付録2.7.6.2.2.2
SOC/PT 別の副作用発現率（003試験）
Safety Analysis Set
Part B

MedDRA System Organ Class Preferred Term	E7090 alone (N=14) n (%)	Rabeprazole alone (N=14) n (%)	E7090 + Rabeprazole (N=14) n (%)	Overall (N=14) n (%)
No Subject Meets Table Criteria				

Percentages are based on the number of treated subjects in relevant header columns for each treatment and the number of Safety Analysis Set for overall.
TEAE = treatment-emergent adverse event.
TEAEs were assigned to E7090 alone if onset was on or after the dose of E7090 on Day 1 but before the first dose of rabeprazole on Day 7.
TEAEs were assigned to rabeprazole alone if onset was on or after the first dose of rabeprazole on Day 7 but before the dose of E7090 + rabeprazole on Day 11.
TEAEs were assigned to E7090 + rabeprazole if onset was on or after the dose of E7090 + rabeprazole on Day 11 but before the end of the study.
A subject with two or more Adverse Events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 24.0.

付録2.7.6.2.2.3
SOC/PT 別の副作用発現率（003試験）
Safety Analysis Set
Part C

MedDRA System Organ Class Preferred Term	E7090 alone (N=14) n (%)	Rifampin alone (N=14) n (%)	E7090 + Rifampin (N=14) n (%)	Overall (N=14) n (%)
Subjects with Any Treatment-Related TEAEs	1 (7.1)	0	1 (7.1)	1 (7.1)
胃腸障害	1 (7.1)	0	0	1 (7.1)
下痢	1 (7.1)	0	0	1 (7.1)
一般・全身障害および投与部位の状態	1 (7.1)	0	1 (7.1)	1 (7.1)
熱感	1 (7.1)	0	0	1 (7.1)
発熱	0	0	1 (7.1)	1 (7.1)

Percentages are based on the number of treated subjects in relevant header columns for each treatment and the number of Safety Analysis Set for overall.
TEAE = treatment-emergent adverse event.
TEAEs were assigned to E7090 alone if onset was on or after the dose of E7090 on Day 1 but before the first dose of rifampin on Day 7.
TEAEs were assigned to rifampin alone if onset was on or after the first dose of rifampin on Day 7 but before the dose of E7090 + rifampin on Day 13.
TEAEs were assigned to E7090 + rifampin if onset was on or after the dose of E7090 + rifampin on Day 13 but before the end of the study.
A subject with two or more Adverse Events in the same system organ class (or with the same preferred term) is counted only once for that system organ class (or preferred term).
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 24.0.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any TEAE	2 (100.0)	0	1 (50.0)	0	1 (50.0)	0	2 (100.0)	0	2 (100.0)	0
血液およびリンパ系障害	0	0	0	0	0	0	0	0	1 (50.0)	0
貧血	0	0	0	0	0	0	0	0	0	0
白血球減少症	0	0	0	0	0	0	0	0	1 (50.0)	0
眼障害	0	0	0	0	0	0	0	0	0	0
漿液性網膜剥離	0	0	0	0	0	0	0	0	0	0
ドライアイ	0	0	0	0	0	0	0	0	0	0
黄斑浮腫	0	0	0	0	0	0	0	0	0	0
胃腸障害	1 (50.0)	0	1 (50.0)	0	1 (50.0)	0	1 (50.0)	0	0	0
悪心	0	0	1 (50.0)	0	0	0	0	0	0	0
下痢	0	0	0	0	0	0	0	0	0	0
便秘	1 (50.0)	0	1 (50.0)	0	0	0	1 (50.0)	0	0	0
嘔吐	0	0	1 (50.0)	0	0	0	0	0	0	0
腹部膨満	0	0	1 (50.0)	0	1 (50.0)	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
口内炎	0	0	0	0	0	0	0	0	0	0
腹痛	0	0	0	0	0	0	0	0	0	0
口内乾燥	0	0	0	0	0	0	0	0	0	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	1 (50.0)	0	2 (100.0)	0
疲労	0	0	0	0	0	0	1 (50.0)	0	1 (50.0)	0
発熱	0	0	0	0	0	0	0	0	1 (50.0)	0
倦怠感	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 (50.0)	0	0	0	0	0
上咽頭炎	0	0	0	0	0	0	0	0	0	0
皮膚感染	0	0	0	0	0	0	0	0	0	0
上気道感染	0	0	0	0	1 (50.0)	0	0	0	0	0
腟感染	0	0	0	0	0	0	0	0	0	0
創傷感染	0	0	0	0	0	0	0	0	0	0
傷害、中毒および処置合併症	0	0	0	0	0	0	1 (50.0)	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
挫傷	0	0	0	0	0	0	1 (50.0)	0	0	0
臨床検査	0	0	0	0	0	0	1 (50.0)	0	2 (100.0)	0
血中クレアチニン増加	0	0	0	0	0	0	1 (50.0)	0	1 (50.0)	0
アラニンアミノトランスフェラーゼ増加	0	0	0	0	0	0	0	0	0	0
リパーゼ増加	0	0	0	0	0	0	0	0	1 (50.0)	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	0	0	0	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	0	0	0	0	0	0	0
リンパ球数減少	0	0	0	0	0	0	0	0	0	0
好中球数減少	0	0	0	0	0	0	0	0	0	0
白血球数減少	0	0	0	0	0	0	0	0	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	0	0	0	0
血小板数減少	0	0	0	0	0	0	0	0	0	0
代謝および栄養障害	0	0	1 (50.0)	0	0	0	0	0	1 (50.0)	0
高リン血症	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
食欲減退	0	0	1 (50.0)	0	0	0	0	0	0	0
低アルブミン血症	0	0	0	0	0	0	0	0	0	0
高カルシウム血症	0	0	0	0	0	0	0	0	1 (50.0)	0
高カリウム血症	0	0	0	0	0	0	0	0	0	0
高尿酸血症	0	0	0	0	0	0	0	0	0	0
低カリウム血症	0	0	0	0	0	0	0	0	0	0
低ナトリウム血症	0	0	0	0	0	0	0	0	0	0
低リン血症	0	0	0	0	0	0	0	0	1 (50.0)	0
筋骨格系および結合組織障害	0	0	0	0	0	0	0	0	0	0
背部痛	0	0	0	0	0	0	0	0	0	0
筋肉痛	0	0	0	0	0	0	0	0	0	0
頚部痛	0	0	0	0	0	0	0	0	0	0
変形性関節症	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	0	0	0	0	0	0	2 (100.0)	0	1 (50.0)	0
腫瘍疼痛	0	0	0	0	0	0	2 (100.0)	0	1 (50.0)	0
神経系障害	0	0	0	0	0	0	0	0	0	0
味覚不全	0	0	0	0	0	0	0	0	0	0
頭痛	0	0	0	0	0	0	0	0	0	0
反回神経麻痺	0	0	0	0	0	0	0	0	0	0
精神障害	1 (50.0)	0	0	0	0	0	1 (50.0)	0	1 (50.0)	0
不眠症	1 (50.0)	0	0	0	0	0	1 (50.0)	0	0	0
激越	0	0	0	0	0	0	0	0	1 (50.0)	0
腎および尿路障害	0	0	0	0	0	0	0	0	0	0
血尿	0	0	0	0	0	0	0	0	0	0
緊張性膀胱	0	0	0	0	0	0	0	0	0	0
蛋白尿	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
生殖系および乳房障害	1 (50.0)	0	0	0	0	0	0	0	0	0
性器出血	1 (50.0)	0	0	0	0	0	0	0	0	0
呼吸器、胸郭および縦隔障害	0	0	1 (50.0)	0	0	0	1 (50.0)	0	0	0
無気肺	0	0	1 (50.0)	0	0	0	0	0	0	0
咳嗽	0	0	0	0	0	0	1 (50.0)	0	0	0
発声障害	0	0	0	0	0	0	0	0	0	0
呼吸困難	0	0	0	0	0	0	1 (50.0)	0	0	0
喉頭痛	0	0	0	0	0	0	0	0	0	0
皮膚および皮下組織障害	1 (50.0)	0	1 (50.0)	0	0	0	0	0	0	0
手掌・足底発赤知覚不全症候群	0	0	0	0	0	0	0	0	0	0
皮膚乾燥	1 (50.0)	0	0	0	0	0	0	0	0	0
爪甲脱落症	0	0	0	0	0	0	0	0	0	0
発疹	0	0	1 (50.0)	0	0	0	0	0	0	0
爪の障害	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
そう痒症	0	0	0	0	0	0	0	0	0	0
斑状丘疹状皮疹	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any TEAE	2 (100.0)	0	3 (100.0)	1 (33.3)	3 (100.0)	0	3 (100.0)	0	3 (100.0)	3 (100.0)	22 (91.7)	4 (16.7)
血液およびリンパ系障害	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	0	0	4 (16.7)	0
貧血	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	0	0	3 (12.5)	0
白血球減少症	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
眼障害	0	0	1 (33.3)	0	2 (66.7)	0	2 (66.7)	0	0	0	5 (20.8)	0
漿液性網膜剥離	0	0	0	0	2 (66.7)	0	1 (33.3)	0	0	0	3 (12.5)	0
ドライアイ	0	0	1 (33.3)	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
黄斑浮腫	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
胃腸障害	2 (100.0)	0	3 (100.0)	0	2 (66.7)	0	2 (66.7)	0	3 (100.0)	1 (33.3)	16 (66.7)	1 (4.2)
悪心	2 (100.0)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	2 (66.7)	0	8 (33.3)	0
下痢	0	0	2 (66.7)	0	0	0	2 (66.7)	0	3 (100.0)	0	7 (29.2)	0
便秘	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	0	5 (20.8)	0
嘔吐	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	1 (33.3)	5 (20.8)	1 (4.2)
腹部膨満	0	0	0	0	0	0	0	0	0	0	2 (8.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
口内炎	0	0	0	0	1 (33.3)	0	0	0	1 (33.3)	0	2 (8.3)	0
腹痛	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
口内乾燥	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
一般・全身障害および投与部位の状態	1 (50.0)	0	1 (33.3)	0	2 (66.7)	0	2 (66.7)	0	2 (66.7)	0	11 (45.8)	0
疲労	1 (50.0)	0	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	6 (25.0)	0
発熱	1 (50.0)	0	0	0	2 (66.7)	0	0	0	1 (33.3)	0	5 (20.8)	0
倦怠感	0	0	1 (33.3)	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
感染症および寄生虫症	1 (50.0)	0	0	0	1 (33.3)	0	0	0	2 (66.7)	0	5 (20.8)	0
上咽頭炎	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
皮膚感染	1 (50.0)	0	0	0	0	0	0	0	0	0	1 (4.2)	0
上気道感染	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
腟感染	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
創傷感染	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
傷害、中毒および処置合併症	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
挫傷	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
臨床検査	1 (50.0)	0	2 (66.7)	1 (33.3)	2 (66.7)	0	3 (100.0)	0	2 (66.7)	2 (66.7)	13 (54.2)	3 (12.5)
血中クレアチニン増加	0	0	2 (66.7)	0	1 (33.3)	0	3 (100.0)	0	1 (33.3)	0	9 (37.5)	0
アラニンアミノトランスフェラーゼ増加	0	0	1 (33.3)	0	0	0	3 (100.0)	0	2 (66.7)	2 (66.7)	6 (25.0)	2 (8.3)
リパーゼ増加	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	5 (20.8)	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	0	0	0	2 (66.7)	0	2 (66.7)	1 (33.3)	4 (16.7)	1 (4.2)
血中アルカリホスファターゼ増加	0	0	0	0	1 (33.3)	0	2 (66.7)	0	0	0	3 (12.5)	0
リンパ球数減少	0	0	1 (33.3)	1 (33.3)	0	0	0	0	1 (33.3)	0	2 (8.3)	1 (4.2)
好中球数減少	0	0	0	0	0	0	0	0	2 (66.7)	1 (33.3)	2 (8.3)	1 (4.2)
白血球数減少	0	0	1 (33.3)	0	0	0	0	0	1 (33.3)	0	2 (8.3)	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
血小板数減少	1 (50.0)	0	0	0	0	0	0	0	0	0	1 (4.2)	0
代謝および栄養障害	0	0	1 (33.3)	0	3 (100.0)	0	3 (100.0)	0	3 (100.0)	1 (33.3)	12 (50.0)	1 (4.2)

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

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Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
高リン血症	0	0	0	0	3 (100.0)	0	3 (100.0)	0	3 (100.0)	0	9 (37.5)	0
食欲減退	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	1 (33.3)	3 (12.5)	1 (4.2)
低アルブミン血症	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	0	2 (8.3)	0
高カルシウム血症	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
高カリウム血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
高尿酸血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
低カリウム血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
低ナトリウム血症	0	0	1 (33.3)	0	0	0	0	0	0	0	1 (4.2)	0
低リン血症	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
筋骨格系および結合組織障害	1 (50.0)	0	1 (33.3)	0	1 (33.3)	0	2 (66.7)	0	1 (33.3)	0	6 (25.0)	0
背部痛	0	0	0	0	1 (33.3)	0	0	0	1 (33.3)	0	2 (8.3)	0
筋肉痛	0	0	1 (33.3)	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
頚部痛	1 (50.0)	0	0	0	0	0	0	0	0	0	1 (4.2)	0
変形性関節症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
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 (50.0)	0	0	0	1 (33.3)	0	0	0	0	0	5 (20.8)	0
腫瘍疼痛	1 (50.0)	0	0	0	1 (33.3)	0	0	0	0	0	5 (20.8)	0
神経系障害	0	0	0	0	0	0	2 (66.7)	0	1 (33.3)	0	3 (12.5)	0
味覚不全	0	0	0	0	0	0	2 (66.7)	0	1 (33.3)	0	3 (12.5)	0
頭痛	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
反回神経麻痺	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
精神障害	0	0	0	0	0	0	0	0	1 (33.3)	0	4 (16.7)	0
不眠症	0	0	0	0	0	0	0	0	1 (33.3)	0	3 (12.5)	0
激越	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
腎および尿路障害	0	0	1 (33.3)	0	1 (33.3)	0	0	0	1 (33.3)	0	3 (12.5)	0
血尿	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
緊張性膀胱	0	0	1 (33.3)	0	0	0	0	0	0	0	1 (4.2)	0
蛋白尿	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
生殖系および乳房障害	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
性器出血	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
呼吸器、胸郭および縦隔障害	0	0	0	0	0	0	0	0	1 (33.3)	0	3 (12.5)	0
無気肺	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
咳嗽	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
発声障害	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
呼吸困難	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
喉頭痛	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
皮膚および皮下組織障害	0	0	1 (33.3)	0	0	0	3 (100.0)	0	2 (66.7)	0	8 (33.3)	0
手掌・足底発赤知覚不全症候群	0	0	1 (33.3)	0	0	0	1 (33.3)	0	2 (66.7)	0	4 (16.7)	0
皮膚乾燥	0	0	0	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
爪甲脱落症	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	0	2 (8.3)	0
発疹	0	0	0	0	0	0	0	0	1 (33.3)	0	2 (8.3)	0
爪の障害	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.1.1

SOC/PT別の有害事象発現率

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Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
そう痒症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
斑状丘疹状皮疹	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.

TEAE = treatment-emergent adverse event.

Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.

Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.

A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.

Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any TEAE	10 (100.0)	7 (70.0)	6 (100.0)	4 (66.7)	16 (100.0)	11 (68.8)
血液およびリンパ系障害	4 (40.0)	2 (20.0)	0	0	4 (25.0)	2 (12.5)
貧血	4 (40.0)	2 (20.0)	0	0	4 (25.0)	2 (12.5)
心臓障害	1 (10.0)	0	0	0	1 (6.3)	0
頻脈	1 (10.0)	0	0	0	1 (6.3)	0
眼障害	2 (20.0)	1 (10.0)	5 (83.3)	0	7 (43.8)	1 (6.3)
ドライアイ	0	0	2 (33.3)	0	2 (12.5)	0
白内障	1 (10.0)	0	0	0	1 (6.3)	0
アレルギー性結膜炎	0	0	1 (16.7)	0	1 (6.3)	0
角膜障害	0	0	1 (16.7)	0	1 (6.3)	0
眼瞼下垂	0	0	1 (16.7)	0	1 (6.3)	0
角膜炎	1 (10.0)	0	0	0	1 (6.3)	0
黄斑浮腫	1 (10.0)	0	0	0	1 (6.3)	0
眼窩周囲浮腫	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
網膜剥離	0	0	1 (16.7)	0	1 (6.3)	0
網膜症	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
漿液性網膜剥離	0	0	1 (16.7)	0	1 (6.3)	0
網膜下液	0	0	1 (16.7)	0	1 (6.3)	0
胃腸障害	9 (90.0)	2 (20.0)	6 (100.0)	1 (16.7)	15 (93.8)	3 (18.8)
下痢	2 (20.0)	0	4 (66.7)	1 (16.7)	6 (37.5)	1 (6.3)
口内炎	3 (30.0)	0	3 (50.0)	0	6 (37.5)	0
腹部膨満	3 (30.0)	1 (10.0)	1 (16.7)	0	4 (25.0)	1 (6.3)
便秘	2 (20.0)	0	1 (16.7)	0	3 (18.8)	0
口内乾燥	2 (20.0)	0	1 (16.7)	0	3 (18.8)	0
腹痛	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
嘔吐	2 (20.0)	1 (10.0)	0	0	2 (12.5)	1 (6.3)
口角口唇炎	1 (10.0)	0	0	0	1 (6.3)	0
嚥下障害	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
舌炎	0	0	1 (16.7)	0	1 (6.3)	0
イレウス	0	0	1 (16.7)	1 (16.7)	1 (6.3)	1 (6.3)
悪性腹水	0	0	1 (16.7)	0	1 (6.3)	0
悪心	1 (10.0)	0	0	0	1 (6.3)	0
歯周病	0	0	1 (16.7)	0	1 (6.3)	0
一般・全身障害および投与部位の状態	5 (50.0)	1 (10.0)	3 (50.0)	0	8 (50.0)	1 (6.3)
発熱	1 (10.0)	0	2 (33.3)	0	3 (18.8)	0
倦怠感	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
疲労	1 (10.0)	0	0	0	1 (6.3)	0
全身健康状態悪化	1 (10.0)	0	0	0	1 (6.3)	0
粘膜出血	1 (10.0)	0	0	0	1 (6.3)	0
粘膜の炎症	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
末梢性浮腫	1 (10.0)	0	0	0	1 (6.3)	0
肝胆道系障害	1 (10.0)	1 (10.0)	1 (16.7)	1 (16.7)	2 (12.5)	2 (12.5)

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
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A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
胆管炎	0	0	1 (16.7)	1 (16.7)	1 (6.3)	1 (6.3)
急性胆嚢炎	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
肝機能異常	0	0	1 (16.7)	0	1 (6.3)	0
感染症および寄生虫症	6 (60.0)	1 (10.0)	4 (66.7)	0	10 (62.5)	1 (6.3)
爪囲炎	5 (50.0)	0	4 (66.7)	0	9 (56.3)	0
上咽頭炎	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
咽頭炎	0	0	1 (16.7)	0	1 (6.3)	0
肺炎	1 (10.0)	0	0	0	1 (6.3)	0
腎盂腎炎	1 (10.0)	0	0	0	1 (6.3)	0
敗血症性ショック	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
傷害、中毒および処置合併症	2 (20.0)	1 (10.0)	0	0	2 (12.5)	1 (6.3)
爪損傷	1 (10.0)	0	0	0	1 (6.3)	0
創合併症	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
臨床検査	7 (70.0)	3 (30.0)	6 (100.0)	2 (33.3)	13 (81.3)	5 (31.3)

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
血中クレアチニン増加	3 (30.0)	0	2 (33.3)	0	5 (31.3)	0
アスパラギン酸アミノトランスフェラーゼ増加	3 (30.0)	2 (20.0)	1 (16.7)	0	4 (25.0)	2 (12.5)
アラニンアミノトランスフェラーゼ増加	3 (30.0)	1 (10.0)	0	0	3 (18.8)	1 (6.3)
血中アルカリホスファターゼ増加	3 (30.0)	2 (20.0)	0	0	3 (18.8)	2 (12.5)
リパーゼ増加	0	0	2 (33.3)	2 (33.3)	2 (12.5)	2 (12.5)
血小板数減少	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
体重減少	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
抱合ビリルビン増加	1 (10.0)	0	0	0	1 (6.3)	0
血中ビリルビン増加	0	0	1 (16.7)	0	1 (6.3)	0
血中乳酸脱水素酵素増加	1 (10.0)	0	0	0	1 (6.3)	0
血中尿素増加	1 (10.0)	0	0	0	1 (6.3)	0
Ｃ－反応性蛋白増加	1 (10.0)	0	0	0	1 (6.3)	0
フィブリンＤダイマー増加	0	0	1 (16.7)	0	1 (6.3)	0
γ－グルタミルトランスフェラーゼ増加	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
リンパ球数減少	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
体重増加	1 (10.0)	0	0	0	1 (6.3)	0
白血球数減少	1 (10.0)	0	0	0	1 (6.3)	0
代謝および栄養障害	10 (100.0)	2 (20.0)	6 (100.0)	2 (33.3)	16 (100.0)	4 (25.0)
高リン血症	10 (100.0)	0	6 (100.0)	0	16 (100.0)	0
食欲減退	5 (50.0)	1 (10.0)	2 (33.3)	1 (16.7)	7 (43.8)	2 (12.5)
低アルブミン血症	3 (30.0)	1 (10.0)	0	0	3 (18.8)	1 (6.3)
低リン血症	0	0	2 (33.3)	1 (16.7)	2 (12.5)	1 (6.3)
脱水	1 (10.0)	0	0	0	1 (6.3)	0
高カルシウム血症	0	0	1 (16.7)	0	1 (6.3)	0
高血糖	1 (10.0)	0	0	0	1 (6.3)	0
高カリウム血症	1 (10.0)	0	0	0	1 (6.3)	0
低ナトリウム血症	0	0	1 (16.7)	1 (16.7)	1 (6.3)	1 (6.3)
筋骨格系および結合組織障害	0	0	4 (66.7)	0	4 (25.0)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
関節痛	0	0	1 (16.7)	0	1 (6.3)	0
背部痛	0	0	1 (16.7)	0	1 (6.3)	0
関節可動域低下	0	0	1 (16.7)	0	1 (6.3)	0
筋肉痛	0	0	1 (16.7)	0	1 (6.3)	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）	5 (50.0)	1 (10.0)	0	0	5 (31.3)	1 (6.3)
癌疼痛	2 (20.0)	0	0	0	2 (12.5)	0
腫瘍熱	2 (20.0)	0	0	0	2 (12.5)	0
腫瘍疼痛	2 (20.0)	1 (10.0)	0	0	2 (12.5)	1 (6.3)
腫瘍性閉塞	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
神経系障害	4 (40.0)	0	3 (50.0)	1 (16.7)	7 (43.8)	1 (6.3)
味覚不全	4 (40.0)	0	2 (33.3)	0	6 (37.5)	0
頭痛	0	0	2 (33.3)	1 (16.7)	2 (12.5)	1 (6.3)
意識レベルの低下	1 (10.0)	0	0	0	1 (6.3)	0
浮動性めまい	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
精神障害	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
不眠症	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
譫妄	0	0	1 (16.7)	0	1 (6.3)	0
腎および尿路障害	2 (20.0)	0	0	0	2 (12.5)	0
排尿困難	1 (10.0)	0	0	0	1 (6.3)	0
水腎症	1 (10.0)	0	0	0	1 (6.3)	0
生殖系および乳房障害	0	0	1 (16.7)	0	1 (6.3)	0
女性化乳房	0	0	1 (16.7)	0	1 (6.3)	0
呼吸器、胸郭および縦隔障害	2 (20.0)	1 (10.0)	1 (16.7)	0	3 (18.8)	1 (6.3)
鼻出血	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
発声障害	0	0	1 (16.7)	0	1 (6.3)	0
胸水	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
皮膚および皮下組織障害	6 (60.0)	0	6 (100.0)	0	12 (75.0)	0
手掌・足底発赤知覚不全症候群	4 (40.0)	0	6 (100.0)	0	10 (62.5)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.1.2

SOC/PT別の有害事象発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
皮膚乾燥	0	0	3 (50.0)	0	3 (18.8)	0
爪の障害	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
そう痒症	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
脱毛症	0	0	1 (16.7)	0	1 (6.3)	0
爪変色	1 (10.0)	0	0	0	1 (6.3)	0
爪線状隆起	0	0	1 (16.7)	0	1 (6.3)	0
爪甲脱落症	0	0	1 (16.7)	0	1 (6.3)	0
斑状丘疹状皮疹	0	0	1 (16.7)	0	1 (6.3)	0
血管障害	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
低血圧	1 (10.0)	0	0	0	1 (6.3)	0
遊走性血栓静脈炎	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any Treatment-Related TEAE	0	0	1 (50.0)	0	1 (50.0)	0	1 (50.0)	0	2 (100.0)	0
血液およびリンパ系障害	0	0	0	0	0	0	0	0	1 (50.0)	0
貧血	0	0	0	0	0	0	0	0	0	0
白血球減少症	0	0	0	0	0	0	0	0	1 (50.0)	0
眼障害	0	0	0	0	0	0	0	0	0	0
漿液性網膜剥離	0	0	0	0	0	0	0	0	0	0
ドライアイ	0	0	0	0	0	0	0	0	0	0
黄斑浮腫	0	0	0	0	0	0	0	0	0	0
胃腸障害	0	0	1 (50.0)	0	1 (50.0)	0	0	0	0	0
下痢	0	0	0	0	0	0	0	0	0	0
悪心	0	0	0	0	0	0	0	0	0	0
嘔吐	0	0	0	0	0	0	0	0	0	0
便秘	0	0	1 (50.0)	0	0	0	0	0	0	0
口内炎	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
腹部膨満	0	0	0	0	1 (50.0)	0	0	0	0	0
口内乾燥	0	0	0	0	0	0	0	0	0	0
一般・全身障害および投与部位の状態	0	0	0	0	0	0	0	0	0	0
倦怠感	0	0	0	0	0	0	0	0	0	0
疲労	0	0	0	0	0	0	0	0	0	0
臨床検査	0	0	0	0	0	0	1 (50.0)	0	2 (100.0)	0
血中クレアチニン増加	0	0	0	0	0	0	1 (50.0)	0	1 (50.0)	0
アラニンアミノトランスフェラーゼ増加	0	0	0	0	0	0	0	0	0	0
リパーゼ増加	0	0	0	0	0	0	0	0	1 (50.0)	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	0	0	0	0	0	0	0
血中アルカリホスファターゼ増加	0	0	0	0	0	0	0	0	0	0
リンパ球数減少	0	0	0	0	0	0	0	0	0	0
好中球数減少	0	0	0	0	0	0	0	0	0	0
白血球数減少	0	0	0	0	0	0	0	0	0	0
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
血小板数減少	0	0	0	0	0	0	0	0	0	0
代謝および栄養障害	0	0	0	0	0	0	0	0	0	0
高リン血症	0	0	0	0	0	0	0	0	0	0
食欲減退	0	0	0	0	0	0	0	0	0	0
高カリウム血症	0	0	0	0	0	0	0	0	0	0
高尿酸血症	0	0	0	0	0	0	0	0	0	0
低アルブミン血症	0	0	0	0	0	0	0	0	0	0
低カリウム血症	0	0	0	0	0	0	0	0	0	0
低ナトリウム血症	0	0	0	0	0	0	0	0	0	0
筋骨格系および結合組織障害	0	0	0	0	0	0	0	0	0	0
筋肉痛	0	0	0	0	0	0	0	0	0	0
神経系障害	0	0	0	0	0	0	0	0	0	0
味覚不全	0	0	0	0	0	0	0	0	0	0
頭痛	0	0	0	0	0	0	0	0	0	0
腎および尿路障害	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	1 mg (N=2) n (%)		2 mg (N=2) n (%)		4 mg (N=2) n (%)		8 mg (N=2) n (%)		16 mg (N=2) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
蛋白尿	0	0	0	0	0	0	0	0	0	0
皮膚および皮下組織障害	0	0	1 (50.0)	0	0	0	0	0	0	0
手掌・足底発赤知覚不全症候群	0	0	0	0	0	0	0	0	0	0
爪甲脱落症	0	0	0	0	0	0	0	0	0	0
皮膚乾燥	0	0	0	0	0	0	0	0	0	0
爪の障害	0	0	0	0	0	0	0	0	0	0
そう痒症	0	0	0	0	0	0	0	0	0	0
発疹	0	0	1 (50.0)	0	0	0	0	0	0	0
斑状丘疹状皮疹	0	0	0	0	0	0	0	0	0	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any Treatment-Related TEAE	1 (50.0)	0	3 (100.0)	1 (33.3)	3 (100.0)	0	3 (100.0)	0	3 (100.0)	3 (100.0)	18 (75.0)	4 (16.7)
血液およびリンパ系障害	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	0	0	4 (16.7)	0
貧血	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	0	0	3 (12.5)	0
白血球減少症	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
眼障害	0	0	0	0	2 (66.7)	0	2 (66.7)	0	0	0	4 (16.7)	0
漿液性網膜剥離	0	0	0	0	2 (66.7)	0	1 (33.3)	0	0	0	3 (12.5)	0
ドライアイ	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
黄斑浮腫	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
胃腸障害	1 (50.0)	0	3 (100.0)	0	2 (66.7)	0	2 (66.7)	0	3 (100.0)	1 (33.3)	13 (54.2)	1 (4.2)
下痢	0	0	2 (66.7)	0	0	0	1 (33.3)	0	3 (100.0)	0	6 (25.0)	0
悪心	1 (50.0)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	5 (20.8)	0
嘔吐	0	0	1 (33.3)	0	0	0	1 (33.3)	0	1 (33.3)	1 (33.3)	3 (12.5)	1 (4.2)
便秘	0	0	0	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
口内炎	0	0	0	0	1 (33.3)	0	0	0	1 (33.3)	0	2 (8.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
腹部膨満	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
口内乾燥	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
一般・全身障害および投与部位の状態	1 (50.0)	0	1 (33.3)	0	0	0	1 (33.3)	0	0	0	3 (12.5)	0
倦怠感	0	0	1 (33.3)	0	0	0	1 (33.3)	0	0	0	2 (8.3)	0
疲労	1 (50.0)	0	0	0	0	0	0	0	0	0	1 (4.2)	0
臨床検査	1 (50.0)	0	2 (66.7)	1 (33.3)	2 (66.7)	0	3 (100.0)	0	2 (66.7)	2 (66.7)	13 (54.2)	3 (12.5)
血中クレアチニン増加	0	0	2 (66.7)	0	1 (33.3)	0	3 (100.0)	0	1 (33.3)	0	9 (37.5)	0
アラニンアミノトランスフェラーゼ増加	0	0	1 (33.3)	0	0	0	3 (100.0)	0	2 (66.7)	2 (66.7)	6 (25.0)	2 (8.3)
リパーゼ増加	0	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	1 (33.3)	0	5 (20.8)	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	0	0	0	2 (66.7)	0	2 (66.7)	1 (33.3)	4 (16.7)	1 (4.2)
血中アルカリホスファターゼ増加	0	0	0	0	1 (33.3)	0	2 (66.7)	0	0	0	3 (12.5)	0
リンパ球数減少	0	0	1 (33.3)	1 (33.3)	0	0	0	0	1 (33.3)	0	2 (8.3)	1 (4.2)
好中球数減少	0	0	0	0	0	0	0	0	2 (66.7)	1 (33.3)	2 (8.3)	1 (4.2)
白血球数減少	0	0	1 (33.3)	0	0	0	0	0	1 (33.3)	0	2 (8.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
γ－グルタミルトランスフェラーゼ増加	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
血小板数減少	1 (50.0)	0	0	0	0	0	0	0	0	0	1 (4.2)	0
代謝および栄養障害	0	0	1 (33.3)	0	3 (100.0)	0	3 (100.0)	0	3 (100.0)	1 (33.3)	10 (41.7)	1 (4.2)
高リン血症	0	0	0	0	3 (100.0)	0	3 (100.0)	0	3 (100.0)	0	9 (37.5)	0
食欲減退	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	1 (33.3)	2 (8.3)	1 (4.2)
高カリウム血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
高尿酸血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
低アルブミン血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
低カリウム血症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
低ナトリウム血症	0	0	1 (33.3)	0	0	0	0	0	0	0	1 (4.2)	0
筋骨格系および結合組織障害	0	0	1 (33.3)	0	0	0	0	0	0	0	1 (4.2)	0
筋肉痛	0	0	1 (33.3)	0	0	0	0	0	0	0	1 (4.2)	0
神経系障害	0	0	0	0	0	0	2 (66.7)	0	1 (33.3)	0	3 (12.5)	0
味覚不全	0	0	0	0	0	0	2 (66.7)	0	1 (33.3)	0	3 (12.5)	0
頭痛	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.2.1

SOC/PT別の副作用発現率

Study 101

Part 1

Safety Analysis Set

MedDRA System Organ Class Preferred Term	30 mg (N=2) n (%)		60 mg (N=3) n (%)		100 mg (N=3) n (%)		140 mg (N=3) n (%)		180 mg (N=3) n (%)		Overall (N=24) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
腎および尿路障害	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
蛋白尿	0	0	0	0	1 (33.3)	0	0	0	0	0	1 (4.2)	0
皮膚および皮下組織障害	0	0	1 (33.3)	0	0	0	3 (100.0)	0	2 (66.7)	0	7 (29.2)	0
手掌・足底発赤知覚不全症候群	0	0	1 (33.3)	0	0	0	1 (33.3)	0	2 (66.7)	0	4 (16.7)	0
爪甲脱落症	0	0	0	0	0	0	1 (33.3)	0	1 (33.3)	0	2 (8.3)	0
皮膚乾燥	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
爪の障害	0	0	0	0	0	0	0	0	1 (33.3)	0	1 (4.2)	0
そう痒症	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0
発疹	0	0	0	0	0	0	0	0	0	0	1 (4.2)	0
斑状丘疹状皮疹	0	0	0	0	0	0	1 (33.3)	0	0	0	1 (4.2)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3.2.2

SOC/PT別の副作用発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with any Treatment-Related TEAE	10 (100.0)	1 (10.0)	6 (100.0)	1 (16.7)	16 (100.0)	2 (12.5)
血液およびリンパ系障害	1 (10.0)	0	0	0	1 (6.3)	0
貧血	1 (10.0)	0	0	0	1 (6.3)	0
眼障害	2 (20.0)	1 (10.0)	3 (50.0)	0	5 (31.3)	1 (6.3)
角膜障害	0	0	1 (16.7)	0	1 (6.3)	0
ドライアイ	0	0	1 (16.7)	0	1 (6.3)	0
角膜炎	1 (10.0)	0	0	0	1 (6.3)	0
黄斑浮腫	1 (10.0)	0	0	0	1 (6.3)	0
網膜剥離	0	0	1 (16.7)	0	1 (6.3)	0
網膜症	1 (10.0)	1 (10.0)	0	0	1 (6.3)	1 (6.3)
漿液性網膜剥離	0	0	1 (16.7)	0	1 (6.3)	0
網膜下液	0	0	1 (16.7)	0	1 (6.3)	0
胃腸障害	5 (50.0)	0	6 (100.0)	0	11 (68.8)	0
口内炎	3 (30.0)	0	3 (50.0)	0	6 (37.5)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3,2.2

SOC/PT別の副作用発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
下痢	1 (10.0)	0	3 (50.0)	0	4 (25.0)	0
口内乾燥	2 (20.0)	0	1 (16.7)	0	3 (18.8)	0
口角口唇炎	1 (10.0)	0	0	0	1 (6.3)	0
便秘	1 (10.0)	0	0	0	1 (6.3)	0
舌炎	0	0	1 (16.7)	0	1 (6.3)	0
一般・全身障害および投与部位の状態	3 (30.0)	0	2 (33.3)	0	5 (31.3)	0
倦怠感	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
疲労	1 (10.0)	0	0	0	1 (6.3)	0
粘膜出血	1 (10.0)	0	0	0	1 (6.3)	0
発熱	0	0	1 (16.7)	0	1 (6.3)	0
感染症および寄生虫症	4 (40.0)	0	4 (66.7)	0	8 (50.0)	0
爪囲炎	4 (40.0)	0	4 (66.7)	0	8 (50.0)	0
傷害、中毒および処置合併症	1 (10.0)	0	0	0	1 (6.3)	0
爪損傷	1 (10.0)	0	0	0	1 (6.3)	0
臨床検査	2 (20.0)	1 (10.0)	5 (83.3)	1 (16.7)	7 (43.8)	2 (12.5)

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3,2.2

SOC/PT別の副作用発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
アスパラギン酸アミノトランスフェラーゼ増加	2 (20.0)	1 (10.0)	1 (16.7)	0	3 (18.8)	1 (6.3)
血中クレアチニン増加	1 (10.0)	0	2 (33.3)	0	3 (18.8)	0
アラニンアミノトランスフェラーゼ増加	2 (20.0)	0	0	0	2 (12.5)	0
血中アルカリホスファターゼ増加	1 (10.0)	0	0	0	1 (6.3)	0
血中ビリルビン増加	0	0	1 (16.7)	0	1 (6.3)	0
リパーゼ増加	0	0	1 (16.7)	1 (16.7)	1 (6.3)	1 (6.3)
血小板数減少	0	0	1 (16.7)	0	1 (6.3)	0
代謝および栄養障害	10 (100.0)	0	6 (100.0)	0	16 (100.0)	0
高リン血症	10 (100.0)	0	6 (100.0)	0	16 (100.0)	0
食欲減退	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
高カルシウム血症	0	0	1 (16.7)	0	1 (6.3)	0
低リン血症	0	0	1 (16.7)	0	1 (6.3)	0
筋骨格系および結合組織障害	0	0	2 (33.3)	0	2 (12.5)	0
関節痛	0	0	1 (16.7)	0	1 (6.3)	0
関節可動域低下	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.3,2.2

SOC/PT別の副作用発現率

Study 101
Part 2
Safety Analysis Set

MedDRA System Organ Class Preferred Term	Gastric Cancer (N=10) n (%)		Cholangiocarcinoma (N=6) n (%)		Overall (N=16) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
神経系障害	3 (30.0)	0	2 (33.3)	0	5 (31.3)	0
味覚不全	3 (30.0)	0	2 (33.3)	0	5 (31.3)	0
生殖系および乳房障害	0	0	1 (16.7)	0	1 (6.3)	0
女性化乳房	0	0	1 (16.7)	0	1 (6.3)	0
呼吸器、胸郭および縦隔障害	0	0	1 (16.7)	0	1 (6.3)	0
鼻出血	0	0	1 (16.7)	0	1 (6.3)	0
皮膚および皮下組織障害	6 (60.0)	0	6 (100.0)	0	12 (75.0)	0
手掌・足底発赤知覚不全症候群	4 (40.0)	0	6 (100.0)	0	10 (62.5)	0
皮膚乾燥	0	0	3 (50.0)	0	3 (18.8)	0
爪の障害	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
そう痒症	1 (10.0)	0	1 (16.7)	0	2 (12.5)	0
脱毛症	0	0	1 (16.7)	0	1 (6.3)	0
爪変色	1 (10.0)	0	0	0	1 (6.3)	0
爪甲脱落症	0	0	1 (16.7)	0	1 (6.3)	0

Percentages are based on the total number of treated subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with Any TEAEs	28 (100.0)	17 (60.7)	35 (100.0)	18 (51.4)	63 (100.0)	35 (55.6)
血液およびリンパ系障害	2 (7.1)	1 (3.6)	11 (31.4)	2 (5.7)	13 (20.6)	3 (4.8)
血小板減少症	0	0	6 (17.1)	1 (2.9)	6 (9.5)	1 (1.6)
貧血	1 (3.6)	1 (3.6)	4 (11.4)	1 (2.9)	5 (7.9)	2 (3.2)
白血球減少症	0	0	4 (11.4)	1 (2.9)	4 (6.3)	1 (1.6)
好酸球増加症	1 (3.6)	0	0	0	1 (1.6)	0
骨髄抑制	0	0	1 (2.9)	0	1 (1.6)	0
好中球減少症	0	0	1 (2.9)	0	1 (1.6)	0
心臓障害	1 (3.6)	1 (3.6)	4 (11.4)	0	5 (7.9)	1 (1.6)
冠動脈硬化症	0	0	1 (2.9)	0	1 (1.6)	0
心筋梗塞	0	0	1 (2.9)	0	1 (1.6)	0
心筋虚血	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
動悸	0	0	1 (2.9)	0	1 (1.6)	0
洞性頻脈	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
心室性期外収縮	0	0	1 (2.9)	0	1 (1.6)	0
先天性、家族性および遺伝性障害	1 (3.6)	0	0	0	1 (1.6)	0
硬化性胼胝腫	1 (3.6)	0	0	0	1 (1.6)	0
耳および迷路障害	2 (7.1)	0	1 (2.9)	0	3 (4.8)	0
耳鳴	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
回転性めまい	1 (3.6)	0	0	0	1 (1.6)	0
眼障害	20 (71.4)	1 (3.6)	29 (82.9)	2 (5.7)	49 (77.8)	3 (4.8)
角膜炎	8 (28.6)	0	5 (14.3)	0	13 (20.6)	0
ドライアイ	6 (21.4)	1 (3.6)	3 (8.6)	0	9 (14.3)	1 (1.6)
角膜上皮欠損	1 (3.6)	0	7 (20.0)	1 (2.9)	8 (12.7)	1 (1.6)
眼球乾燥症	0	0	8 (22.9)	0	8 (12.7)	0
黄斑浮腫	5 (17.9)	0	2 (5.7)	0	7 (11.1)	0
網膜剥離	1 (3.6)	0	4 (11.4)	0	5 (7.9)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
漿液性網膜剥離	5 (17.9)	0	0	0	5 (7.9)	0
霧視	0	0	5 (14.3)	1 (2.9)	5 (7.9)	1 (1.6)
白内障	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
角膜混濁	1 (3.6)	1 (3.6)	2 (5.7)	0	3 (4.8)	1 (1.6)
網膜下液	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
黄斑変性	0	0	2 (5.7)	1 (2.9)	2 (3.2)	1 (1.6)
点状角膜炎	2 (7.1)	0	0	0	2 (3.2)	0
一過性黒内障	0	0	1 (2.9)	0	1 (1.6)	0
眼瞼炎	0	0	1 (2.9)	0	1 (1.6)	0
中心性漿液性脈絡網膜症	1 (3.6)	0	0	0	1 (1.6)	0
結膜出血	1 (3.6)	0	0	0	1 (1.6)	0
結膜充血	0	0	1 (2.9)	0	1 (1.6)	0
角膜障害	1 (3.6)	0	0	0	1 (1.6)	0
角膜びらん	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
角膜菲薄化	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
眼瞼外反	1 (3.6)	0	0	0	1 (1.6)	0
網膜上膜	0	0	1 (2.9)	0	1 (1.6)	0
眼脂	1 (3.6)	0	0	0	1 (1.6)	0
緑内障	0	0	1 (2.9)	0	1 (1.6)	0
流涙増加	1 (3.6)	0	0	0	1 (1.6)	0
黄斑剥離	0	0	1 (2.9)	0	1 (1.6)	0
黄斑肥厚	0	0	1 (2.9)	0	1 (1.6)	0
黄斑症	0	0	1 (2.9)	0	1 (1.6)	0
マイボーム腺機能不全	0	0	1 (2.9)	0	1 (1.6)	0
視神経乳頭陥凹	1 (3.6)	0	0	0	1 (1.6)	0
視神経症	0	0	1 (2.9)	0	1 (1.6)	0
瞼裂斑	0	0	1 (2.9)	0	1 (1.6)	0
屈折障害	0	0	1 (2.9)	0	1 (1.6)	0
網膜出血	1 (3.6)	0	0	0	1 (1.6)	0
網膜症	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
睫毛乱生	0	0	1 (2.9)	0	1 (1.6)	0
視力障害	0	0	1 (2.9)	0	1 (1.6)	0
胃腸障害	25 (89.3)	2 (7.1)	24 (68.6)	2 (5.7)	49 (77.8)	4 (6.3)
下痢	12 (42.9)	0	11 (31.4)	0	23 (36.5)	0
口内炎	14 (50.0)	1 (3.6)	2 (5.7)	0	16 (25.4)	1 (1.6)
口内乾燥	6 (21.4)	0	8 (22.9)	0	14 (22.2)	0
便秘	4 (14.3)	0	4 (11.4)	0	8 (12.7)	0
悪心	8 (28.6)	0	0	0	8 (12.7)	0
嘔吐	5 (17.9)	0	3 (8.6)	0	8 (12.7)	0
腹痛	2 (7.1)	0	2 (5.7)	0	4 (6.3)	0
口腔内潰瘍形成	0	0	4 (11.4)	0	4 (6.3)	0
腹部膨満	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
上腹部痛	3 (10.7)	0	0	0	3 (4.8)	0
食道炎	2 (7.1)	0	0	0	2 (3.2)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
腹部不快感	0	0	1 (2.9)	0	1 (1.6)	0
口角口唇炎	1 (3.6)	0	0	0	1 (1.6)	0
腹水	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
口唇炎	1 (3.6)	0	0	0	1 (1.6)	0
慢性胃炎	0	0	1 (2.9)	0	1 (1.6)	0
齲歯	1 (3.6)	0	0	0	1 (1.6)	0
消化不良	0	0	1 (2.9)	0	1 (1.6)	0
嚥下障害	0	0	1 (2.9)	0	1 (1.6)	0
おくび	1 (3.6)	0	0	0	1 (1.6)	0
胃食道逆流性疾患	0	0	1 (2.9)	0	1 (1.6)	0
歯肉出血	1 (3.6)	0	0	0	1 (1.6)	0
痔核	1 (3.6)	0	0	0	1 (1.6)	0
腸閉塞	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
大腸出血	1 (3.6)	0	0	0	1 (1.6)	0
大腸ポリープ	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

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Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
口腔血性水疱	0	0	1 (2.9)	0	1 (1.6)	0
口腔知覚不全	1 (3.6)	0	0	0	1 (1.6)	0
膵炎	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
歯の発育障害	0	0	1 (2.9)	0	1 (1.6)	0
歯痛	1 (3.6)	0	0	0	1 (1.6)	0
一般・全身障害および投与部位の状態	14 (50.0)	2 (7.1)	8 (22.9)	1 (2.9)	22 (34.9)	3 (4.8)
発熱	10 (35.7)	0	4 (11.4)	0	14 (22.2)	0
疲労	2 (7.1)	0	3 (8.6)	0	5 (7.9)	0
倦怠感	4 (14.3)	0	0	0	4 (6.3)	0
口渇	2 (7.1)	0	1 (2.9)	0	3 (4.8)	0
死亡	1 (3.6)	1 (3.6)	1 (2.9)	1 (2.9)	2 (3.2)	2 (3.2)
熱感	0	0	1 (2.9)	0	1 (1.6)	0
インフルエンザ様疾患	0	0	1 (2.9)	0	1 (1.6)	0
医療機器使用部位疼痛	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

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Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
多臓器機能不全症候群	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
肝胆道系障害	5 (17.9)	4 (14.3)	7 (20.0)	3 (8.6)	12 (19.0)	7 (11.1)
肝機能異常	2 (7.1)	2 (7.1)	3 (8.6)	2 (5.7)	5 (7.9)	4 (6.3)
肝損傷	0	0	3 (8.6)	1 (2.9)	3 (4.8)	1 (1.6)
高ビリルビン血症	0	0	2 (5.7)	0	2 (3.2)	0
胆管狭窄	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
胆管結石	1 (3.6)	0	0	0	1 (1.6)	0
胆道仙痛	0	0	1 (2.9)	0	1 (1.6)	0
胆道閉塞	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
胆管炎	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
胆汁うっ滞性黄疸	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
感染症および寄生虫症	14 (50.0)	0	20 (57.1)	2 (5.7)	34 (54.0)	2 (3.2)
爪囲炎	11 (39.3)	0	3 (8.6)	0	14 (22.2)	0

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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
ＣＯＶＩＤ－１９	0	0	6 (17.1)	0	6 (9.5)	0
尿路感染	0	0	5 (14.3)	0	5 (7.9)	0
上気道感染	0	0	3 (8.6)	0	3 (4.8)	0
結膜炎	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
咽頭炎	0	0	2 (5.7)	0	2 (3.2)	0
肺炎	0	0	2 (5.7)	1 (2.9)	2 (3.2)	1 (1.6)
鼻炎	0	0	2 (5.7)	0	2 (3.2)	0
胆道感染	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
膀胱炎	1 (3.6)	0	0	0	1 (1.6)	0
胃腸炎	0	0	1 (2.9)	0	1 (1.6)	0
歯肉炎	1 (3.6)	0	0	0	1 (1.6)	0
咽喉頭炎	0	0	1 (2.9)	0	1 (1.6)	0
肝膿瘍	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
上咽頭炎	1 (3.6)	0	0	0	1 (1.6)	0
爪真菌症	0	0	1 (2.9)	0	1 (1.6)	0

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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
誤嚥性肺炎	1 (3.6)	0	0	0	1 (1.6)	0
皮膚感染	1 (3.6)	0	0	0	1 (1.6)	0
傷害、中毒および処置合併症	1 (3.6)	0	0	0	1 (1.6)	0
転倒	1 (3.6)	0	0	0	1 (1.6)	0
臨床検査	20 (71.4)	7 (25.0)	32 (91.4)	7 (20.0)	52 (82.5)	14 (22.2)
アスパラギン酸アミノトランスフェラーゼ増加	6 (21.4)	1 (3.6)	14 (40.0)	1 (2.9)	20 (31.7)	2 (3.2)
アラニンアミノトランスフェラーゼ増加	4 (14.3)	1 (3.6)	14 (40.0)	1 (2.9)	18 (28.6)	2 (3.2)
血中アルカリホスファターゼ増加	3 (10.7)	1 (3.6)	10 (28.6)	1 (2.9)	13 (20.6)	2 (3.2)
血中クレアチニン増加	5 (17.9)	0	8 (22.9)	0	13 (20.6)	0
リパーゼ増加	8 (28.6)	3 (10.7)	5 (14.3)	2 (5.7)	13 (20.6)	5 (7.9)
好中球数減少	3 (10.7)	0	7 (20.0)	2 (5.7)	10 (15.9)	2 (3.2)
白血球数減少	1 (3.6)	0	9 (25.7)	1 (2.9)	10 (15.9)	1 (1.6)
γ－グルタミルトランスフェラーゼ増加	4 (14.3)	3 (10.7)	5 (14.3)	2 (5.7)	9 (14.3)	5 (7.9)

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
血小板数減少	1 (3.6)	0	6 (17.1)	1 (2.9)	7 (11.1)	1 (1.6)
血中ビリルビン増加	0	0	5 (14.3)	0	5 (7.9)	0
ヘモグロビン減少	0	0	4 (11.4)	0	4 (6.3)	0
体重減少	2 (7.1)	0	2 (5.7)	0	4 (6.3)	0
血中尿素増加	0	0	3 (8.6)	0	3 (4.8)	0
Ｃ－反応性蛋白増加	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
心電図ＱＴ延長	2 (7.1)	0	1 (2.9)	0	3 (4.8)	0
リンパ球数減少	0	0	3 (8.6)	1 (2.9)	3 (4.8)	1 (1.6)
抱合ビリルビン増加	0	0	2 (5.7)	0	2 (3.2)	0
血中カルシウム減少	0	0	2 (5.7)	0	2 (3.2)	0
血中クレアチンホスホキナーゼ増加	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
心電図異常Ｔ波	0	0	2 (5.7)	0	2 (3.2)	0
プレアルブミン減少	0	0	2 (5.7)	0	2 (3.2)	0
尿中蛋白陽性	0	0	2 (5.7)	0	2 (3.2)	0
体重増加	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0

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TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
尿中白血球陽性	0	0	2 (5.7)	0	2 (3.2)	0
アミラーゼ増加	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
胆汁酸増加	0	0	1 (2.9)	0	1 (1.6)	0
血中アルブミン減少	0	0	1 (2.9)	0	1 (1.6)	0
血中クレアチニン減少	0	0	1 (2.9)	0	1 (1.6)	0
血中マグネシウム減少	0	0	1 (2.9)	0	1 (1.6)	0
血中トリグリセリド増加	0	0	1 (2.9)	0	1 (1.6)	0
フィブリンＤダイマー増加	0	0	1 (2.9)	0	1 (1.6)	0
遊離脂肪酸増加	0	0	1 (2.9)	0	1 (1.6)	0
糸球体濾過率減少	0	0	1 (2.9)	0	1 (1.6)	0
好中球数増加	0	0	1 (2.9)	0	1 (1.6)	0
プロトロンビン時間延長	0	0	1 (2.9)	0	1 (1.6)	0
ＳＡＲＳ－ＣｏＶ－２検査陽性	0	0	1 (2.9)	0	1 (1.6)	0
尿潜血陽性	0	0	1 (2.9)	0	1 (1.6)	0

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TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
代謝および栄養障害	22 (78.6)	4 (14.3)	32 (91.4)	6 (17.1)	54 (85.7)	10 (15.9)
高リン血症	21 (75.0)	2 (7.1)	30 (85.7)	1 (2.9)	51 (81.0)	3 (4.8)
食欲減退	7 (25.0)	1 (3.6)	2 (5.7)	0	9 (14.3)	1 (1.6)
低ナトリウム血症	0	0	8 (22.9)	3 (8.6)	8 (12.7)	3 (4.8)
高カルシウム血症	2 (7.1)	0	5 (14.3)	2 (5.7)	7 (11.1)	2 (3.2)
高尿酸血症	3 (10.7)	0	4 (11.4)	0	7 (11.1)	0
高脂血症	0	0	5 (14.3)	0	5 (7.9)	0
低リン血症	1 (3.6)	1 (3.6)	4 (11.4)	1 (2.9)	5 (7.9)	2 (3.2)
低アルブミン血症	1 (3.6)	0	3 (8.6)	0	4 (6.3)	0
低クロール血症	0	0	4 (11.4)	1 (2.9)	4 (6.3)	1 (1.6)
低カリウム血症	0	0	4 (11.4)	0	4 (6.3)	0
低蛋白血症	0	0	4 (11.4)	0	4 (6.3)	0
低マグネシウム血症	0	0	3 (8.6)	0	3 (4.8)	0
高血糖	0	0	2 (5.7)	0	2 (3.2)	0
高トリグリセリド血症	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0

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MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
低カルシウム血症	0	0	2 (5.7)	0	2 (3.2)	0
脱水	1 (3.6)	0	0	0	1 (1.6)	0
筋骨格系および結合組織障害	8 (28.6)	0	7 (20.0)	1 (2.9)	15 (23.8)	1 (1.6)
関節痛	4 (14.3)	0	3 (8.6)	1 (2.9)	7 (11.1)	1 (1.6)
四肢痛	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
背部痛	1 (3.6)	0	0	0	1 (1.6)	0
肋骨部痛	1 (3.6)	0	0	0	1 (1.6)	0
筋力低下	0	0	1 (2.9)	0	1 (1.6)	0
筋骨格痛	0	0	1 (2.9)	0	1 (1.6)	0
頚部痛	1 (3.6)	0	0	0	1 (1.6)	0
病的骨折	0	0	1 (2.9)	0	1 (1.6)	0
関節周囲炎	1 (3.6)	0	0	0	1 (1.6)	0
横紋筋融解症	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
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）	5 (17.9)	2 (7.1)	2 (5.7)	1 (2.9)	7 (11.1)	3 (4.8)
癌疼痛	2 (7.1)	1 (3.6)	2 (5.7)	1 (2.9)	4 (6.3)	2 (3.2)
眼表面扁平上皮腫瘍	2 (7.1)	0	0	0	2 (3.2)	0
悪性胸水	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
腫瘍熱	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
神経系障害	12 (42.9)	1 (3.6)	6 (17.1)	0	18 (28.6)	1 (1.6)
味覚不全	9 (32.1)	0	2 (5.7)	0	11 (17.5)	0
味覚障害	1 (3.6)	0	3 (8.6)	0	4 (6.3)	0
頭痛	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
脳梗塞	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
頚髄神経根障害	1 (3.6)	0	0	0	1 (1.6)	0
味覚過敏	1 (3.6)	0	0	0	1 (1.6)	0
神経毒性	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
精神障害	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
不眠症	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
腎および尿路障害	3 (10.7)	0	5 (14.3)	0	8 (12.7)	0
蛋白尿	1 (3.6)	0	3 (8.6)	0	4 (6.3)	0
アルブミン尿	0	0	2 (5.7)	0	2 (3.2)	0
血尿	1 (3.6)	0	0	0	1 (1.6)	0
腎機能障害	1 (3.6)	0	0	0	1 (1.6)	0
生殖系および乳房障害	1 (3.6)	0	0	0	1 (1.6)	0
良性前立腺肥大症	1 (3.6)	0	0	0	1 (1.6)	0
呼吸器、胸郭および縦隔障害	9 (32.1)	2 (7.1)	12 (34.3)	1 (2.9)	21 (33.3)	3 (4.8)
鼻出血	5 (17.9)	0	4 (11.4)	0	9 (14.3)	0
咳嗽	1 (3.6)	0	3 (8.6)	0	4 (6.3)	0
鼻乾燥	0	0	4 (11.4)	0	4 (6.3)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
呼吸困難	3 (10.7)	1 (3.6)	0	0	3 (4.8)	1 (1.6)
喀血	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
間質性肺疾患	0	0	1 (2.9)	0	1 (1.6)	0
喉頭痛	1 (3.6)	0	0	0	1 (1.6)	0
胸水	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
アレルギー性鼻炎	1 (3.6)	0	0	0	1 (1.6)	0
皮膚および皮下組織障害	22 (78.6)	2 (7.1)	28 (80.0)	0	50 (79.4)	2 (3.2)
手掌・足底発赤知覚不全症候群	14 (50.0)	2 (7.1)	14 (40.0)	0	28 (44.4)	2 (3.2)
爪変色	4 (14.3)	0	8 (22.9)	0	12 (19.0)	0
爪甲剥離症	7 (25.0)	0	5 (14.3)	0	12 (19.0)	0
爪床出血	7 (25.0)	0	3 (8.6)	0	10 (15.9)	0
脱毛症	4 (14.3)	0	4 (11.4)	0	8 (12.7)	0
爪甲脱落症	2 (7.1)	0	5 (14.3)	0	7 (11.1)	0
爪痛	0	0	6 (17.1)	0	6 (9.5)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
発疹	0	0	5 (14.3)	0	5 (7.9)	0
皮膚乾燥	3 (10.7)	0	1 (2.9)	0	4 (6.3)	0
過角化	3 (10.7)	0	0	0	3 (4.8)	0
爪の障害	0	0	3 (8.6)	0	3 (4.8)	0
爪破損	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
無爪症	0	0	2 (5.7)	0	2 (3.2)	0
爪肥厚	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
そう痒症	2 (7.1)	0	0	0	2 (3.2)	0
皮膚亀裂	0	0	2 (5.7)	0	2 (3.2)	0
皮脂欠乏症	1 (3.6)	0	0	0	1 (1.6)	0
ざ瘡様皮膚炎	1 (3.6)	0	0	0	1 (1.6)	0
接触皮膚炎	1 (3.6)	0	0	0	1 (1.6)	0
薬疹	0	0	1 (2.9)	0	1 (1.6)	0
湿疹	1 (3.6)	0	0	0	1 (1.6)	0
皮脂欠乏性湿疹	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.1

SOC/PT別の有害事象発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
多汗症	0	0	1 (2.9)	0	1 (1.6)	0
斑状丘疹状皮疹	1 (3.6)	0	0	0	1 (1.6)	0
日光皮膚炎	1 (3.6)	0	0	0	1 (1.6)	0
蕁麻疹	1 (3.6)	0	0	0	1 (1.6)	0
尋常性白斑	0	0	1 (2.9)	0	1 (1.6)	0
血管障害	2 (7.1)	1 (3.6)	3 (8.6)	0	5 (7.9)	1 (1.6)
高血圧	1 (3.6)	1 (3.6)	3 (8.6)	0	4 (6.3)	1 (1.6)
静脈瘤	1 (3.6)	0	0	0	1 (1.6)	0
血管炎	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
A preferred terms 'Neoplasm Progression', 'Malignant Neoplasm Progression' and 'Disease Progression' will be excluded from TEAE summary tables, if not related to the study drug.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
Subjects with Any Treatment-Related TEAEs	26 (92.9)	7 (25.0)	35 (100.0)	11 (31.4)	61 (96.8)	18 (28.6)
血液およびリンパ系障害	1 (3.6)	0	9 (25.7)	1 (2.9)	10 (15.9)	1 (1.6)
血小板減少症	0	0	6 (17.1)	1 (2.9)	6 (9.5)	1 (1.6)
白血球減少症	0	0	3 (8.6)	0	3 (4.8)	0
貧血	0	0	1 (2.9)	0	1 (1.6)	0
好酸球増加症	1 (3.6)	0	0	0	1 (1.6)	0
骨髄抑制	0	0	1 (2.9)	0	1 (1.6)	0
心臓障害	0	0	1 (2.9)	0	1 (1.6)	0
動悸	0	0	1 (2.9)	0	1 (1.6)	0
先天性、家族性および遺伝性障害	1 (3.6)	0	0	0	1 (1.6)	0
硬化性胼胝腫	1 (3.6)	0	0	0	1 (1.6)	0
耳および迷路障害	1 (3.6)	0	0	0	1 (1.6)	0
耳鳴	1 (3.6)	0	0	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
眼障害	20 (71.4)	1 (3.6)	27 (77.1)	2 (5.7)	47 (74.6)	3 (4.8)
角膜炎	4 (14.3)	0	5 (14.3)	0	9 (14.3)	0
角膜上皮欠損	1 (3.6)	0	7 (20.0)	1 (2.9)	8 (12.7)	1 (1.6)
ドライアイ	6 (21.4)	1 (3.6)	2 (5.7)	0	8 (12.7)	1 (1.6)
眼球乾燥症	0	0	8 (22.9)	0	8 (12.7)	0
黄斑浮腫	5 (17.9)	0	2 (5.7)	0	7 (11.1)	0
網膜剥離	1 (3.6)	0	4 (11.4)	0	5 (7.9)	0
漿液性網膜剥離	5 (17.9)	0	0	0	5 (7.9)	0
霧視	0	0	5 (14.3)	1 (2.9)	5 (7.9)	1 (1.6)
白内障	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
角膜混濁	1 (3.6)	1 (3.6)	2 (5.7)	0	3 (4.8)	1 (1.6)
網膜下液	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
黄斑変性	0	0	2 (5.7)	1 (2.9)	2 (3.2)	1 (1.6)
点状角膜炎	2 (7.1)	0	0	0	2 (3.2)	0
一過性黒内障	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
眼瞼炎	0	0	1 (2.9)	0	1 (1.6)	0
中心性漿液性脈絡網膜症	1 (3.6)	0	0	0	1 (1.6)	0
結膜充血	0	0	1 (2.9)	0	1 (1.6)	0
角膜障害	1 (3.6)	0	0	0	1 (1.6)	0
角膜びらん	1 (3.6)	1 (3.6)	0	0	1 (1.6)	1 (1.6)
角膜菲薄化	0	0	1 (2.9)	0	1 (1.6)	0
眼瞼外反	1 (3.6)	0	0	0	1 (1.6)	0
網膜上膜	0	0	1 (2.9)	0	1 (1.6)	0
流涙増加	1 (3.6)	0	0	0	1 (1.6)	0
黄斑剥離	0	0	1 (2.9)	0	1 (1.6)	0
黄斑肥厚	0	0	1 (2.9)	0	1 (1.6)	0
黄斑症	0	0	1 (2.9)	0	1 (1.6)	0
マイボーム腺機能不全	0	0	1 (2.9)	0	1 (1.6)	0
視神経乳頭陥凹	1 (3.6)	0	0	0	1 (1.6)	0
視神経症	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
屈折障害	0	0	1 (2.9)	0	1 (1.6)	0
網膜出血	1 (3.6)	0	0	0	1 (1.6)	0
網膜症	0	0	1 (2.9)	0	1 (1.6)	0
睫毛乱生	0	0	1 (2.9)	0	1 (1.6)	0
視力障害	0	0	1 (2.9)	0	1 (1.6)	0
胃腸障害	21 (75.0)	1 (3.6)	20 (57.1)	0	41 (65.1)	1 (1.6)
下痢	10 (35.7)	0	10 (28.6)	0	20 (31.7)	0
口内炎	12 (42.9)	1 (3.6)	2 (5.7)	0	14 (22.2)	1 (1.6)
口内乾燥	5 (17.9)	0	7 (20.0)	0	12 (19.0)	0
便秘	4 (14.3)	0	1 (2.9)	0	5 (7.9)	0
悪心	5 (17.9)	0	0	0	5 (7.9)	0
嘔吐	3 (10.7)	0	1 (2.9)	0	4 (6.3)	0
腹痛	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
口腔内潰瘍形成	0	0	3 (8.6)	0	3 (4.8)	0
腹部膨満	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
Subject with two or more TEAEs reported in the same system organ class (or with the same preferred term) is only counted once using the highest CTCAE grade.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
食道炎	2 (7.1)	0	0	0	2 (3.2)	0
口角口唇炎	1 (3.6)	0	0	0	1 (1.6)	0
口唇炎	1 (3.6)	0	0	0	1 (1.6)	0
慢性胃炎	0	0	1 (2.9)	0	1 (1.6)	0
嚥下障害	0	0	1 (2.9)	0	1 (1.6)	0
おくび	1 (3.6)	0	0	0	1 (1.6)	0
胃食道逆流性疾患	0	0	1 (2.9)	0	1 (1.6)	0
歯肉出血	1 (3.6)	0	0	0	1 (1.6)	0
口腔血性水疱	0	0	1 (2.9)	0	1 (1.6)	0
口腔知覚不全	1 (3.6)	0	0	0	1 (1.6)	0
一般・全身障害および投与部位の状態	6 (21.4)	0	3 (8.6)	0	9 (14.3)	0
疲労	2 (7.1)	0	1 (2.9)	0	3 (4.8)	0
倦怠感	3 (10.7)	0	0	0	3 (4.8)	0
口渇	2 (7.1)	0	1 (2.9)	0	3 (4.8)	0
インフルエンザ様疾患	0	0	1 (2.9)	0	1 (1.6)	0

Percentages are based on the total number of subjects in the relevant treatment group.
TEAE = treatment-emergent adverse event.
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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

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Study 201

Safety Analysis Set

MedDRA System Organ Class Preferred Term	Japanese (N=28) n (%)		Chinese (N=35) n (%)		Overall (N=63) n (%)	
	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
肝胆道系障害	0	0	4 (11.4)	2 (5.7)	4 (6.3)	2 (3.2)
肝損傷	0	0	3 (8.6)	1 (2.9)	3 (4.8)	1 (1.6)
肝機能異常	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
高ビリルビン血症	0	0	1 (2.9)	0	1 (1.6)	0
感染症および寄生虫症	12 (42.9)	0	8 (22.9)	0	20 (31.7)	0
爪囲炎	11 (39.3)	0	3 (8.6)	0	14 (22.2)	0
咽頭炎	0	0	2 (5.7)	0	2 (3.2)	0
鼻炎	0	0	2 (5.7)	0	2 (3.2)	0
結膜炎	0	0	1 (2.9)	0	1 (1.6)	0
咽喉頭炎	0	0	1 (2.9)	0	1 (1.6)	0
皮膚感染	1 (3.6)	0	0	0	1 (1.6)	0
尿路感染	0	0	1 (2.9)	0	1 (1.6)	0
臨床検査	11 (39.3)	2 (7.1)	26 (74.3)	5 (14.3)	37 (58.7)	7 (11.1)

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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 26.0.
Adverse Events were graded using Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

付録 2.7.6.4.2

SOC/PT別の副作用発現率

Study 201

Safety Analysis Set

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	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
アスパラギン酸アミノトランスフェラーゼ増加	1 (3.6)	0	11 (31.4)	0	12 (19.0)	0
アラニンアミノトランスフェラーゼ増加	1 (3.6)	0	10 (28.6)	1 (2.9)	11 (17.5)	1 (1.6)
リパーゼ増加	5 (17.9)	2 (7.1)	5 (14.3)	2 (5.7)	10 (15.9)	4 (6.3)
血中クレアチニン増加	5 (17.9)	0	4 (11.4)	0	9 (14.3)	0
白血球数減少	1 (3.6)	0	8 (22.9)	1 (2.9)	9 (14.3)	1 (1.6)
好中球数減少	2 (7.1)	0	6 (17.1)	1 (2.9)	8 (12.7)	1 (1.6)
血中アルカリホスファターゼ増加	0	0	6 (17.1)	1 (2.9)	6 (9.5)	1 (1.6)
血小板数減少	0	0	6 (17.1)	1 (2.9)	6 (9.5)	1 (1.6)
血中ビリルビン増加	0	0	5 (14.3)	0	5 (7.9)	0
リンパ球数減少	0	0	3 (8.6)	1 (2.9)	3 (4.8)	1 (1.6)
抱合ビリルビン増加	0	0	2 (5.7)	0	2 (3.2)	0
血中クレアチンホスホキナーゼ増加	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
γ－グルタミルトランスフェラーゼ増加	0	0	2 (5.7)	0	2 (3.2)	0
ヘモグロビン減少	0	0	2 (5.7)	0	2 (3.2)	0
尿中蛋白陽性	0	0	2 (5.7)	0	2 (3.2)	0

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Safety Analysis Set

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	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
尿中白血球陽性	0	0	2 (5.7)	0	2 (3.2)	0
アミラーゼ増加	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
血中クレアチニン減少	0	0	1 (2.9)	0	1 (1.6)	0
血中トリグリセリド増加	0	0	1 (2.9)	0	1 (1.6)	0
心電図ＱＴ延長	0	0	1 (2.9)	0	1 (1.6)	0
プロトロンビン時間延長	0	0	1 (2.9)	0	1 (1.6)	0
尿潜血陽性	0	0	1 (2.9)	0	1 (1.6)	0
体重減少	1 (3.6)	0	0	0	1 (1.6)	0
代謝および栄養障害	21 (75.0)	3 (10.7)	32 (91.4)	1 (2.9)	53 (84.1)	4 (6.3)
高リン血症	21 (75.0)	2 (7.1)	30 (85.7)	1 (2.9)	51 (81.0)	3 (4.8)
高尿酸血症	3 (10.7)	0	4 (11.4)	0	7 (11.1)	0
食欲減退	6 (21.4)	1 (3.6)	0	0	6 (9.5)	1 (1.6)
高カルシウム血症	2 (7.1)	0	4 (11.4)	0	6 (9.5)	0
低マグネシウム血症	0	0	3 (8.6)	0	3 (4.8)	0
低ナトリウム血症	0	0	3 (8.6)	0	3 (4.8)	0

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Safety Analysis Set

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	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
低アルブミン血症	0	0	2 (5.7)	0	2 (3.2)	0
低クロール血症	0	0	2 (5.7)	0	2 (3.2)	0
低カリウム血症	0	0	2 (5.7)	0	2 (3.2)	0
低リン血症	0	0	2 (5.7)	0	2 (3.2)	0
高血糖	0	0	1 (2.9)	0	1 (1.6)	0
高脂血症	0	0	1 (2.9)	0	1 (1.6)	0
高トリグリセリド血症	1 (3.6)	0	0	0	1 (1.6)	0
低カルシウム血症	0	0	1 (2.9)	0	1 (1.6)	0
低蛋白血症	0	0	1 (2.9)	0	1 (1.6)	0
筋骨格系および結合組織障害	4 (14.3)	0	5 (14.3)	1 (2.9)	9 (14.3)	1 (1.6)
関節痛	2 (7.1)	0	3 (8.6)	1 (2.9)	5 (7.9)	1 (1.6)
背部痛	1 (3.6)	0	0	0	1 (1.6)	0
筋骨格痛	0	0	1 (2.9)	0	1 (1.6)	0
四肢痛	0	0	1 (2.9)	0	1 (1.6)	0
関節周囲炎	1 (3.6)	0	0	0	1 (1.6)	0

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	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
横紋筋融解症	1 (3.6)	0	0	0	1 (1.6)	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）	2 (7.1)	0	0	0	2 (3.2)	0
眼表面扁平上皮腫瘍	2 (7.1)	0	0	0	2 (3.2)	0
神経系障害	10 (35.7)	0	6 (17.1)	0	16 (25.4)	0
味覚不全	8 (28.6)	0	2 (5.7)	0	10 (15.9)	0
味覚障害	1 (3.6)	0	3 (8.6)	0	4 (6.3)	0
頭痛	1 (3.6)	0	0	0	1 (1.6)	0
味覚過敏	1 (3.6)	0	0	0	1 (1.6)	0
神経毒性	0	0	1 (2.9)	0	1 (1.6)	0
精神障害	0	0	2 (5.7)	0	2 (3.2)	0
不眠症	0	0	2 (5.7)	0	2 (3.2)	0
腎および尿路障害	3 (10.7)	0	0	0	3 (4.8)	0

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	Any Grade	Grade >= 3	Any Grade	Grade >= 3	Any Grade	Grade >= 3
血尿	1 (3.6)	0	0	0	1 (1.6)	0
蛋白尿	1 (3.6)	0	0	0	1 (1.6)	0
腎機能障害	1 (3.6)	0	0	0	1 (1.6)	0
呼吸器、胸郭および縦隔障害	2 (7.1)	0	10 (28.6)	1 (2.9)	12 (19.0)	1 (1.6)
鼻出血	2 (7.1)	0	3 (8.6)	0	5 (7.9)	0
鼻乾燥	0	0	4 (11.4)	0	4 (6.3)	0
咳嗽	0	0	1 (2.9)	0	1 (1.6)	0
喀血	0	0	1 (2.9)	1 (2.9)	1 (1.6)	1 (1.6)
間質性肺疾患	0	0	1 (2.9)	0	1 (1.6)	0
皮膚および皮下組織障害	22 (78.6)	2 (7.1)	28 (80.0)	0	50 (79.4)	2 (3.2)
手掌・足底発赤知覚不全症候群	14 (50.0)	2 (7.1)	14 (40.0)	0	28 (44.4)	2 (3.2)
爪変色	4 (14.3)	0	8 (22.9)	0	12 (19.0)	0
爪甲剥離症	7 (25.0)	0	5 (14.3)	0	12 (19.0)	0
爪床出血	6 (21.4)	0	3 (8.6)	0	9 (14.3)	0

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脱毛症	4 (14.3)	0	4 (11.4)	0	8 (12.7)	0
爪痛	0	0	6 (17.1)	0	6 (9.5)	0
爪甲脱落症	1 (3.6)	0	5 (14.3)	0	6 (9.5)	0
皮膚乾燥	3 (10.7)	0	1 (2.9)	0	4 (6.3)	0
発疹	0	0	4 (11.4)	0	4 (6.3)	0
過角化	3 (10.7)	0	0	0	3 (4.8)	0
爪の障害	0	0	3 (8.6)	0	3 (4.8)	0
爪破損	1 (3.6)	0	2 (5.7)	0	3 (4.8)	0
無爪症	0	0	2 (5.7)	0	2 (3.2)	0
爪肥厚	1 (3.6)	0	1 (2.9)	0	2 (3.2)	0
そう痒症	2 (7.1)	0	0	0	2 (3.2)	0
皮膚亀裂	0	0	2 (5.7)	0	2 (3.2)	0
ざ瘡様皮膚炎	1 (3.6)	0	0	0	1 (1.6)	0
薬疹	0	0	1 (2.9)	0	1 (1.6)	0
皮脂欠乏性湿疹	1 (3.6)	0	0	0	1 (1.6)	0

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斑状丘疹状皮疹	1 (3.6)	0	0	0	1 (1.6)	0
血管障害	0	0	2 (5.7)	0	2 (3.2)	0
高血圧	0	0	2 (5.7)	0	2 (3.2)	0

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