔障害	1 (8.3)	1	0 (0.0)	0
鼻漏	1 (8.3)	1	0 (0.0)	0

MedDRA version 21.0.
e = Number of events; N = Number of subjects; n = Number of subjects with at least one event