付録 2.7.4.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
無感情	1 (0.2)	0 (0.0)
抑うつ気分	1 (0.2)	0 (0.0)
大うつ病	1 (0.2)	1 (0.2)
精神運動制止遅滞	1 (0.2)	0 (0.0)
落ち着きのなさ	1 (0.2)	0 (0.0)
睡眠障害	1 (0.2)	0 (0.0)
自殺企図	1 (0.2)	1 (0.2)
腎および尿路障害	162 (32.7)	43 (8.7)
蛋白尿	128 (25.8)	32 (6.5)
血尿	26 (5.2)	1 (0.2)
急性腎障害	9 (1.8)	4 (0.8)
腎機能障害	5 (1.0)	1 (0.2)
排尿困難	4 (0.8)	0 (0.0)
ビリルビン尿	3 (0.6)	0 (0.0)
着色尿	3 (0.6)	0 (0.0)
尿閉	3 (0.6)	1 (0.2)
慢性腎臓病	2 (0.4)	0 (0.0)
白血球尿	2 (0.4)	0 (0.0)
夜間頻尿	2 (0.4)	0 (0.0)
頻尿	2 (0.4)	0 (0.0)
腎仙痛	2 (0.4)	0 (0.0)
腎不全	2 (0.4)	2 (0.4)
無尿	1 (0.2)	1 (0.2)
高窒素血症	1 (0.2)	1 (0.2)
膀胱障害	1 (0.2)	0 (0.0)
膀胱腫瘤	1 (0.2)	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
尿路結石	1 (0.2)	0 (0.0)
非感染性膀胱炎	1 (0.2)	0 (0.0)
糖尿	1 (0.2)	0 (0.0)
ＩｇＡ腎症	1 (0.2)	0 (0.0)
ケトン尿	1 (0.2)	0 (0.0)
腎炎	1 (0.2)	0 (0.0)
腎結石症	1 (0.2)	0 (0.0)
乏尿	1 (0.2)	0 (0.0)
腎梗塞	1 (0.2)	0 (0.0)
腎尿細管壊死	1 (0.2)	0 (0.0)
尿失禁	1 (0.2)	0 (0.0)
尿流量減少	1 (0.2)	0 (0.0)
生殖系および乳房障害	27 (5.4)	2 (0.4)
女性化乳房	6 (1.2)	0 (0.0)
骨盤痛	4 (0.8)	1 (0.2)
後天性陰嚢水瘤	2 (0.4)	0 (0.0)
良性前立腺肥大症	2 (0.4)	0 (0.0)
乳房痛	2 (0.4)	0 (0.0)
陰部そう痒症	2 (0.4)	0 (0.0)
陰嚢紅斑	2 (0.4)	0 (0.0)
陰嚢潰瘍	2 (0.4)	0 (0.0)
性器発疹	1 (0.2)	0 (0.0)
不規則月経	1 (0.2)	1 (0.2)
乳頭痛	1 (0.2)	0 (0.0)
性器浮腫	1 (0.2)	0 (0.0)
骨盤液貯留	1 (0.2)	0 (0.0)

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付録 2.7.4.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
陰茎浮腫	1 (0.2)	0 (0.0)
前立腺閉塞	1 (0.2)	0 (0.0)
陰嚢血瘤	1 (0.2)	0 (0.0)
陰嚢浮腫	1 (0.2)	0 (0.0)
精巣痛	1 (0.2)	0 (0.0)
呼吸器、胸郭および縦隔障害	225 (45.4)	25 (5.0)
発声障害	121 (24.4)	1 (0.2)
咳嗽	48 (9.7)	0 (0.0)
鼻出血	38 (7.7)	1 (0.2)
呼吸困難	37 (7.5)	9 (1.8)
口腔咽頭痛	23 (4.6)	0 (0.0)
胸水	10 (2.0)	0 (0.0)
喀血	9 (1.8)	1 (0.2)
しゃっくり	4 (0.8)	0 (0.0)
湿性咳嗽	4 (0.8)	0 (0.0)
肺塞栓症	4 (0.8)	4 (0.8)
鼻漏	4 (0.8)	0 (0.0)
誤嚥性肺炎	3 (0.6)	3 (0.6)
呼吸不全	3 (0.6)	3 (0.6)
アレルギー性鼻炎	3 (0.6)	0 (0.0)
上気道の炎症	3 (0.6)	0 (0.0)
肝肺症候群	2 (0.4)	1 (0.2)
非心原性肺水腫	2 (0.4)	1 (0.2)
気胸	2 (0.4)	1 (0.2)
肺梗塞	2 (0.4)	1 (0.2)
喘鳴	2 (0.4)	1 (0.2)

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Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	Lenvatinib (N=496) Grade >= 3 n (%)
急性呼吸不全	1 (0.2)	1 (0.2)
無気肺	1 (0.2)	1 (0.2)
慢性気管支炎	1 (0.2)	0 (0.0)
気管支痙攣	1 (0.2)	1 (0.2)
気管支狭窄	1 (0.2)	0 (0.0)
慢性閉塞性肺疾患	1 (0.2)	0 (0.0)
労作性呼吸困難	1 (0.2)	0 (0.0)
低酸素症	1 (0.2)	0 (0.0)
特発性肺線維症	1 (0.2)	0 (0.0)
上気道分泌増加	1 (0.2)	0 (0.0)
喉頭の炎症	1 (0.2)	0 (0.0)
鼻閉	1 (0.2)	0 (0.0)
鼻乾燥	1 (0.2)	0 (0.0)
壊死性細気管支炎	1 (0.2)	0 (0.0)
口腔咽頭不快感	1 (0.2)	0 (0.0)
咽頭びらん	1 (0.2)	0 (0.0)
胸膜炎	1 (0.2)	0 (0.0)
胸膜痛	1 (0.2)	0 (0.0)
肺臓炎	1 (0.2)	0 (0.0)
肺腫瘤	1 (0.2)	0 (0.0)
呼吸抑制	1 (0.2)	1 (0.2)
呼吸窮迫	1 (0.2)	0 (0.0)
鼻痛	1 (0.2)	0 (0.0)
変色痰	1 (0.2)	0 (0.0)
喀痰増加	1 (0.2)	0 (0.0)
痰貯留	1 (0.2)	0 (0.0)

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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
上気道うっ血	1 (0.2)	0 (0.0)
上気道咳症候群	1 (0.2)	0 (0.0)
皮膚および皮下組織障害	257 (51.8)	18 (3.6)
手掌・足底発赤知覚不全症候群	144 (29.0)	15 (3.0)
発疹	51 (10.3)	0 (0.0)
そう痒症	36 (7.3)	0 (0.0)
皮膚乾燥	24 (4.8)	0 (0.0)
脱毛症	16 (3.2)	0 (0.0)
紅斑	10 (2.0)	0 (0.0)
過角化	10 (2.0)	0 (0.0)
斑状丘疹状皮疹	6 (1.2)	0 (0.0)
皮膚剥脱	6 (1.2)	0 (0.0)
蕁麻疹	6 (1.2)	0 (0.0)
褥瘡性潰瘍	5 (1.0)	1 (0.2)
湿疹	5 (1.0)	1 (0.2)
ざ瘡様皮膚炎	4 (0.8)	0 (0.0)
多汗症	4 (0.8)	0 (0.0)
爪変色	4 (0.8)	0 (0.0)
皮膚反応	4 (0.8)	0 (0.0)
ざ瘡	3 (0.6)	0 (0.0)
水疱	3 (0.6)	0 (0.0)
皮膚炎	3 (0.6)	0 (0.0)
寝汗	3 (0.6)	0 (0.0)
皮膚嚢腫	2 (0.4)	0 (0.0)
水疱性皮膚炎	2 (0.4)	0 (0.0)
多形紅斑	2 (0.4)	0 (0.0)

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付録 2.7.4.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
点状出血	2 (0.4)	0 (0.0)
紫斑	2 (0.4)	0 (0.0)
丘疹性皮疹	2 (0.4)	0 (0.0)
そう痒性皮疹	2 (0.4)	0 (0.0)
皮膚びらん	2 (0.4)	0 (0.0)
皮膚潰瘍	2 (0.4)	0 (0.0)
皮膚血管炎	1 (0.2)	1 (0.2)
接触皮膚炎	1 (0.2)	0 (0.0)
異汗性湿疹	1 (0.2)	0 (0.0)
斑状出血	1 (0.2)	0 (0.0)
環状肉芽腫	1 (0.2)	0 (0.0)
間擦疹	1 (0.2)	1 (0.2)
爪床圧痛	1 (0.2)	0 (0.0)
爪の障害	1 (0.2)	0 (0.0)
爪線状隆起	1 (0.2)	0 (0.0)
爪破損	1 (0.2)	0 (0.0)
皮膚疼痛	1 (0.2)	0 (0.0)
手掌紅斑	1 (0.2)	0 (0.0)
白色粃糠疹	1 (0.2)	0 (0.0)
乾癬	1 (0.2)	0 (0.0)
紅斑性皮疹	1 (0.2)	0 (0.0)
脂漏性皮膚炎	1 (0.2)	1 (0.2)
皮膚障害	1 (0.2)	0 (0.0)
皮膚色素減少	1 (0.2)	0 (0.0)
皮膚刺激	1 (0.2)	0 (0.0)
皮膚病変	1 (0.2)	0 (0.0)

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付録 2.7.4.9
Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
くも状母斑	1 (0.2)	0 (0.0)
顔面腫脹	1 (0.2)	0 (0.0)
毛細血管拡張症	1 (0.2)	0 (0.0)
乾皮症	1 (0.2)	0 (0.0)
血管障害	231 (46.6)	130 (26.2)
高血圧	218 (44.0)	125 (25.2)
低血圧	6 (1.2)	2 (0.4)
起立性低血圧	3 (0.6)	0 (0.0)
循環虚脱	2 (0.4)	1 (0.2)
潮紅	2 (0.4)	0 (0.0)
大動脈解離	1 (0.2)	1 (0.2)
動脈硬化症	1 (0.2)	0 (0.0)
動脈解離	1 (0.2)	0 (0.0)
深部静脈血栓症	1 (0.2)	1 (0.2)
静脈塞栓症	1 (0.2)	0 (0.0)
ほてり	1 (0.2)	0 (0.0)
充血	1 (0.2)	0 (0.0)
リンパ浮腫	1 (0.2)	0 (0.0)
起立性高血圧	1 (0.2)	0 (0.0)
静脈炎	1 (0.2)	0 (0.0)
血栓性静脈炎	1 (0.2)	0 (0.0)
静脈瘤	1 (0.2)	0 (0.0)
大静脈血栓症	1 (0.2)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	Lenvatinib (N=496) Grade >= 3 n (%)
Subjects with Any Related TEAEs	466 (94.0)	288 (58.1)
血液およびリンパ系障害	68 (13.7)	26 (5.2)
血小板減少症	37 (7.5)	12 (2.4)
好中球減少症	23 (4.6)	6 (1.2)
白血球減少症	15 (3.0)	1 (0.2)
貧血	14 (2.8)	4 (0.8)
骨髄機能不全	2 (0.4)	2 (0.4)
白血球増加症	1 (0.2)	1 (0.2)
リンパ節症	1 (0.2)	0 (0.0)
リンパ球減少症	1 (0.2)	1 (0.2)
汎血球減少症	1 (0.2)	0 (0.0)
赤血球増加症	1 (0.2)	0 (0.0)
心臓障害	19 (3.8)	3 (0.6)
心筋梗塞	3 (0.6)	3 (0.6)
洞性徐脈	3 (0.6)	0 (0.0)
心房細動	2 (0.4)	0 (0.0)
心筋虚血	2 (0.4)	0 (0.0)
動悸	2 (0.4)	0 (0.0)
上室性期外収縮	2 (0.4)	0 (0.0)
第一度房室ブロック	1 (0.2)	0 (0.0)
左脚ブロック	1 (0.2)	0 (0.0)
期外収縮	1 (0.2)	0 (0.0)
左室肥大	1 (0.2)	0 (0.0)
プリンツメタル狭心症	1 (0.2)	0 (0.0)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
洞性不整脈	1 (0.2)	0 (0.0)
洞性頻脈	1 (0.2)	0 (0.0)
頻脈	1 (0.2)	0 (0.0)
心室性期外収縮	1 (0.2)	0 (0.0)
耳および迷路障害	11 (2.2)	0 (0.0)
耳鳴	4 (0.8)	0 (0.0)
回転性めまい	3 (0.6)	0 (0.0)
耳不快感	2 (0.4)	0 (0.0)
難聴	1 (0.2)	0 (0.0)
耳の障害	1 (0.2)	0 (0.0)
内分泌障害	76 (15.3)	0 (0.0)
甲状腺機能低下症	71 (14.3)	0 (0.0)
甲状腺機能亢進症	4 (0.8)	0 (0.0)
甲状腺炎	2 (0.4)	0 (0.0)
眼障害	6 (1.2)	0 (0.0)
結膜出血	1 (0.2)	0 (0.0)
眼刺激	1 (0.2)	0 (0.0)
眼痛	1 (0.2)	0 (0.0)
眼瞼浮腫	1 (0.2)	0 (0.0)
眼瞼そう痒症	1 (0.2)	0 (0.0)
眼充血	1 (0.2)	0 (0.0)
胃腸障害	298 (60.1)	38 (7.7)
下痢	147 (29.6)	20 (4.0)
悪心	73 (14.7)	2 (0.4)

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Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
口内炎	48 (9.7)	1 (0.2)
嘔吐	48 (9.7)	2 (0.4)
腹痛	34 (6.9)	2 (0.4)
腹水	34 (6.9)	7 (1.4)
便秘	32 (6.5)	0 (0.0)
上腹部痛	31 (6.3)	1 (0.2)
口内乾燥	28 (5.6)	0 (0.0)
消化不良	23 (4.6)	0 (0.0)
腹部膨満	16 (3.2)	0 (0.0)
歯肉腫脹	8 (1.6)	0 (0.0)
歯肉出血	7 (1.4)	0 (0.0)
歯肉痛	6 (1.2)	0 (0.0)
鼓腸	5 (1.0)	0 (0.0)
胃潰瘍	4 (0.8)	0 (0.0)
痔核	4 (0.8)	0 (0.0)
口腔内潰瘍形成	4 (0.8)	1 (0.2)
食道静脈瘤出血	4 (0.8)	4 (0.8)
直腸炎	4 (0.8)	0 (0.0)
歯痛	4 (0.8)	0 (0.0)
おくび	3 (0.6)	0 (0.0)
舌痛	3 (0.6)	0 (0.0)
痔出血	3 (0.6)	0 (0.0)
口腔内出血	3 (0.6)	0 (0.0)
口腔内痛	3 (0.6)	0 (0.0)

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Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
歯周病	3 (0.6)	0 (0.0)
上部消化管出血	3 (0.6)	2 (0.4)
排便回数増加	2 (0.4)	0 (0.0)
胃炎	2 (0.4)	0 (0.0)
消化器痛	2 (0.4)	0 (0.0)
舌炎	2 (0.4)	0 (0.0)
嚥下痛	2 (0.4)	0 (0.0)
直腸出血	2 (0.4)	0 (0.0)
腹部不快感	1 (0.2)	0 (0.0)
裂肛	1 (0.2)	0 (0.0)
肛門の炎症	1 (0.2)	0 (0.0)
口唇のひび割れ	1 (0.2)	0 (0.0)
十二指腸潰瘍	1 (0.2)	0 (0.0)
出血性十二指腸潰瘍	1 (0.2)	0 (0.0)
排便障害	1 (0.2)	0 (0.0)
嚥下障害	1 (0.2)	0 (0.0)
腸炎	1 (0.2)	0 (0.0)
心窩部不快感	1 (0.2)	0 (0.0)
糞塊	1 (0.2)	0 (0.0)
軟便	1 (0.2)	0 (0.0)
胃出血	1 (0.2)	0 (0.0)
消化管運動障害	1 (0.2)	0 (0.0)
胃食道逆流性疾患	1 (0.2)	0 (0.0)
歯肉潰瘍	1 (0.2)	0 (0.0)

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Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	Lenvatinib (N=496) Grade >= 3 n (%)
口唇痛	1 (0.2)	0 (0.0)
舌不快感	1 (0.2)	0 (0.0)
食道静脈瘤	1 (0.2)	1 (0.2)
一般・全身障害および投与部位の状態	211 (42.5)	24 (4.8)
疲労	121 (24.4)	10 (2.0)
末梢性浮腫	37 (7.5)	1 (0.2)
無力症	36 (7.3)	9 (1.8)
発熱	30 (6.0)	0 (0.0)
倦怠感	21 (4.2)	0 (0.0)
悪寒	6 (1.2)	0 (0.0)
全身性浮腫	3 (0.6)	0 (0.0)
肝疾患による浮腫	3 (0.6)	0 (0.0)
顔面浮腫	2 (0.4)	0 (0.0)
全身健康状態低下	2 (0.4)	2 (0.4)
非心臓性胸痛	2 (0.4)	0 (0.0)
疼痛	2 (0.4)	0 (0.0)
口渇	2 (0.4)	0 (0.0)
乾燥症	2 (0.4)	0 (0.0)
胸痛	1 (0.2)	0 (0.0)
薬物不耐性	1 (0.2)	1 (0.2)
早期満腹	1 (0.2)	0 (0.0)
冷感	1 (0.2)	0 (0.0)
高熱	1 (0.2)	0 (0.0)
治癒不良	1 (0.2)	1 (0.2)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
インフルエンザ様疾患	1 (0.2)	0 (0.0)
限局性浮腫	1 (0.2)	0 (0.0)
粘膜の炎症	1 (0.2)	0 (0.0)
小結節	1 (0.2)	0 (0.0)
温度変化不耐症	1 (0.2)	0 (0.0)
肝胆道系障害	38 (7.7)	23 (4.6)
肝機能異常	8 (1.6)	6 (1.2)
高ビリルビン血症	8 (1.6)	3 (0.6)
肝不全	6 (1.2)	6 (1.2)
門脈血栓症	4 (0.8)	1 (0.2)
胆管炎	2 (0.4)	1 (0.2)
胆嚢炎	2 (0.4)	1 (0.2)
肝臓痛	2 (0.4)	1 (0.2)
黄疸	2 (0.4)	1 (0.2)
胆汁うっ滞性黄疸	2 (0.4)	2 (0.4)
胆管結石	1 (0.2)	1 (0.2)
後天性胆管拡張症	1 (0.2)	1 (0.2)
血性胆汁	1 (0.2)	1 (0.2)
肝硬変	1 (0.2)	1 (0.2)
肝腎症候群	1 (0.2)	1 (0.2)
肝障害	1 (0.2)	0 (0.0)
門脈圧亢進症	1 (0.2)	1 (0.2)
感染症および寄生虫症	40 (8.1)	7 (1.4)
咽頭炎	5 (1.0)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
口角口唇炎	4 (0.8)	0 (0.0)
毛包炎	3 (0.6)	0 (0.0)
胃腸炎	2 (0.4)	0 (0.0)
歯肉炎	2 (0.4)	0 (0.0)
鼻咽頭炎	2 (0.4)	0 (0.0)
肺炎	2 (0.4)	1 (0.2)
膿疱性皮疹	2 (0.4)	0 (0.0)
副鼻腔炎	2 (0.4)	1 (0.2)
気管支肺アスペルギルス症	1 (0.2)	0 (0.0)
結膜炎	1 (0.2)	0 (0.0)
膀胱炎	1 (0.2)	0 (0.0)
耳感染	1 (0.2)	1 (0.2)
細菌性胃腸炎	1 (0.2)	0 (0.0)
インフルエンザ	1 (0.2)	0 (0.0)
腎感染	1 (0.2)	1 (0.2)
肺感染	1 (0.2)	1 (0.2)
爪感染	1 (0.2)	0 (0.0)
口腔カンジダ症	1 (0.2)	0 (0.0)
爪囲炎	1 (0.2)	0 (0.0)
歯周炎	1 (0.2)	0 (0.0)
術後膿瘍	1 (0.2)	1 (0.2)
陰嚢感染	1 (0.2)	1 (0.2)
敗血症	1 (0.2)	1 (0.2)
皮膚感染	1 (0.2)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	Lenvatinib (N=496) Grade >= 3 n (%)
歯感染	1 (0.2)	0 (0.0)
気管炎	1 (0.2)	0 (0.0)
上気道感染	1 (0.2)	0 (0.0)
尿路感染	1 (0.2)	0 (0.0)
傷害、中毒および処置合併症	1 (0.2)	0 (0.0)
サンバーン	1 (0.2)	0 (0.0)
臨床検査	242 (48.8)	95 (19.2)
体重減少	90 (18.1)	20 (4.0)
血小板数減少	68 (13.7)	23 (4.6)
血中ビリルビン増加	44 (8.9)	14 (2.8)
アスパラギン酸アミノトランスフェラーゼ増加	41 (8.3)	10 (2.0)
好中球数減少	40 (8.1)	14 (2.8)
白血球数減少	37 (7.5)	8 (1.6)
アラニンアミノトランスフェラーゼ増加	34 (6.9)	9 (1.8)
血中甲状腺刺激ホルモン増加	30 (6.0)	0 (0.0)
γ－グルタミルトランスフェラーゼ増加	19 (3.8)	13 (2.6)
血中アルカリホスファターゼ増加	18 (3.6)	3 (0.6)
心電図ＱＴ延長	16 (3.2)	1 (0.2)
リパーゼ増加	12 (2.4)	7 (1.4)
血圧上昇	9 (1.8)	1 (0.2)
尿中蛋白陽性	9 (1.8)	1 (0.2)
血中アルブミン減少	8 (1.6)	0 (0.0)
血中乳酸脱水素酵素増加	8 (1.6)	0 (0.0)
Ｃ－反応性蛋白増加	8 (1.6)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
リンパ球数減少	8 (1.6)	4 (0.8)
国際標準比増加	7 (1.4)	0 (0.0)
血中コレステロール増加	6 (1.2)	0 (0.0)
アミラーゼ増加	5 (1.0)	2 (0.4)
血中クレアチニン増加	5 (1.0)	0 (0.0)
血中尿素増加	4 (0.8)	0 (0.0)
プロトロンビン時間延長	3 (0.6)	0 (0.0)
抱合ビリルビン増加	2 (0.4)	0 (0.0)
血中カルシウム減少	2 (0.4)	0 (0.0)
血中甲状腺刺激ホルモン減少	2 (0.4)	0 (0.0)
尿中血陽性	2 (0.4)	0 (0.0)
ヘモグロビン増加	2 (0.4)	0 (0.0)
赤血球数減少	2 (0.4)	0 (0.0)
尿中ビリルビン増加	2 (0.4)	0 (0.0)
体重増加	2 (0.4)	0 (0.0)
尿中白血球陽性	2 (0.4)	0 (0.0)
アンモニア増加	1 (0.2)	0 (0.0)
血中クレアチニン減少	1 (0.2)	0 (0.0)
血中フィブリノゲン増加	1 (0.2)	0 (0.0)
血中カリウム減少	1 (0.2)	0 (0.0)
拡張期血圧上昇	1 (0.2)	0 (0.0)
血中ナトリウム減少	1 (0.2)	1 (0.2)
体温上昇	1 (0.2)	0 (0.0)
ＥＣＯＧパフォーマンスステータス悪化	1 (0.2)	0 (0.0)

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Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
心電図ＳＴ部分下降	1 (0.2)	0 (0.0)
心電図異常Ｔ波	1 (0.2)	0 (0.0)
尿中ブドウ糖	1 (0.2)	0 (0.0)
尿中ブドウ糖陽性	1 (0.2)	0 (0.0)
肝酵素上昇	1 (0.2)	1 (0.2)
国際標準比減少	1 (0.2)	0 (0.0)
リパーゼ減少	1 (0.2)	0 (0.0)
リンパ球数増加	1 (0.2)	0 (0.0)
好中球数増加	1 (0.2)	0 (0.0)
総蛋白減少	1 (0.2)	0 (0.0)
プロトロンビン量増加	1 (0.2)	0 (0.0)
トランスアミナーゼ上昇	1 (0.2)	1 (0.2)
トリヨードチロニン増加	1 (0.2)	0 (0.0)
トロポニンＴ増加	1 (0.2)	0 (0.0)
尿中蛋白／クレアチニン比増加	1 (0.2)	1 (0.2)
尿中ウロビリノーゲン増加	1 (0.2)	0 (0.0)
白血球数増加	1 (0.2)	0 (0.0)
代謝および栄養障害	162 (32.7)	35 (7.1)
食欲減退	132 (26.6)	16 (3.2)
低アルブミン血症	24 (4.8)	2 (0.4)
脱水	10 (2.0)	2 (0.4)
低ナトリウム血症	9 (1.8)	9 (1.8)
高アンモニア血症	8 (1.6)	0 (0.0)
高カリウム血症	4 (0.8)	1 (0.2)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
低カルシウム血症	3 (0.6)	1 (0.2)
低マグネシウム血症	3 (0.6)	1 (0.2)
高血糖	2 (0.4)	1 (0.2)
低血糖	2 (0.4)	1 (0.2)
低カリウム血症	2 (0.4)	1 (0.2)
低リン酸血症	2 (0.4)	2 (0.4)
糖尿病性代謝代償不全	1 (0.2)	1 (0.2)
痛風	1 (0.2)	0 (0.0)
高コレステロール血症	1 (0.2)	1 (0.2)
高脂血症	1 (0.2)	0 (0.0)
高尿酸血症	1 (0.2)	0 (0.0)
過小食	1 (0.2)	0 (0.0)
低蛋白血症	1 (0.2)	0 (0.0)
筋骨格系および結合組織障害	79 (15.9)	1 (0.2)
関節痛	22 (4.4)	0 (0.0)
筋肉痛	16 (3.2)	0 (0.0)
四肢痛	15 (3.0)	1 (0.2)
筋骨格痛	11 (2.2)	0 (0.0)
背部痛	10 (2.0)	0 (0.0)
筋力低下	7 (1.4)	0 (0.0)
頚部痛	5 (1.0)	0 (0.0)
筋痙縮	3 (0.6)	0 (0.0)
側腹部痛	2 (0.4)	0 (0.0)
骨痛	1 (0.2)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
関節腫脹	1 (0.2)	0 (0.0)
筋緊張	1 (0.2)	0 (0.0)
筋骨格系胸痛	1 (0.2)	0 (0.0)
筋骨格不快感	1 (0.2)	0 (0.0)
脊椎痛	1 (0.2)	0 (0.0)
良性、悪性および詳細不明の新生物（嚢胞およびポリープを含む）	2 (0.4)	1 (0.2)
腫瘍熱	1 (0.2)	0 (0.0)
腫瘍出血	1 (0.2)	1 (0.2)
神経系障害	109 (22.0)	20 (4.0)
頭痛	26 (5.2)	1 (0.2)
浮動性めまい	21 (4.2)	0 (0.0)
味覚異常	21 (4.2)	0 (0.0)
肝性脳症	20 (4.0)	10 (2.0)
嗜眠	4 (0.8)	0 (0.0)
末梢性感覚ニューロパチー	4 (0.8)	0 (0.0)
傾眠	4 (0.8)	1 (0.2)
脳出血	3 (0.6)	3 (0.6)
感覚鈍麻	3 (0.6)	0 (0.0)
失語症	2 (0.4)	0 (0.0)
脳梗塞	2 (0.4)	2 (0.4)
錯感覚	2 (0.4)	0 (0.0)
多発ニューロパチー	2 (0.4)	0 (0.0)
緊張性頭痛	2 (0.4)	0 (0.0)
平衡障害	1 (0.2)	0 (0.0)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
灼熱感	1 (0.2)	0 (0.0)
脳血管発作	1 (0.2)	1 (0.2)
肝性昏睡	1 (0.2)	1 (0.2)
ジスキネジア	1 (0.2)	0 (0.0)
顔面麻痺	1 (0.2)	1 (0.2)
蟻走感	1 (0.2)	0 (0.0)
頭蓋内出血	1 (0.2)	0 (0.0)
味覚減退	1 (0.2)	0 (0.0)
末梢性ニューロパチー	1 (0.2)	0 (0.0)
末梢性運動ニューロパチー	1 (0.2)	0 (0.0)
末梢性感覚運動ニューロパチー	1 (0.2)	0 (0.0)
可逆性後白質脳症症候群	1 (0.2)	0 (0.0)
痙攣発作	1 (0.2)	0 (0.0)
中毒性ニューロパチー	1 (0.2)	0 (0.0)
振戦	1 (0.2)	0 (0.0)
三叉神経痛	1 (0.2)	0 (0.0)
精神障害	16 (3.2)	2 (0.4)
不眠症	12 (2.4)	0 (0.0)
錯乱状態	2 (0.4)	1 (0.2)
うつ病	2 (0.4)	1 (0.2)
無感情	1 (0.2)	0 (0.0)
抑うつ気分	1 (0.2)	0 (0.0)
腎および尿路障害	133 (26.8)	35 (7.1)
蛋白尿	124 (25.0)	32 (6.5)

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付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
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System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
血尿	15 (3.0)	0 (0.0)
急性腎障害	2 (0.4)	1 (0.2)
ビリルビン尿	2 (0.4)	0 (0.0)
着色尿	2 (0.4)	0 (0.0)
夜間頻尿	2 (0.4)	0 (0.0)
腎機能障害	2 (0.4)	0 (0.0)
無尿	1 (0.2)	1 (0.2)
慢性腎臓病	1 (0.2)	0 (0.0)
排尿困難	1 (0.2)	0 (0.0)
糖尿	1 (0.2)	0 (0.0)
白血球尿	1 (0.2)	0 (0.0)
頻尿	1 (0.2)	0 (0.0)
腎仙痛	1 (0.2)	0 (0.0)
腎不全	1 (0.2)	1 (0.2)
腎梗塞	1 (0.2)	0 (0.0)
腎尿細管壊死	1 (0.2)	0 (0.0)
生殖系および乳房障害	15 (3.0)	1 (0.2)
後天性陰嚢水瘤	2 (0.4)	0 (0.0)
女性化乳房	2 (0.4)	0 (0.0)
骨盤痛	2 (0.4)	0 (0.0)
性器発疹	1 (0.2)	0 (0.0)
不規則月経	1 (0.2)	1 (0.2)
骨盤液貯留	1 (0.2)	0 (0.0)
前立腺閉塞	1 (0.2)	0 (0.0)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
陰部そう痒症	1 (0.2)	0 (0.0)
陰嚢血瘤	1 (0.2)	0 (0.0)
陰嚢浮腫	1 (0.2)	0 (0.0)
陰嚢潰瘍	1 (0.2)	0 (0.0)
精巣痛	1 (0.2)	0 (0.0)
呼吸器、胸郭および縦隔障害	143 (28.8)	7 (1.4)
発声障害	112 (22.6)	0 (0.0)
鼻出血	16 (3.2)	0 (0.0)
呼吸困難	12 (2.4)	2 (0.4)
口腔咽頭痛	10 (2.0)	0 (0.0)
咳嗽	6 (1.2)	0 (0.0)
喀血	6 (1.2)	1 (0.2)
胸水	6 (1.2)	0 (0.0)
肺塞栓症	3 (0.6)	3 (0.6)
呼吸不全	2 (0.4)	2 (0.4)
慢性気管支炎	1 (0.2)	0 (0.0)
しゃっくり	1 (0.2)	0 (0.0)
特発性肺線維症	1 (0.2)	0 (0.0)
喉頭の炎症	1 (0.2)	0 (0.0)
壊死性細気管支炎	1 (0.2)	0 (0.0)
非心原性肺水腫	1 (0.2)	1 (0.2)
口腔咽頭不快感	1 (0.2)	0 (0.0)
肺臓炎	1 (0.2)	0 (0.0)
肺梗塞	1 (0.2)	0 (0.0)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
肺腫瘤	1 (0.2)	0 (0.0)
鼻痛	1 (0.2)	0 (0.0)
鼻漏	1 (0.2)	0 (0.0)
上気道の炎症	1 (0.2)	0 (0.0)
皮膚および皮下組織障害	229 (46.2)	17 (3.4)
手掌・足底発赤知覚不全症候群	141 (28.4)	15 (3.0)
発疹	43 (8.7)	0 (0.0)
そう痒症	25 (5.0)	0 (0.0)
皮膚乾燥	15 (3.0)	0 (0.0)
脱毛症	14 (2.8)	0 (0.0)
紅斑	8 (1.6)	0 (0.0)
斑状丘疹状皮疹	6 (1.2)	0 (0.0)
過角化	5 (1.0)	0 (0.0)
ざ瘡様皮膚炎	4 (0.8)	0 (0.0)
爪変色	4 (0.8)	0 (0.0)
皮膚剥脱	4 (0.8)	0 (0.0)
皮膚反応	4 (0.8)	0 (0.0)
ざ瘡	3 (0.6)	0 (0.0)
水疱	3 (0.6)	0 (0.0)
湿疹	3 (0.6)	0 (0.0)
皮膚炎	2 (0.4)	0 (0.0)
多形紅斑	2 (0.4)	0 (0.0)
紫斑	2 (0.4)	0 (0.0)
丘疹性皮疹	2 (0.4)	0 (0.0)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.10
Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	 Grade >= 3 n (%)
そう痒性皮疹	2 (0.4)	0 (0.0)
皮膚血管炎	1 (0.2)	1 (0.2)
皮膚嚢腫	1 (0.2)	0 (0.0)
接触皮膚炎	1 (0.2)	0 (0.0)
異汗性湿疹	1 (0.2)	0 (0.0)
間擦疹	1 (0.2)	1 (0.2)
爪線状隆起	1 (0.2)	0 (0.0)
寝汗	1 (0.2)	0 (0.0)
爪破損	1 (0.2)	0 (0.0)
皮膚疼痛	1 (0.2)	0 (0.0)
手掌紅斑	1 (0.2)	0 (0.0)
点状出血	1 (0.2)	0 (0.0)
紅斑性皮疹	1 (0.2)	0 (0.0)
脂漏性皮膚炎	1 (0.2)	1 (0.2)
皮膚障害	1 (0.2)	0 (0.0)
皮膚びらん	1 (0.2)	0 (0.0)
皮膚色素減少	1 (0.2)	0 (0.0)
皮膚刺激	1 (0.2)	0 (0.0)
顔面腫脹	1 (0.2)	0 (0.0)
蕁麻疹	1 (0.2)	0 (0.0)
乾皮症	1 (0.2)	0 (0.0)
血管障害	214 (43.1)	122 (24.6)
高血圧	208 (41.9)	119 (24.0)
循環虚脱	2 (0.4)	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.10

Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term

HCC Lenvatinib Safety Set

ISS Safety Set

System organ Class Preferred Term	Lenvatinib (N=496) Any Grade n (%)	Lenvatinib (N=496) Grade >= 3 n (%)
潮紅	2 (0.4)	0 (0.0)
大動脈解離	1 (0.2)	1 (0.2)
動脈解離	1 (0.2)	0 (0.0)
深部静脈血栓症	1 (0.2)	1 (0.2)
静脈塞栓症	1 (0.2)	0 (0.0)
起立性低血圧	1 (0.2)	0 (0.0)
血栓性静脈炎	1 (0.2)	0 (0.0)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.

Subject with two or more TEAEs reported in the same SOC or PT term will be only counted once.

Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.

TEAE = Treatment-emergent adverse event.

付録 2.7.4.11
Fatal Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any Fatal TEAEs	62 (12.5)
肝不全	10 (2.0)
悪性新生物進行	10 (2.0)
敗血症	5 (1.0)
脳出血	3 (0.6)
呼吸不全	3 (0.6)
脳血管発作	2 (0.4)
肝性昏睡	2 (0.4)
全身健康状態低下	2 (0.4)
肝性脳症	2 (0.4)
多臓器機能不全症候群	2 (0.4)
誤嚥性肺炎	2 (0.4)
門脈血栓症	2 (0.4)
上部消化管出血	2 (0.4)
急性肝不全	1 (0.2)
急性呼吸不全	1 (0.2)
胆管閉塞	1 (0.2)
悪液質	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.11
Fatal Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
心肺不全	1 (0.2)
胆管炎	1 (0.2)
慢性肝不全	1 (0.2)
循環虚脱	1 (0.2)
死亡	1 (0.2)
播種性血管内凝固	1 (0.2)
呼吸困難	1 (0.2)
大腸菌性敗血症	1 (0.2)
肝硬変	1 (0.2)
腸出血	1 (0.2)
肝癌破裂	1 (0.2)
中枢神経系転移	1 (0.2)
心筋梗塞	1 (0.2)
臓器不全	1 (0.2)
急性膵炎	1 (0.2)
細菌性腹膜炎	1 (0.2)
肺塞栓症	1 (0.2)
肺梗塞	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.11
Fatal Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
腎機能障害	1 (0.2)
突然死	1 (0.2)
腫瘍出血	1 (0.2)
腫瘍破裂	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.12
Fatal Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any Fatal Related TEAEs	11 (2.2)
脳出血	3 (0.6)
肝不全	3 (0.6)
呼吸不全	2 (0.4)
脳血管発作	1 (0.2)
循環虚脱	1 (0.2)
心筋梗塞	1 (0.2)
敗血症	1 (0.2)
上部消化管出血	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any Serious TEAEs	210 (42.3)
肝性脳症	23 (4.6)
肝不全	14 (2.8)
腹水	12 (2.4)
食欲減退	11 (2.2)
悪性新生物進行	10 (2.0)
下痢	8 (1.6)
無力症	7 (1.4)
血中ビリルビン増加	7 (1.4)
胆汁うっ滞性黄疸	7 (1.4)
食道静脈瘤出血	7 (1.4)
敗血症	7 (1.4)
腹痛	6 (1.2)
発熱	6 (1.2)
嘔吐	6 (1.2)
呼吸困難	5 (1.0)
全身健康状態低下	5 (1.0)
肺炎	5 (1.0)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
上部消化管出血	5 (1.0)
癌疼痛	4 (0.8)
心筋梗塞	4 (0.8)
門脈血栓症	4 (0.8)
肺塞栓症	4 (0.8)
急性腎障害	3 (0.6)
脳出血	3 (0.6)
胆管炎	3 (0.6)
肝性昏睡	3 (0.6)
出血性十二指腸潰瘍	3 (0.6)
肝硬変	3 (0.6)
低ナトリウム血症	3 (0.6)
悪心	3 (0.6)
末梢性浮腫	3 (0.6)
誤嚥性肺炎	3 (0.6)
蛋白尿	3 (0.6)
呼吸不全	3 (0.6)
腫瘍出血	3 (0.6)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
上腹部痛	2 (0.4)
偶発的過量投与	2 (0.4)
アスパラギン酸アミノトランスフェラーゼ増加	2 (0.4)
背部痛	2 (0.4)
胆管閉塞	2 (0.4)
胆管結石	2 (0.4)
蜂巣炎	2 (0.4)
脳梗塞	2 (0.4)
脳血管発作	2 (0.4)
胆嚢炎	2 (0.4)
脱水	2 (0.4)
十二指腸潰瘍	2 (0.4)
疲労	2 (0.4)
胃潰瘍	2 (0.4)
胃腸炎	2 (0.4)
頭痛	2 (0.4)
肝肺症候群	2 (0.4)
高カリウム血症	2 (0.4)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
低アルブミン血症	2 (0.4)
肝膿瘍	2 (0.4)
肝癌破裂	2 (0.4)
肺感染	2 (0.4)
中枢神経系転移	2 (0.4)
脊椎転移	2 (0.4)
多臓器機能不全症候群	2 (0.4)
筋力低下	2 (0.4)
病的骨折	2 (0.4)
骨盤痛	2 (0.4)
細菌性腹膜炎	2 (0.4)
腎不全	2 (0.4)
腎機能障害	2 (0.4)
痙攣発作	2 (0.4)
脊髄圧迫	2 (0.4)
腫瘍破裂	2 (0.4)
臍ヘルニア	2 (0.4)
尿路感染	2 (0.4)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
腹部膨満	1 (0.2)
下腹部痛	1 (0.2)
急性肝不全	1 (0.2)
急性呼吸不全	1 (0.2)
アラニンアミノトランスフェラーゼ増加	1 (0.2)
貧血	1 (0.2)
大動脈解離	1 (0.2)
虫垂膿瘍	1 (0.2)
心房細動	1 (0.2)
菌血症	1 (0.2)
胆管拡張	1 (0.2)
胆道感染	1 (0.2)
血圧低下	1 (0.2)
骨髄機能不全	1 (0.2)
骨痛	1 (0.2)
悪液質	1 (0.2)
心肺不全	1 (0.2)
急性胆嚢炎	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
慢性肝不全	1 (0.2)
循環虚脱	1 (0.2)
クロストリジウム検査陽性	1 (0.2)
錯乱状態	1 (0.2)
死亡	1 (0.2)
深部静脈血栓症	1 (0.2)
デング熱	1 (0.2)
糖尿病	1 (0.2)
両麻痺	1 (0.2)
播種性血管内凝固	1 (0.2)
注意力障害	1 (0.2)
憩室炎	1 (0.2)
浮動性めまい	1 (0.2)
消化不良	1 (0.2)
大腸菌性敗血症	1 (0.2)
顔面麻痺	1 (0.2)
転倒	1 (0.2)
側腹部痛	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
胃出血	1 (0.2)
胃炎	1 (0.2)
ウイルス性消化管感染	1 (0.2)
全身性浮腫	1 (0.2)
鼠径部膿瘍	1 (0.2)
血尿	1 (0.2)
血性胆汁	1 (0.2)
肝酵素上昇	1 (0.2)
肝機能異常	1 (0.2)
肝臓痛	1 (0.2)
肝腎症候群	1 (0.2)
しゃっくり	1 (0.2)
水腫性胆嚢炎	1 (0.2)
高ビリルビン血症	1 (0.2)
高カルシウム血症	1 (0.2)
低カルシウム血症	1 (0.2)
低血糖	1 (0.2)
低マグネシウム血症	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
ＩｇＡ腎症	1 (0.2)
感染性新生物	1 (0.2)
感染	1 (0.2)
感染性胸水	1 (0.2)
企図的過量投与	1 (0.2)
間擦疹	1 (0.2)
椎間板突出	1 (0.2)
腸出血	1 (0.2)
頭蓋内腫瘍出血	1 (0.2)
黄疸	1 (0.2)
肝損傷	1 (0.2)
腰部脊柱管狭窄症	1 (0.2)
肺膿瘍	1 (0.2)
リンパ腫	1 (0.2)
大うつ病	1 (0.2)
髄膜腫	1 (0.2)
骨転移	1 (0.2)
頚部痛	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
壊死性細気管支炎	1 (0.2)
好中球数減少	1 (0.2)
非心原性肺水腫	1 (0.2)
臓器不全	1 (0.2)
口腔咽頭痛	1 (0.2)
変形性関節症	1 (0.2)
四肢痛	1 (0.2)
急性膵炎	1 (0.2)
反回神経麻痺	1 (0.2)
肝周囲膿瘍	1 (0.2)
歯周炎	1 (0.2)
末梢腫脹	1 (0.2)
胸膜感染	1 (0.2)
気胸	1 (0.2)
可逆性後白質脳症症候群	1 (0.2)
術後膿瘍	1 (0.2)
肺梗塞	1 (0.2)
肺結核	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
腎細胞癌	1 (0.2)
腎尿細管壊死	1 (0.2)
横紋筋融解症	1 (0.2)
サルモネラ症	1 (0.2)
陰嚢感染	1 (0.2)
脂漏性皮膚炎	1 (0.2)
敗血症性ショック	1 (0.2)
脊柱管狭窄症	1 (0.2)
脊椎圧迫骨折	1 (0.2)
突然死	1 (0.2)
自殺企図	1 (0.2)
失神	1 (0.2)
胸椎骨折	1 (0.2)
血栓性静脈炎	1 (0.2)
一過性脳虚血発作	1 (0.2)
結核	1 (0.2)
腫瘍壊死	1 (0.2)
腫瘍疼痛	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.13
Serious Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
腸球菌性尿路感染	1 (0.2)
尿路性敗血症	1 (0.2)
食道静脈瘤	1 (0.2)
体重減少	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.14
Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any Serious Related TEAEs	86 (17.3)
肝性脳症	11 (2.2)
食欲減退	8 (1.6)
下痢	7 (1.4)
腹水	6 (1.2)
肝不全	5 (1.0)
無力症	4 (0.8)
血中ビリルビン増加	3 (0.6)
脳出血	3 (0.6)
心筋梗塞	3 (0.6)
食道静脈瘤出血	3 (0.6)
蛋白尿	3 (0.6)
肺塞栓症	3 (0.6)
発熱	3 (0.6)
上部消化管出血	3 (0.6)
脳梗塞	2 (0.4)
胆嚢炎	2 (0.4)
胆汁うっ滞性黄疸	2 (0.4)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.14
Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
呼吸不全	2 (0.4)
嘔吐	2 (0.4)
急性腎障害	1 (0.2)
大動脈解離	1 (0.2)
胆管結石	1 (0.2)
骨髄機能不全	1 (0.2)
脳血管発作	1 (0.2)
胆管炎	1 (0.2)
循環虚脱	1 (0.2)
肝性昏睡	1 (0.2)
深部静脈血栓症	1 (0.2)
脱水	1 (0.2)
十二指腸潰瘍	1 (0.2)
出血性十二指腸潰瘍	1 (0.2)
呼吸困難	1 (0.2)
顔面麻痺	1 (0.2)
疲労	1 (0.2)
胃出血	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.14
Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
胃潰瘍	1 (0.2)
全身健康状態低下	1 (0.2)
全身性浮腫	1 (0.2)
血尿	1 (0.2)
血性胆汁	1 (0.2)
肝硬変	1 (0.2)
肝酵素上昇	1 (0.2)
肝機能異常	1 (0.2)
肝臓痛	1 (0.2)
肝腎症候群	1 (0.2)
しゃっくり	1 (0.2)
高カリウム血症	1 (0.2)
低アルブミン血症	1 (0.2)
低カルシウム血症	1 (0.2)
低血糖	1 (0.2)
低マグネシウム血症	1 (0.2)
低ナトリウム血症	1 (0.2)
間擦疹	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.14
Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
肺感染	1 (0.2)
筋力低下	1 (0.2)
悪心	1 (0.2)
壊死性細気管支炎	1 (0.2)
好中球数減少	1 (0.2)
非心原性肺水腫	1 (0.2)
末梢性浮腫	1 (0.2)
骨盤痛	1 (0.2)
肺炎	1 (0.2)
門脈血栓症	1 (0.2)
可逆性後白質脳症症候群	1 (0.2)
術後膿瘍	1 (0.2)
腎不全	1 (0.2)
腎機能障害	1 (0.2)
腎尿細管壊死	1 (0.2)
陰嚢感染	1 (0.2)
脂漏性皮膚炎	1 (0.2)
敗血症	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.14
Serious Related Treatment-Emergent Adverse Events by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
血栓性静脈炎	1 (0.2)
腫瘍出血	1 (0.2)
食道静脈瘤	1 (0.2)

Related TEAEs include TEAEs that were considered by the Investigator to be possibly or probably related to study drug or TEAEs with a missing causality.
Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.15
Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any TEAEs Leading to Treatment Discontinuation	100 (20.2)
肝性脳症	8 (1.6)
疲労	7 (1.4)
血中ビリルビン増加	6 (1.2)
蛋白尿	6 (1.2)
肝不全	5 (1.0)
脳出血	3 (0.6)
胆汁うっ滞性黄疸	3 (0.6)
心筋梗塞	3 (0.6)
敗血症	3 (0.6)
腹痛	2 (0.4)
上腹部痛	2 (0.4)
胆管閉塞	2 (0.4)
脳血管発作	2 (0.4)
ＥＣＯＧパフォーマンスステータス悪化	2 (0.4)
全身健康状態低下	2 (0.4)
悪性新生物進行	2 (0.4)
多臓器機能不全症候群	2 (0.4)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.15
Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
門脈血栓症	2 (0.4)
腫瘍破裂	2 (0.4)
上部消化管出血	2 (0.4)
腹部膨満	1 (0.2)
副腎腺腫	1 (0.2)
腹水	1 (0.2)
無力症	1 (0.2)
血中アルカリホスファターゼ増加	1 (0.2)
骨髄機能不全	1 (0.2)
気管支肺アスペルギルス症	1 (0.2)
癌疼痛	1 (0.2)
脳梗塞	1 (0.2)
後天性胆管拡張症	1 (0.2)
胆管炎	1 (0.2)
慢性肝不全	1 (0.2)
循環虚脱	1 (0.2)
肝性昏睡	1 (0.2)
死亡	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.15
Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
食欲減退	1 (0.2)
両麻痺	1 (0.2)
播種性血管内凝固	1 (0.2)
薬物不耐性	1 (0.2)
呼吸困難	1 (0.2)
脳症	1 (0.2)
大腸菌性敗血症	1 (0.2)
γ－グルタミルトランスフェラーゼ増加	1 (0.2)
頭痛	1 (0.2)
肝機能異常	1 (0.2)
高血圧	1 (0.2)
治癒不良	1 (0.2)
肝膿瘍	1 (0.2)
肝癌破裂	1 (0.2)
肝損傷	1 (0.2)
中枢神経系転移	1 (0.2)
口腔内潰瘍形成	1 (0.2)
好中球数減少	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

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付録 2.7.4.15
Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
末梢性浮腫	1 (0.2)
食道静脈瘤出血	1 (0.2)
臓器不全	1 (0.2)
四肢痛	1 (0.2)
急性膵炎	1 (0.2)
血小板数減少	1 (0.2)
肺炎	1 (0.2)
肺塞栓症	1 (0.2)
肺梗塞	1 (0.2)
発熱	1 (0.2)
腎細胞癌	1 (0.2)
腎不全	1 (0.2)
腎機能障害	1 (0.2)
呼吸不全	1 (0.2)
脊髄圧迫	1 (0.2)
突然死	1 (0.2)
腫瘍出血	1 (0.2)
腫瘍壊死	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.15
Treatment-Emergent Adverse Events Leading to Treatment Discontinuation by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
臍ヘルニア	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
Subjects with Any TEAEs Leading to Treatment Modification	309 (62.3)
食欲減退	38 (7.7)
蛋白尿	37 (7.5)
下痢	36 (7.3)
疲労	29 (5.8)
高血圧	29 (5.8)
手掌・足底発赤知覚不全症候群	27 (5.4)
血小板数減少	25 (5.0)
肝性脳症	21 (4.2)
体重減少	21 (4.2)
血中ビリルビン増加	20 (4.0)
悪心	17 (3.4)
無力症	16 (3.2)
嘔吐	13 (2.6)
発熱	12 (2.4)
好中球数減少	11 (2.2)
腹水	10 (2.0)
アスパラギン酸アミノトランスフェラーゼ増加	9 (1.8)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
呼吸困難	8 (1.6)
血小板減少症	8 (1.6)
γ－グルタミルトランスフェラーゼ増加	7 (1.4)
腹痛	6 (1.2)
アラニンアミノトランスフェラーゼ増加	6 (1.2)
脱水	6 (1.2)
好中球減少症	6 (1.2)
末梢性浮腫	6 (1.2)
口内炎	6 (1.2)
白血球数減少	6 (1.2)
上腹部痛	5 (1.0)
低ナトリウム血症	5 (1.0)
倦怠感	5 (1.0)
筋肉痛	5 (1.0)
食道静脈瘤出血	5 (1.0)
急性腎障害	4 (0.8)
血中アルカリホスファターゼ増加	4 (0.8)
高アンモニア血症	4 (0.8)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
高ビリルビン血症	4 (0.8)
四肢痛	4 (0.8)
貧血	3 (0.6)
胆管炎	3 (0.6)
便秘	3 (0.6)
出血性十二指腸潰瘍	3 (0.6)
胃潰瘍	3 (0.6)
血尿	3 (0.6)
喀血	3 (0.6)
肝不全	3 (0.6)
低アルブミン血症	3 (0.6)
黄疸	3 (0.6)
嗜眠	3 (0.6)
筋力低下	3 (0.6)
鼻咽頭炎	3 (0.6)
尿路感染	3 (0.6)
胆管閉塞	2 (0.4)
胆管結石	2 (0.4)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
骨髄機能不全	2 (0.4)
脳梗塞	2 (0.4)
脳血管発作	2 (0.4)
胆嚢炎	2 (0.4)
錯乱状態	2 (0.4)
十二指腸潰瘍	2 (0.4)
消化不良	2 (0.4)
肝硬変	2 (0.4)
肝機能異常	2 (0.4)
高カリウム血症	2 (0.4)
リパーゼ増加	2 (0.4)
頚部痛	2 (0.4)
歯周炎	2 (0.4)
誤嚥性肺炎	2 (0.4)
肺塞栓症	2 (0.4)
発疹	2 (0.4)
上部消化管出血	2 (0.4)
腹部膨満	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
下腹部痛	1 (0.2)
偶発的過量投与	1 (0.2)
後天性陰嚢水瘤	1 (0.2)
急性呼吸不全	1 (0.2)
肛門膿瘍	1 (0.2)
大動脈解離	1 (0.2)
虫垂膿瘍	1 (0.2)
関節痛	1 (0.2)
心房細動	1 (0.2)
背部痛	1 (0.2)
菌血症	1 (0.2)
胆管拡張	1 (0.2)
左脚ブロック	1 (0.2)
癌疼痛	1 (0.2)
急性胆嚢炎	1 (0.2)
慢性腎臓病	1 (0.2)
循環虚脱	1 (0.2)
クロストリジウム検査陽性	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
肝性昏睡	1 (0.2)
細菌性結膜炎	1 (0.2)
皮膚血管炎	1 (0.2)
深部静脈血栓症	1 (0.2)
デング熱	1 (0.2)
注意力障害	1 (0.2)
浮動性めまい	1 (0.2)
口内乾燥	1 (0.2)
湿疹	1 (0.2)
心電図ＱＴ延長	1 (0.2)
ウイルス性消化管感染	1 (0.2)
全身性浮腫	1 (0.2)
鼡径部膿瘍	1 (0.2)
吐血	1 (0.2)
頭痛	1 (0.2)
肝肺症候群	1 (0.2)
肝腎症候群	1 (0.2)
水腫性胆嚢炎	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
高カルシウム血症	1 (0.2)
高コレステロール血症	1 (0.2)
低カルシウム血症	1 (0.2)
低カリウム血症	1 (0.2)
低リン酸血症	1 (0.2)
低血圧	1 (0.2)
甲状腺機能低下症	1 (0.2)
特発性肺線維症	1 (0.2)
感染	1 (0.2)
感染性胸水	1 (0.2)
インフルエンザ	1 (0.2)
鼡径ヘルニア	1 (0.2)
企図的過量投与	1 (0.2)
椎間板突出	1 (0.2)
胆汁うっ滞性黄疸	1 (0.2)
腎感染	1 (0.2)
白血球減少症	1 (0.2)
肝膿瘍	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
肺感染	1 (0.2)
リンパ球数減少	1 (0.2)
リンパ球減少症	1 (0.2)
大うつ病	1 (0.2)
悪性新生物進行	1 (0.2)
精神状態変化	1 (0.2)
口腔内潰瘍形成	1 (0.2)
心筋梗塞	1 (0.2)
壊死性細気管支炎	1 (0.2)
非心臓性胸痛	1 (0.2)
肝疾患による浮腫	1 (0.2)
口腔咽頭痛	1 (0.2)
変形性関節症	1 (0.2)
手掌紅斑	1 (0.2)
急性膵炎	1 (0.2)
反回神経麻痺	1 (0.2)
歯周病	1 (0.2)
末梢腫脹	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
細菌性腹膜炎	1 (0.2)
胸膜感染	1 (0.2)
肺炎	1 (0.2)
門脈血栓症	1 (0.2)
可逆性後白質脳症症候群	1 (0.2)
術後膿瘍	1 (0.2)
尿中蛋白陽性	1 (0.2)
プロトロンビン量増加	1 (0.2)
腎機能障害	1 (0.2)
腎尿細管壊死	1 (0.2)
横紋筋融解症	1 (0.2)
サルモネラ症	1 (0.2)
陰嚢感染	1 (0.2)
痙攣発作	1 (0.2)
敗血症	1 (0.2)
傾眠	1 (0.2)
自殺企図	1 (0.2)
全身性炎症反応症候群	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4.16
Treatment-Emergent Adverse Events Leading to Treatment Modification (Interruption or Reduction) by Preferred Term
HCC Lenvatinib Safety Set
ISS Safety Set

Preferred Term	Lenvatinib (N=496) n (%)
胸椎骨折	1 (0.2)
甲状腺炎	1 (0.2)
歯痛	1 (0.2)
トランスアミナーゼ上昇	1 (0.2)
一過性脳虚血発作	1 (0.2)
結核	1 (0.2)
腫瘍出血	1 (0.2)
上気道感染	1 (0.2)
尿中ビリルビン増加	1 (0.2)
尿中蛋白／クレアチニン比増加	1 (0.2)
食道静脈瘤	1 (0.2)
外陰腟真菌感染	1 (0.2)
体重増加	1 (0.2)

Percentages are based on the total number of subjects in the Safety Analysis Set within the relevant treatment group.
Subjects with two or more adverse events in the same preferred term will be counted only once.
Adverse Events terms were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 19.1.
TEAE = Treatment-emergent adverse event.

付録 2.7.4-17 特に関心のある有害事象の定義

高血圧事象

コード	PT（英名）	PT（和名）
10000358	Accelerated hypertension	進行性高血圧
10005732	Blood pressure ambulatory increased	外来血圧上昇
10005739	Blood pressure diastolic increased	拡張期血圧上昇
10051128	Blood pressure inadequately controlled	コントロール不良の血圧
10005750	Blood pressure increased	血圧上昇
10063926	Blood pressure management	血圧管理
10053355	Blood pressure orthostatic increased	起立血圧上昇
10005760	Blood pressure systolic increased	収縮期血圧上昇
10012758	Diastolic hypertension	拡張期高血圧
10014129	Eclampsia	子癇
10057615	Endocrine hypertension	内分泌性高血圧
10015488	Essential hypertension	本態性高血圧症
10070538	Gestational hypertension	妊娠高血圧
10049058	HELLP syndrome	HELLP 症候群
10020571	Hyperaldosteronism	高アルドステロン症
10020772	Hypertension	高血圧
10049781	Hypertension neonatal	新生児高血圧
10059238	Hypertensive angiopathy	高血圧性血管障害
10020801	Hypertensive cardiomegaly	高血圧性心拡大
10058222	Hypertensive cardiomyopathy	高血圧性心筋症
10077000	Hypertensive cerebrovascular disease	高血圧性脳血管疾患
10020802	Hypertensive crisis	高血圧クリーゼ
10058179	Hypertensive emergency	高血圧緊急症
10020803	Hypertensive encephalopathy	高血圧性脳症
10020823	Hypertensive heart disease	高血圧性心疾患
10055171	Hypertensive nephropathy	高血圧性腎症
10049079	Labile hypertension	不安定高血圧
10025600	Malignant hypertension	悪性高血圧
10025603	Malignant hypertensive heart disease	悪性高血圧性心疾患
10026674	Malignant renal hypertension	悪性腎性高血圧
10026924	Maternal hypertension affecting foetus	胎児に影響する母体の高血圧症
10026985	Mean arterial pressure increased	平均動脈圧上昇
10052066	Metabolic syndrome	代謝症候群
10067598	Neurogenic hypertension	神経性高血圧
10065508	Orthostatic hypertension	起立性高血圧
10076704	Page kidney	ページ腎
10036485	Pre-eclampsia	子癇前症
10065918	Prehypertension	高血圧前症
10062886	Procedural hypertension	処置による高血圧
10038464	Renal hypertension	腎性高血圧
10074864	Renal sympathetic nerve ablation	腎交感神経アブレーション
10038562	Renovascular hypertension	腎血管性高血圧
10038926	Retinopathy hypertensive	高血圧性網膜症
10039808	Secondary aldosteronism	続発性アルドステロン症
10039834	Secondary hypertension	二次性高血圧
10042957	Systolic hypertension	収縮期高血圧
10048007	Withdrawal hypertension	断薬性高血圧

出血事象

コード	PT（英名）	PT（和名）
10067383	Abdominal wall haematoma	腹壁血腫
10067788	Abdominal wall haemorrhage	腹壁出血
10069195	Abnormal withdrawal bleeding	異常消退出血
10058994	Acute haemorrhagic leukoencephalitis	急性出血性白質脳炎
10075634	Acute haemorrhagic ulcerative colitis	急性出血性潰瘍性大腸炎
10075094	Administration site bruise	投与部位内出血
10075100	Administration site haematoma	投与部位血腫
10075101	Administration site haemorrhage	投与部位出血
10059194	Adrenal haematoma	副腎血腫
10001361	Adrenal haemorrhage	副腎出血
10049555	Anal haemorrhage	肛門出血
10063896	Anal ulcer haemorrhage	出血性肛門潰瘍
10056346	Anastomotic haemorrhage	吻合部出血
10002244	Anastomotic ulcer haemorrhage	出血性吻合部潰瘍
10048380	Aneurysm ruptured	動脈瘤破裂
10064223	Angina bullosa haemorrhagica	水疱性出血性口峡炎
10068925	Anorectal varices haemorrhage	肛門直腸静脈瘤出血
10002886	Aortic aneurysm rupture	大動脈瘤破裂
10068119	Aortic dissection rupture	大動脈解離破裂
10067975	Aortic intramural haematoma	大動脈壁内血腫
10075729	Aortic perforation	大動脈穿孔
10060874	Aortic rupture	大動脈破裂
10075330	Aponeurosis contusion	腱膜挫傷
10050114	Application site bruise	適用部位内出血
10068317	Application site haematoma	適用部位血腫
10072694	Application site haemorrhage	適用部位出血
10050182	Application site purpura	適用部位紫斑
10060964	Arterial haemorrhage	動脈出血
10074971	Arterial intramural haematoma	動脈壁内血腫
10075732	Arterial perforation	動脈穿孔
10003173	Arterial rupture	動脈破裂
10055150	Arteriovenous fistula site haematoma	動静脈瘻部位血腫
10055123	Arteriovenous fistula site haemorrhage	動静脈瘻部位出血
10055152	Arteriovenous graft site haematoma	動静脈グラフト部位血腫
10055126	Arteriovenous graft site haemorrhage	動静脈グラフト部位出血
10067372	Astringent therapy	収れん薬療法
10048761	Atrial rupture	心房破裂
10003797	Auricular haematoma	耳介血腫
10077031	Basal ganglia haematoma	大脳基底核血腫
10067057	Basal ganglia haemorrhage	大脳基底核出血
10075736	Basilar artery perforation	脳底動脈穿孔
10062656	Bladder tamponade	膀胱タンポナーデ
10005144	Bleeding varicose vein	出血性静脈瘤
10005372	Blood blister	血性水疱
10005863	Blood urine	尿中血
10018870	Blood urine present	尿中血陽性
10057687	Bloody discharge	血性分泌物
10067442	Bloody peritoneal effluent	血性腹膜透析排液
10066251	Bone contusion	骨挫傷
10073581	Bone marrow haemorrhage	骨髄出血

出血事象（続き）

コード	PT（英名）	PT（和名）
10052346	Brain contusion	脳挫傷
10073230	Brain stem haematoma	脳幹血腫
10006145	Brain stem haemorrhage	脳幹出血
10071205	Brain stem microhaemorrhage	脳幹微小出血
10064753	Breast haematoma	乳房血腫
10006254	Breast haemorrhage	乳房出血
10006375	Broad ligament haematoma	子宮広間膜血腫
10065739	Bronchial haemorrhage	気管支出血
10077818	Bursal haematoma	滑液包血腫
10073356	Cardiac contusion	心臓挫傷
10051328	Carotid aneurysm rupture	頚動脈瘤破裂
10075728	Carotid artery perforation	頚動脈穿孔
10063587	Catheter site bruise	カテーテル留置部位内出血
10055662	Catheter site haematoma	カテーテル留置部位血腫
10051099	Catheter site haemorrhage	カテーテル留置部位出血
10072043	Central nervous system haemorrhage	中枢神経系出血
10008014	Cephalhaematoma	頭血腫
10061038	Cerebellar haematoma	小脳血腫
10008030	Cerebellar haemorrhage	小脳出血
10071206	Cerebellar microhaemorrhage	小脳微小出血
10075394	Cerebral aneurysm perforation	脳動脈瘤穿孔
10008076	Cerebral aneurysm ruptured syphilitic	梅毒性脳動脈瘤破裂
10008086	Cerebral arteriovenous malformation haemorrhagic	出血性脳動静脈奇形
10075734	Cerebral artery perforation	大脳動脈穿孔
10053942	Cerebral haematoma	脳血腫
10008111	Cerebral haemorrhage	脳出血
10050157	Cerebral haemorrhage foetal	胎児脳出血
10008112	Cerebral haemorrhage neonatal	新生児脳出血
10067277	Cerebral microhaemorrhage	脳微小出血
10050020	Cervix haematoma uterine	子宮頚部血腫
10050022	Cervix haemorrhage uterine	子宮頚部出血
10076597	Chest wall haematoma	胸壁血腫
10068642	Choroidal haematoma	脈絡膜血腫
10008786	Choroidal haemorrhage	脈絡膜出血
10050399	Chronic gastrointestinal bleeding	慢性胃腸出血
10072726	Chronic pigmented purpura	慢性色素性紫斑
10057417	Ciliary body haemorrhage	毛様体出血
10065019	Coital bleeding	性交出血
10009996	Colonic haematoma	結腸血腫
10010719	Conjunctival haemorrhage	結膜出血
10050584	Contusion	挫傷
10051558	Corneal bleeding	角膜出血
10059029	Cullen's sign	カレン徴候
10011793	Cystitis haemorrhagic	出血性膀胱炎
10074718	Deep dissecting haematoma	深部解離性血腫
10012741	Diarrhoea haemorrhagic	血性下痢
10013442	Disseminated intravascular coagulation	播種性血管内凝固
10013541	Diverticulitis intestinal haemorrhagic	出血性腸憩室炎
10013560	Diverticulum intestinal haemorrhagic	出血性腸憩室

出血事象（続き）

コード	PT（英名）	PT（和名）
10013839	Duodenal ulcer haemorrhage	出血性十二指腸潰瘍
10013865	Duodenitis haemorrhagic	出血性十二指腸炎
10013908	Dysfunctional uterine bleeding	機能不全性子宮出血
10014009	Ear haemorrhage	耳出血
10014080	Ecchymosis	斑状出血
10014589	Encephalitis haemorrhagic	出血性脳炎
10014896	Enterocolitis haemorrhagic	出血性腸炎
10073681	Epidural haemorrhage	硬膜外出血
10015090	Epistaxis	鼻出血
10015719	Exsanguination	失血
10078254	Extra-axial haemorrhage	脳実質外出血
10015769	Extradural haematoma	硬膜外血腫
10015867	Extravasation blood	血液溢出
10073354	Eye contusion	眼挫傷
10015926	Eye haemorrhage	眼出血
10053196	Eyelid bleeding	眼瞼出血
10075018	Eyelid contusion	眼瞼挫傷
10064976	Eyelid haematoma	眼瞼血腫
10075739	Femoral artery perforation	大腿動脈穿孔
10075745	Femoral vein perforation	大腿静脈穿孔
10016871	Foetal-maternal haemorrhage	胎児・母体間出血
10017788	Gastric haemorrhage	胃出血
10017826	Gastric ulcer haemorrhage	出血性胃潰瘍
10017829	Gastric ulcer haemorrhage, obstructive	閉塞性出血性胃潰瘍
10057572	Gastric varices haemorrhage	胃静脈瘤出血
10017857	Gastritis alcoholic haemorrhagic	出血性アルコール胃炎
10017866	Gastritis haemorrhagic	出血性胃炎
10053768	Gastroduodenal haemorrhage	胃十二指腸出血
10048712	Gastroduodenitis haemorrhagic	出血性胃十二指腸炎
10017929	Gastrointestinal angiodysplasia haemorrhagic	出血性胃腸管血管異形成
10017955	Gastrointestinal haemorrhage	胃腸出血
10074437	Gastrointestinal polyp haemorrhage	胃腸ポリープ出血
10056743	Gastrointestinal ulcer haemorrhage	出血性胃腸潰瘍
10073355	Genital contusion	生殖器挫傷
10061178	Genital haemorrhage	性器出血
10018276	Gingival bleeding	歯肉出血
10063577	Graft haemorrhage	移植部位出血
10075426	Grey Turner's sign	グレイ・ターナー徴候
10018829	Haemarthrosis	出血性関節症
10018830	Haematemesis	吐血
10018836	Haematochezia	血便排泄
10018833	Haematocoele	血瘤
10018852	Haematoma	血腫
10060733	Haematoma evacuation	血腫除去
10051564	Haematoma infection	血腫感染
10050468	Haematosalpinx	卵管留血症
10018866	Haematospermia	血精液症
10063013	Haematotympanum	鼓室内出血
10018867	Haematuria	血尿
10018871	Haematuria traumatic	外傷性血尿

出血事象（続き）

コード	PT（英名）	PT（和名）
10058947	Haemobilia	血性胆汁
10065057	Haemophilic arthropathy	血友病性関節症
10018964	Haemoptysis	喀血
10055798	Haemorrhage	出血
10055803	Haemorrhage coronary artery	冠動脈出血
10061191	Haemorrhage foetal	胎児出血
10018981	Haemorrhage in pregnancy	妊娠時出血
10018985	Haemorrhage intracranial	頭蓋内出血
10061993	Haemorrhage neonatal	新生児出血
10018999	Haemorrhage subcutaneous	皮下出血
10019001	Haemorrhage subepidermal	表皮下出血
10055847	Haemorrhage urinary tract	尿路出血
10052293	Haemorrhagic anaemia	出血性貧血
10064595	Haemorrhagic arteriovenous malformation	出血性動静脈奇形
10059766	Haemorrhagic ascites	血性腹水
10077443	Haemorrhagic breast cyst	出血性乳房嚢胞
10019005	Haemorrhagic cerebral infarction	出血性脳梗塞
10059189	Haemorrhagic cyst	出血性嚢胞
10062713	Haemorrhagic diathesis	出血性素因
10019008	Haemorrhagic disease of newborn	新生児出血性疾患
10019009	Haemorrhagic disorder	出血性障害
10067786	Haemorrhagic erosive gastritis	出血性びらん性胃炎
10067796	Haemorrhagic hepatic cyst	出血性肝嚢胞
10019013	Haemorrhagic infarction	出血性梗塞
10076058	Haemorrhagic necrotic pancreatitis	出血性壊死性膵炎
10060781	Haemorrhagic ovarian cyst	出血性卵巣嚢胞
10019016	Haemorrhagic stroke	出血性卒中
10072256	Haemorrhagic thyroid cyst	出血性甲状腺嚢胞
10055677	Haemorrhagic transformation stroke	卒中の出血性変化
10054096	Haemorrhagic tumour necrosis	出血性腫瘍壊死
10059499	Haemorrhagic urticaria	出血性蕁麻疹
10071252	Haemorrhagic vasculitis	出血性血管炎
10054787	Haemorrhoidal haemorrhage	痔出血
10067439	Haemostasis	止血
10019027	Haemothorax	血胸
10019617	Henoch-Schonlein purpura	ヘノッホ・シェーンライン紫斑病
10054885	Hepatic haemangioma rupture	肝臓血管腫破裂
10019676	Hepatic haematoma	肝血腫
10019677	Hepatic haemorrhage	肝出血
10019883	Hereditary haemorrhagic telangiectasia	遺伝性出血性毛細血管拡張症
10074737	Hyperfibrinolysis	線溶亢進
10020923	Hyphaema	前房出血
10075731	Iliac artery perforation	腸骨動脈穿孔
10072789	Iliac artery rupture	腸骨動脈破裂
10075744	Iliac vein perforation	腸骨静脈穿孔
10074667	Immune thrombocytopenic purpura	免疫性血小板減少性紫斑病
10063850	Implant site bruising	埋込み部位内出血
10063780	Implant site haematoma	埋込み部位血腫
10053995	Implant site haemorrhage	埋込み部位出血
10059241	Incision site haematoma	切開部位血腫

出血事象（続き）

コード	PT（英名）	PT（和名）
10051100	Incision site haemorrhage	切開部位出血
10021688	Increased tendency to bruise	内出血発生の増加傾向
10052844	Induced abortion haemorrhage	人工流産による出血
10075742	Inferior vena cava perforation	下大静脈穿孔
10059203	Infusion site bruising	注入部位内出血
10065463	Infusion site haematoma	注入部位血腫
10065464	Infusion site haemorrhage	注入部位出血
10022052	Injection site bruising	注射部位内出血
10022066	Injection site haematoma	注射部位血腫
10022067	Injection site haemorrhage	注射部位出血
10073630	Instillation site bruise	滴下投与部位内出血
10073609	Instillation site haematoma	滴下投与部位血腫
10073610	Instillation site haemorrhage	滴下投与部位出血
10075192	Internal haemorrhage	内出血
10069829	Intestinal haematoma	腸血腫
10059175	Intestinal haemorrhage	腸出血
10078058	Intestinal varices haemorrhage	腸静脈瘤出血
10056457	Intra-abdominal haematoma	腹腔内血腫
10061249	Intra-abdominal haemorrhage	腹腔内出血
10062025	Intracerebral haematoma evacuation	脳内血腫除去術
10059491	Intracranial haematoma	頭蓋内血腫
10022775	Intracranial tumour haemorrhage	頭蓋内腫瘍出血
10071934	Intraocular haematoma	眼内血腫
10067703	Intrapartum haemorrhage	分娩時出血
10022840	Intraventricular haemorrhage	脳室内出血
10022841	Intraventricular haemorrhage neonatal	新生児脳室内出血
10057418	Iris haemorrhage	虹彩出血
10077666	Joint microhaemorrhage	関節微小出血
10023413	Kidney contusion	腎挫傷
10069930	Lacrimal haemorrhage	涙器出血
10052534	Large intestinal haemorrhage	大腸出血
10061262	Large intestinal ulcer haemorrhage	出血性大腸潰瘍
10070885	Laryngeal haematoma	喉頭血腫
10065740	Laryngeal haemorrhage	喉頭出血
10066304	Lip haematoma	口唇血腫
10049297	Lip haemorrhage	口唇出血
10067266	Liver contusion	肝挫傷
10050953	Lower gastrointestinal haemorrhage	下部消化管出血
10075730	Lower limb artery perforation	下肢動脈穿孔
10074270	Lymph node haemorrhage	リンパ節出血
10026712	Mallory-Weiss syndrome	マロリー・ワイス症候群
10049941	Mediastinal haematoma	縦隔血腫
10056343	Mediastinal haemorrhage	縦隔出血
10075570	Medical device site bruise	医療機器使用部位内出血
10075577	Medical device site haematoma	医療機器使用部位血腫
10075578	Medical device site haemorrhage	医療機器使用部位出血
10027141	Melaena	メレナ
10049777	Melaena neonatal	新生児メレナ
10052593	Meningorrhagia	髄膜出血
10027295	Menometrorrhagia	過長過多不規則月経

出血事象（続き）

コード	PT（英名）	PT（和名）
10027313	Menorrhagia	月経過多
10071557	Mesenteric haematoma	腸間膜血腫
10060717	Mesenteric haemorrhage	腸間膜出血
10027514	Metrorrhagia	不正子宮出血
10028024	Mouth haemorrhage	口腔内出血
10076048	Mucocutaneous haemorrhage	皮膚粘膜出血
10061298	Mucosal haemorrhage	粘膜出血
10070757	Muscle contusion	筋挫傷
10028309	Muscle haemorrhage	筋肉内出血
10048849	Myocardial haemorrhage	心筋出血
10028604	Myocardial rupture	心筋断裂
10062955	Naevus haemorrhage	母斑出血
10048891	Nail bed bleeding	爪床出血
10075027	Nasal septum haematoma	鼻中隔血腫
10074159	Neonatal gastrointestinal haemorrhage	新生児胃腸出血
10029132	Nephritis haemorrhagic	出血性腎炎
10029418	Nipple exudate bloody	血性乳頭滲出液
10057571	Ocular retrobulbar haemorrhage	眼球後出血
10030172	Oesophageal haemorrhage	食道出血
10077486	Oesophageal intramural haematoma	食道壁内血腫
10030202	Oesophageal ulcer haemorrhage	食道潰瘍出血
10030210	Oesophageal varices haemorrhage	食道静脈瘤出血
10030219	Oesophagitis haemorrhagic	出血性食道炎
10030919	Optic disc haemorrhage	視神経乳頭出血
10030941	Optic nerve sheath haemorrhage	視神経鞘出血
10078170	Oral contusion	口腔挫傷
10074779	Oral mucosa haematoma	口腔粘膜血腫
10051937	Osteorrhagia	骨出血
10033263	Ovarian haematoma	卵巣血腫
10065741	Ovarian haemorrhage	卵巣出血
10056872	Palpable purpura	触知可能紫斑病
10033625	Pancreatic haemorrhage	膵臓出血
10033650	Pancreatitis haemorrhagic	出血性膵炎
10059164	Papillary muscle haemorrhage	乳頭筋出血
10069702	Paranasal sinus haematoma	副鼻腔血腫
10059051	Parathyroid haemorrhage	副甲状腺出血
10051166	Parotid gland haemorrhage	耳下腺出血
10054974	Pelvic haematoma	骨盤血腫
10034248	Pelvic haematoma obstetric	産科的骨盤血腫
10063678	Pelvic haemorrhage	骨盤内出血
10073352	Penile contusion	陰茎挫傷
10070656	Penile haematoma	陰茎血腫
10034305	Penile haemorrhage	陰茎出血
10034344	Peptic ulcer haemorrhage	出血性消化性潰瘍
10034476	Pericardial haemorrhage	心嚢内出血
10034520	Perineal haematoma	会陰血腫
10034544	Periorbital haematoma	眼窩周囲血腫
10071697	Periorbital haemorrhage	眼窩周囲出血
10077341	Periosteal haematoma	骨膜血腫
10072693	Peripartum haemorrhage	分娩前後出血

出血事象（続き）

コード	PT（英名）	PT（和名）
10049450	Perirenal haematoma	腎周囲血腫
10058095	Peritoneal haematoma	腹膜血腫
10034666	Peritoneal haemorrhage	腹膜出血
10076706	Periventricular haemorrhage neonatal	新生児脳室周囲出血
10034754	Petechiae	点状出血
10068121	Pharyngeal haematoma	咽頭血腫
10034827	Pharyngeal haemorrhage	咽頭出血
10049760	Pituitary haemorrhage	下垂体出血
10035121	Placenta praevia haemorrhage	前置胎盤による出血
10064050	Polymenorrhagia	頻発過多月経
10036246	Post abortion haemorrhage	流産後の出血
10073353	Post procedural contusion	処置後挫傷
10063188	Post procedural haematoma	処置後血腫
10066225	Post procedural haematuria	処置後血尿
10051077	Post procedural haemorrhage	処置後出血
10072265	Post transfusion purpura	輸血後紫斑病
10055870	Postmenopausal haemorrhage	閉経後出血
10036417	Postpartum haemorrhage	分娩後出血
10071639	Post-traumatic punctate intraepidermal haemorrhage	外傷後点状表皮内出血
10036608	Premature separation of placenta	胎盤早期剥離
10071229	Procedural haemorrhage	処置による出血
10036778	Proctitis haemorrhagic	出血性直腸炎
10036960	Prostatic haemorrhage	前立腺出血
10037313	Pulmonary alveolar haemorrhage	肺胞出血
10037370	Pulmonary contusion	肺挫傷
10054991	Pulmonary haematoma	肺血腫
10037394	Pulmonary haemorrhage	肺出血
10051101	Puncture site haemorrhage	穿刺部位出血
10037549	Purpura	紫斑
10037556	Purpura fulminans	電撃性紫斑病
10037557	Purpura neonatal	新生児紫斑
10057739	Purpura non-thrombocytopenic	血小板非減少性紫斑病
10037560	Purpura senile	老人性紫斑
10058940	Putamen haemorrhage	被殻出血
10072281	Radiation associated haemorrhage	放射線関連出血
10038063	Rectal haemorrhage	直腸出血
10038081	Rectal ulcer haemorrhage	出血性直腸潰瘍
10075737	Renal artery perforation	腎動脈穿孔
10059846	Renal cyst haemorrhage	腎嚢胞出血
10038459	Renal haematoma	腎血腫
10038460	Renal haemorrhage	腎出血
10038727	Respiratory tract haemorrhage	気道出血
10038728	Respiratory tract haemorrhage neonatal	新生児気道出血
10038867	Retinal haemorrhage	網膜出血
10051447	Retinopathy haemorrhagic	出血性網膜症
10058360	Retroperitoneal haematoma	後腹膜血腫
10038980	Retroperitoneal haemorrhage	後腹膜出血
10054798	Retroplacental haematoma	胎盤後血腫
10039330	Ruptured cerebral aneurysm	破裂性脳動脈瘤

出血事象（続き）

コード	PT（英名）	PT（和名）
10050508	Scleral haemorrhage	強膜出血
10061517	Scrotal haematocoele	陰嚢血瘤
10039749	Scrotal haematoma	陰嚢血腫
10049771	Shock haemorrhagic	出血性ショック
10064265	Skin haemorrhage	皮膚出血
10060712	Skin neoplasm bleeding	皮膚新生物出血
10050377	Skin ulcer haemorrhage	出血性皮膚潰瘍
10052535	Small intestinal haemorrhage	小腸出血
10061550	Small intestinal ulcer haemorrhage	出血性小腸潰瘍
10051297	Soft tissue haemorrhage	軟部組織出血
10065742	Spermatic cord haemorrhage	精索出血
10076051	Spinal cord haematoma	脊髄血腫
10048992	Spinal cord haemorrhage	脊髄出血
10050162	Spinal epidural haematoma	脊髄硬膜外血腫
10049236	Spinal epidural haemorrhage	脊髄硬膜外出血
10073564	Spinal subarachnoid haemorrhage	脊髄くも膜下出血
10050164	Spinal subdural haematoma	脊髄硬膜下血腫
10073563	Spinal subdural haemorrhage	脊髄硬膜下出血
10073533	Spleen contusion	脾臓挫傷
10075738	Splenic artery perforation	脾動脈穿孔
10041646	Splenic haematoma	脾血腫
10041647	Splenic haemorrhage	脾臓出血
10068662	Splenic varices haemorrhage	脾静脈瘤出血
10041663	Splinter haemorrhages	線状出血
10065304	Spontaneous haematoma	特発性血腫
10074557	Spontaneous haemorrhage	特発性出血
10074508	Stoma site haemorrhage	ストーマ部出血
10042132	Stomatitis haemorrhagic	出血性口内炎
10076701	Subarachnoid haematoma	くも膜下血腫
10042316	Subarachnoid haemorrhage	くも膜下出血
10042317	Subarachnoid haemorrhage neonatal	新生児くも膜下出血
10072596	Subchorionic haematoma	絨毛膜下血腫
10071010	Subchorionic haemorrhage	絨毛膜下出血
10075740	Subclavian artery perforation	鎖骨下動脈穿孔
10075743	Subclavian vein perforation	鎖骨下静脈穿孔
10042345	Subcutaneous haematoma	皮下血腫
10042361	Subdural haematoma	硬膜下血腫
10042363	Subdural haematoma evacuation	硬膜下血腫除去
10042364	Subdural haemorrhage	硬膜下出血
10042365	Subdural haemorrhage neonatal	新生児硬膜下出血
10069510	Subgaleal haematoma	帽状腱膜下血腫
10071935	Subretinal haematoma	網膜下血腫
10075741	Superior vena cava perforation	上大静脈穿孔
10051877	Testicular haemorrhage	精巣出血
10058939	Thalamus haemorrhage	視床出血
10043449	Third stage postpartum haemorrhage	分娩第 3 期出血
10062744	Thoracic haemorrhage	胸部出血
10043561	Thrombocytopenic purpura	血小板減少性紫斑病
10043648	Thrombotic thrombocytopenic purpura	血栓性血小板減少性紫斑病
10064224	Thyroid haemorrhage	甲状腺出血