表3.1.3.2.1: 3　死亡及び重篤な有害事象の一覧表（1479-0001試験，第Ib相コホート2）

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Blood and lymphatic system disorders (血液およびリンパ系障害)/														
Anaemia (貧血)	BI 0 mg QD	[redacted]	[redacted]/F	8	10	3	3	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
Cardiac disorders (心臓障害)/														
Myocardial injury (心筋損傷)	REP	[redacted]	[redacted]/M	153			1	Yes	No	No	Nrec	OTHER	NoChg	No
Pericardial effusion (心嚢液貯留)	BI 120 mg QD	[redacted]	[redacted]/M	124	132	9	4	No	No	No	Rcver	LIFE THR/REQ/ PROL HSP	NoChg	Yes
	REP	[redacted]	[redacted]/M	88	97	10	3	No	No	No	Rcver	REQ/PROL HSP	NA	Yes
	BI 120 mg QD	[redacted]	[redacted]/F	30	35	6	3	No	No	No	Seq	REQ/PROL HSP	NoChg	No
	BI 0 mg QD	[redacted]	[redacted]/F	15	22	8	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	[redacted]/F	102	126	25	4	No	No	No	Nrec	REQ/PROL HSP	Withdr	Yes
	REP	[redacted]	[redacted]/F	127	127	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/ PROL HSP	NA	Yes
Pericarditis (心膜炎)	BI 120 mg QD	[redacted]	[redacted]/M	88	89	2	2	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Gastrointestinal disorders (胃腸障害)/														
Diarrhoea (下痢)	BI 0 mg QD	[redacted]	[redacted]/F	22	29	8	3	Yes	No	Yes	Rcver	REQ/PROL HSP	NoChg	Yes
Lower gastrointestinal haemorrhage (下部消化管出血)	BI 0 mg QD	[redacted]	[redacted]/F	8	17	10	3	Yes	No	Yes	Nrec	REQ/PROL HSP	Reduc	Yes
Vomiting (嘔吐)	BI 0 mg QD	[redacted]	[redacted]/F	22	29	8	2	Yes	No	Yes	Rcver	REQ/PROL HSP	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
General disorders and administration site conditions (一般・全身障害および投与部位の状態)/														
Disease progression (疾患進行)	REP	[redacted]	6[redacted]/M	181	181	1	5	No	Yes	No	Fatal	FATAL	NA	No
Hepatobiliary disorders (肝胆道系障害)/														
Drug-induced liver injury (薬物性肝障害)	BI 0 mg QD	[redacted]	5[redacted]/F	42	53	12	3	Yes	No	Yes	Rcver	OTHER	NoChg	Yes
	BI 120 mg QD	[redacted]	8[redacted]/F	43	50	8		Yes	No	Yes	Rcver	OTHER	Reduc	No
Infections and infestations (感染症および寄生虫症)/														
Appendicitis (虫垂炎)	BI 0 mg QD	[redacted]	3[redacted]/M	23	28	6	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	No
Paronychia (爪囲炎)	BI 120 mg QD	[redacted]	6[redacted]/M	89			1	Yes	No	Yes	Nrec	OTHER	Reduc	Yes
Pneumonia (肺炎)	BI 120 mg QD	[redacted]	6[redacted]/M	129	169	41	2	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Injury, poisoning and procedural complications (傷害、中毒および処置合併症)/														
Fall (転倒)	BI 120 mg QD	[redacted]	6[redacted]/M	79	79	1	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	No
Metabolism and nutrition disorders (代謝および栄養障害)/														
Hypoalbuminaemia (低アルブミン血症)	BI 120 mg QD	[redacted]	6[redacted]/M	149	159	11	2	Yes	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Hypokalaemia (低カリウム血症)	BI 120 mg QD	[redacted]	6[redacted]/M	149	153	5	3	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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))/														
Lung adenocarcinoma (肺腺癌)	BI 120 mg QD	[redacted]	5[redacted]/M	127			3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Malignant neoplasm progression (悪性新生物進行)	BI 0 mg QD	[redacted]	7[redacted]/M	43			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Metastases to central nervous system (中枢神経系転移)	BI 120 mg QD	[redacted]	5[redacted]/M	127			3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Nervous system disorders (神経系障害)/														
Brain oedema (脳浮腫)	BI 0 mg QD	[redacted]	5[redacted]/F	136			3	No	Yes	No	Nrec	OTHER	NoChg	Yes
Cognitive disorder (認知障害)	REP	[redacted]	6[redacted]/M	168			3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Seizure (痙攣発作)	BI 120 mg QD	[redacted]	6[redacted]/M	79	79	1	2	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
	BI 0 mg QD	[redacted]	6[redacted]/M	107	107	1	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Renal and urinary disorders (腎および尿路障害)/														
Hydronephrosis (水腎症)	BI 120 mg QD	[redacted]	6[redacted]/F	209			1	No	No	No	Nrec	OTHER	NoChg	No
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/														
Interstitial lung disease (間質性肺疾患)	REP	[redacted]	7[redacted]/F	58	72	15	2	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
Pleural effusion (胸水)	BI 120 mg QD	[redacted]	6[redacted]/M	14	18	5	2	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	6[redacted]/M	18	63	46	1	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	No
	BI 120 mg QD	[redacted]	6[redacted]/M	63	67	5	2	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	6[redacted]/M	67			1	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	No
	BI 120 mg QD	[redacted]	7[redacted]/F	30	35	6	3	No	No	No	Seq	REQ/PROL HSP	NoChg	Yes
	BI 0 mg QD	[redacted]	4[redacted]/F	15	22	8	2	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Pulmonary haemorrhage (肺出血)	BI 120 mg QD	[redacted]	7[redacted]/M	18			2	No	No	No	Nrec	OTHER	NoChg	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Respiratory failure (呼吸不全)	REP	[redacted]	7[redacted]/F	136	136	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Infections and infestations (感染症および寄生虫症)/														
Device related infection (医療機器関連感染)	BI 240 mg QD	[redacted]	7[redacted]/F	89	106	18	2	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Investigations (臨床検査)/														
Platelet count decreased (血小板数減少)	REP	[redacted]	5[redacted]/F	70	73	4	4	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
	REP	[redacted]	5[redacted]/F	74	74	1	3	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
	REP	[redacted]	5[redacted]/F	75			4	Yes	No	Yes	UNK	REQ/PROL HSP	Withdr	Yes
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Metastases to central nervous system (中枢神経系転移)	BI 120 mg QD	[redacted]	5[redacted]/F	125	142	18	1	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Nervous system disorders (神経系障害)/														
Cerebral ischaemia (脳虚血)	BI 240 mg QD	[redacted]	5[redacted]/F	206			1	No	Yes	No	Nrec	OTHER	NoChg	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
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NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved,
Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening,
DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect,
OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.1: 4　死亡及び重篤な有害事象の一覧表（1479-0001試験，第Ib相コホート3）

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 3

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Gastrointestinal disorders（胃腸障害）/														
Diarrhoea（下痢）	BI 0 mg QD	[redacted]	6[redacted]/M	11	12	2	3	Yes	No	Yes	Nrec	REQ/PROL HSP	Reduc	Yes
Nausea（悪心）	REP	[redacted]	7[redacted]/M	62			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	No
Hepatobiliary disorders（肝胆道系障害）/														
Drug-induced liver injury（薬物性肝障害）	BI 120 mg QD	[redacted]	7[redacted]/M	38			3	Yes	No	Yes	Nrec	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	6[redacted]/F	33	66	34	3	Yes	No	Yes	Rcver	REQ/PROL HSP	NoChg	Yes
Infections and infestations（感染症および寄生虫症）/														
Pneumonia（肺炎）	BI 60 mg QD	[redacted]	8[redacted]/F	134	141	8	3	No	Yes	No	Nrec	REQ/PROL HSP	Withdr	Yes
	REP	[redacted]	8[redacted]/F	142	142	1	5	No	Yes	No	Fatal	FATAL	NA	Yes
	BI 0 mg QD	[redacted]	6[redacted]/M	11	21	11	3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Urinary tract infection（尿路感染）	BI 120 mg QD	[redacted]	6[redacted]/F	39	47	9	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Injury, poisoning and procedural complications（傷害，中毒および処置合併症）/														
Femur fracture（大腿骨骨折）	BI 0 mg QD	[redacted]	6[redacted]/M	11			3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Investigations（臨床検査）/														
Alanine aminotransferase increased（アラニンアミノトランスフェラーゼ増加）	BI 120 mg QD	[redacted]	7[redacted]/F	5	103	99	3	Yes	No	No	Rcver	OTHER	Withdr	No
Metabolism and nutrition disorders（代謝および栄養障害）/														
Hypomagnesaemia（低マグネシウム血症）	BI 120 mg QD	[redacted]	5[redacted]/F	1	5	5	2	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 3

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Malignant neoplasm progression (悪性新生物進行)	REP	[redacted]	6[redacted]/F	55	55	1	5	No	Yes	No	Fatal	FATAL	NA	No
Nervous system disorders (神経系障害)/														
Hemiparesis (不全片麻痺)	BI 120 mg QD	[redacted]	6[redacted]/F	39			3	No	No	No	UNK	REQ/PROL HSP	NoChg	Yes
Psychiatric disorders (精神障害)/														
Delirium (譫妄)	BI 60 mg QD	[redacted]	8[redacted]/F	106			2	No	No	No	Nrec	OTHER	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: 3

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Infections and infestations (感染症および寄生虫症)/ Pneumonia (肺炎)	REP	[redacted]	才/M	183			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Vascular disorders (血管障害)/ Subclavian vein thrombosis (鎖骨下静脈血栓症)	BI 240 mg QD	[redacted]	才/F	15	15	1	2	Yes	No	No	Rcver	OTHER	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.1: 5　死亡及び重篤な有害事象の一覧表（1479-0001試験，第Ib相コホート4）

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 4

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
UNCODED	BI 120 mg QD	[redacted]	5[redacted]/F	177	194	18	3	No	No	No	Rcver	REQ/PROL HSP	Withdr	Yes
Cardiac disorders (心臓障害)/ Tachycardia (頻脈)	REP	[redacted]	5[redacted]/F	153	154	2	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	No
Eye disorders (眼障害)/ Optic neuropathy (視神経症)	BI 0 mg QD	[redacted]	5[redacted]/M	148	155	8	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Gastrointestinal disorders (胃腸障害)/ Anal fistula (痔瘻)	BI 120 mg QD	[redacted]	5[redacted]/M	1	2	2	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
General disorders and administration site conditions (一般・全身障害および投与部位の状態)/ Disease progression (疾患進行)	BI 120 mg QD	[redacted]	6[redacted]/M	80	107	28	3	No	No	No	Nrec	LIFE THR/REQ/ PROL HSP	NA	No
	REP	[redacted]	6[redacted]/M	108	108	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/ PROL HSP/OTHER	NA	No
Malaise (倦怠感)	BI 120 mg QD	[redacted]	7[redacted]/F	30			3	Yes	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Pyrexia (発熱)	REP	[redacted]	5[redacted]/F	154			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Hepatobiliary disorders (肝胆道系障害)/ Drug-induced liver injury (薬物性肝障害)	BI 0 mg QD	[redacted]	5[redacted]/M	63	68	6	3	Yes	No	Yes	Rcver	REQ/PROL HSP	NoChg	Yes
Hepatic failure (肝不全)	BI 0 mg QD	[redacted]	5[redacted]/M	63	68	6	3	Yes	No	Yes	Rcver	REQ/PROL HSP	Reduc	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 4

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Infections and infestations (感染症および寄生虫症)/														
Infective exacerbation of chronic obstructive airways disease (感染による慢性閉塞性気道疾患の増悪)	BI 0 mg QD	[redacted]	[redacted]/M	130	134	5	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)/														
Back pain (背部痛)	BI 120 mg QD	[redacted]	[redacted]/M	76			3	No	Yes	No	UNK	REQ/PROL HSP	NoChg	Yes
Nervous system disorders (神経系障害)/														
Seizure (痙攣発作)	REP	[redacted]	[redacted]/M	82	108	27	1	No	No	Yes	Rcver	REQ/PROL HSP	NoChg	No
Psychiatric disorders (精神障害)/														
Confusional state (錯乱状態)	BI 120 mg QD	[redacted]	[redacted]/M	75			3	No	Yes	No	UNK	REQ/PROL HSP	NoChg	Yes
Renal and urinary disorders (腎および尿路障害)/														
Hydronephrosis (水腎症)	BI 0 mg QD	[redacted]	[redacted]/F	15	24	10	2	No	Yes	No	Nrec	OTHER	NoChg	No
	BI 0 mg QD	[redacted]	[redacted]/F	15	39	25	2	No	Yes	No	Rcver	OTHER	NoChg	No
	BI 0 mg QD	[redacted]	[redacted]/F	24	27	4	3	No	Yes	No	Nrec	REQ/PROL HSP/OTHER	NoChg	Yes
	BI 0 mg QD	[redacted]	[redacted]/F	27	39	13	2	No	Yes	No	Rcver	OTHER	NoChg	No
Nephrolithiasis (腎結石症)	BI 0 mg QD	[redacted]	[redacted]/F	15			2	No	Yes	No	Nrec	OTHER	NoChg	Yes
Ureterolithiasis (尿管結石症)	BI 0 mg QD	[redacted]	[redacted]/F	14	24	11	2	No	No	No	Nrec	OTHER	NoChg	No
	BI 0 mg QD	[redacted]	[redacted]/F	24	27	4	3	No	No	No	Nrec	REQ/PROL HSP/OTHER	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

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Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 4

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Ureterolithiasis (尿管結石症)	BI 0 mg QD	[redacted]	[redacted]/F	27	39	13	2	No	No	No	Rcver	OTHER	NoChg	No
Urinary retention (尿閉)	BI 120 mg QD	[redacted]	[redacted]/F	41	45	5	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/														
Aspiration (誤嚥)	BI 120 mg QD	[redacted]	[redacted]/F	116	116	1	5	No	Yes	No	Fatal	FATAL	NA	No
Bronchopneumopathy (気管支肺症)	BI 60 mg QD	[redacted]	[redacted]/F	106	111	6	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Chronic obstructive pulmonary disease (慢性閉塞性肺疾患)	BI 120 mg QD	[redacted]	[redacted]/M	138	145	8	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Dyspnoea (呼吸困難)	REP	[redacted]	[redacted]/F	153	154	2	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Pleural effusion (胸水)	BI 60 mg QD	[redacted]	[redacted]/F	42	102	61	3	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes

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DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect,
OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.1: 6　死亡及び重篤な有害事象の一覧表（1479-0001試験，第Ib相コホート5）

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Gastrointestinal disorders（胃腸障害）/														
Dysphagia（嚥下障害）	BI 120 mg QD	[redacted]	[redacted]/M	187	202	16	2	No	No	No	Rcver	REQ/PROL HSP	NoChg	Yes
Gastrointestinal disorder（胃腸障害）	REP	[redacted]	[redacted]/M	85			3	No	Yes	No	UNK	REQ/PROL HSP	NoChg	Yes
General disorders and administration site conditions（一般・全身障害および投与部位の状態）/														
Chest pain（胸痛）	BI 120 mg QD	[redacted]	[redacted]/M	3	5	3	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
Disease progression（疾患進行）	REP	[redacted]	[redacted]/M	87	87	1	5	No	Yes	No	Fatal	FATAL	NA	Yes
	REP	[redacted]	[redacted]/M	202	202	1	5	No	No	No	Fatal	FATAL/REQ/PROL HSP	NA	No
	REP	[redacted]	[redacted]/M	206	206	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	[redacted]/F	95	96	2	3	No	No	No	Nrec	REQ/PROL HSP	Withdr	No
	REP	[redacted]	[redacted]/F	97	97	1	5	No	Yes	No	Fatal	FATAL/REQ/PROL HSP	NA	No
Infections and infestations（感染症および寄生虫症）/														
COVID-19（ＣＯＶＩＤ－１９）	BI 120 mg QD	[redacted]	[redacted]/F	132			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Pneumonia（肺炎）	REP	[redacted]	[redacted]/M	82			3	No	Yes	No	UNK	REQ/PROL HSP	NA	Yes
Neoplasms benign, malignant and unspecified (incl cysts and polyps)（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））/														
Lung neoplasm malignant（肺の悪性新生物）	BI 120 mg QD	[redacted]	[redacted]/M	31	42	12	4	No	Yes	No	Nrec	LIFE THR/REQ/PROL HSP	NoChg	Yes
	REP	[redacted]	[redacted]/M	42	42	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/PROL HSP	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasm progression (新生物進行)	REP	[redacted]	5[redacted]/M	82	91	10	3	No	Yes	No	Nrec	REQ/PROL HSP	NA	Yes
	REP	[redacted]	5[redacted]/M	92	92	1	5	No	Yes	No	Fatal	FATAL	NA	Yes
Nervous system disorders (神経系障害)/														
Epilepsy (てんかん)	BI 120 mg QD	[redacted]	3[redacted]/F	7	8	2	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	3[redacted]/F	74	74	1	3	No	Yes	No	Rcver	OTHER	NoChg	No
	BI 120 mg QD	[redacted]	3[redacted]/F	90	91	2	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	Yes
	REP	[redacted]	3[redacted]/F	93			3	No	Yes	No	UNK	REQ/PROL HSP	NA	Yes
Hydrocephalus (水頭症)	BI 120 mg QD	[redacted]	4[redacted]/M	168	178	11	3	No	Yes	No	Seq	REQ/PROL HSP	NoChg	Yes
Ischaemic stroke (虚血性脳卒中)	BI 120 mg QD	[redacted]	6[redacted]/F	37	39	3	3	No	Yes	No	Rcver	REQ/PROL HSP	NoChg	No
Seizure (痙攣発作)	BI 120 mg QD	[redacted]	4[redacted]/M	191	194	4	3	No	Yes	No	Rcver	REQ/PROL HSP/OTHER	NoChg	Yes
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/														
Dyspnoea (呼吸困難)	REP	[redacted]	6[redacted]/F	274			3	No	No	No	Nrec	REQ/PROL HSP	NA	No
	BI 120 mg QD	[redacted]	6[redacted]/M	187	199	13	2	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	6[redacted]/M	200	202	3	3	No	No	No	Rcver	REQ/PROL HSP	Withdr	Yes
Haemoptysis (喀血)	BI 120 mg QD	[redacted]	6[redacted]/M	195	199	5	1	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
	BI 120 mg QD	[redacted]	6[redacted]/M	200	202	3	3	No	No	No	Rcver	REQ/PROL HSP	Withdr	Yes
Pleural effusion (胸水)	BI 120 mg QD	[redacted]	4[redacted]/M	126			2	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
	REP	[redacted]	5[redacted]/M	82			3	No	Yes	No	UNK	REQ/PROL HSP	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
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NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Pneumothorax (気胸)	BI 120 mg QD	[redacted]	[redacted]/M	135			3	No	No	No	Nrec	REQ/PROL HSP	NoChg	Yes
Pulmonary embolism (肺塞栓症)	BI 120 mg QD	[redacted]	[redacted]/M	167			2	No	No	No	Nrec	OTHER	NoChg	Yes
	BI 120 mg QD	[redacted]	[redacted]/M	43	84	42	2	No	Yes	No	Rcver	OTHER	NoChg	Yes
	BI 120 mg QD		[redacted]/F	89	105	17	1	No	No	No	Rcver	OTHER	NoChg	Yes
	BI 120 mg QD		[redacted]/F	84			2	No	No	No	Nrec	OTHER	NoChg	Yes
Pulmonary oedema (肺水腫)	BI 120 mg QD		[redacted]/M				3	No	Yes	No	UNK	OTHER	NoChg	Yes

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NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Musculoskeletal and connective tissue disorders (筋骨格系および結合組織障害)/														
Back pain (背部痛)	REP	[redacted]	6[redacted]/M	123			3	No	Yes	No	Nrec	REQ/PROL HSP	NoChg	Yes
Nervous system disorders (神経系障害)/														
Depressed level of consciousness (意識レベルの低下)	REP	[redacted]	5[redacted]/F	88	90	3	3	No	Yes	Yes	Nrec	LIFE THR/REQ/ PROL HSP	Withdr	Yes
	REP	[redacted]	5[redacted]/F	91	91	1	5	No	Yes	Yes	Fatal	FATAL/LIFE THR/REQ/ PROL HSP	NA	Yes
Renal and urinary disorders (腎および尿路障害)/														
Hydronephrosis (水腎症)	BI 240 mg QD	[redacted]	6[redacted]/F	118			3	No	No	No	Nrec	OTHER	NoChg	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.1: 7　死亡及び重篤な有害事象の一覧表（1479-0001試験，第Ib相コホート6）

Listing J.3.7.4: 2 Patients with serious adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 6

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
UNCODED	BI 120 mg QD	[redacted]	4[redacted]/F	2			4	No	No	No	Nrec	REQ/PROL HSP	NoChg	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved,
Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening,
DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect,
OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 1　死亡に至った有害事象の一覧表（1479-0001試験，第Ia相）

Listing J.3.7.4: 8　Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 60 mg QD, Study: 1479.1, Cohort: QD Escalation

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Lung neoplasm malignant (肺の悪性新生物)	REP	[redacted]	3[redacted]/M	112	112	1	5	No	Yes	No	Fatal	FATAL	NA	No
Nervous system disorders (神経系障害)/														
Hypoxic-ischaemic encephalopathy (低酸素性虚血性脳症)	REP	[redacted]	4[redacted]/M	232	232	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: QD Escalation

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Lung neoplasm malignant (肺の悪性新生物)	REP	[redacted]	才/F	523	523	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: QD Escalation

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Lung neoplasm malignant (肺の悪性新生物)	REP	[redacted]	3[redacted]/F	299	299	1	5	No	Yes	No	Fatal	FATAL	NA	No
Malignant neoplasm progression (悪性新生物進行)	REP	[redacted]	7[redacted]/M	126	126	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	5[redacted]/F	96	96	1	5	No	Yes	No	Fatal	FATAL	NA	No
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/														
Acute respiratory failure (急性呼吸不全)	REP	[redacted]	6[redacted]/M	42	42	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI Total BID, Study: 1479.1, Cohort: BID Escalation

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps)（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））/														
Malignant neoplasm progression（悪性新生物進行）	REP	[redacted]	6[redacted]/F	85	85	1	5	No	Yes	No	Fatal	FATAL/REQ/PROL HSP	NA	No
	REP	[redacted]	7[redacted]/M	143	143	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	5[redacted]/F	39	39	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 2　死亡に至った有害事象の一覧表（1479-0001試験，第Ib相コホート1）

Listing J.3.7.4: 8　Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 1

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps)（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））/														
Malignant neoplasm progression（悪性新生物進行）	REP	[redacted]	5[redacted]/F	96	96	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	8[redacted]/M	148	148	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	5[redacted]/F	220	220	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	4[redacted]/F	426	426	1	5	No	Yes	No	Fatal	FATAL	NA	No
Respiratory, thoracic and mediastinal disorders（呼吸器、胸郭および縦隔障害）/														
Acute respiratory failure（急性呼吸不全）	REP	[redacted]	3[redacted]/M	50	50	1	5	No	Yes	Yes	Fatal	FATAL	NA	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: 1

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Neoplasms benign, malignant and unspecified (incl cysts and polyps)（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））/														
Lung neoplasm malignant（肺の悪性新生物）	REP	[redacted]	4[redacted]/M	239	239	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	4[redacted]/F	215	215	1	5	No	Yes	No	Fatal	FATAL	NA	No
Malignant neoplasm progression（悪性新生物進行）	REP	[redacted]	6[redacted]/F	137	137	1	5	No	Yes	No	Fatal	FATAL/REQ/PROL HSP	NA	No
	REP	[redacted]	7[redacted]/M	357	357	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	6[redacted]/M	259	259	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 3　死亡に至った有害事象の一覧表（1479-0001試験，第Ib相コホート2）

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 2

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Cardiac disorders (心臓障害)/ Pericardial effusion (心嚢液貯留)	REP	[redacted]	4[redacted]/F	127	127	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/PROL HSP	NA	Yes
General disorders and administration site conditions (一般・全身障害および投与部位の状態)/ Disease progression (疾患進行)	REP	[redacted]	6[redacted]/M	181	181	1	5	No	Yes	No	Fatal	FATAL	NA	No
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/ Respiratory failure (呼吸不全)	REP	[redacted]	7[redacted]/F	136	136	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 4　死亡に至った有害事象の一覧表（1479-0001試験，第Ib相コホート3）

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 3

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
Infections and infestations (感染症および寄生虫症)/														
Pneumonia (肺炎)	REP	[redacted]	8[redacted]/F	142	142	1	5	No	Yes	No	Fatal	FATAL	NA	Yes
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (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）)/														
Malignant neoplasm progression (悪性新生物進行)	REP	[redacted]	6[redacted]/F	55	55	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 5　死亡に至った有害事象の一覧表（1479-0001試験，第Ib相コホート4）

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 4

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura-tion	CTCAE grade	Related to zonger-tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out-come	Serious	Action taken with zonger-tinib	Therapy for event
General disorders and administration site conditions (一般・全身障害および投与部位の状態)/														
Disease progression (疾患進行)	REP	[redacted]	6[redacted]/M	108	108	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/PROL HSP/OTHER	NA	No
Respiratory, thoracic and mediastinal disorders (呼吸器、胸郭および縦隔障害)/														
Aspiration (誤嚥)	BI 120 mg QD	[redacted]	6[redacted]/F	116	116	1	5	No	Yes	No	Fatal	FATAL	NA	No

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

表3.1.3.2.2: 6　死亡に至った有害事象の一覧表（1479-0001試験，第Ib相コホート5）

Listing J.3.7.4: 8　Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 120 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
General disorders and administration site conditions（一般・全身障害および投与部位の状態）/														
Disease progression（疾患進行）	REP	[redacted]	5[redacted]/M	87	87	1	5	No	Yes	No	Fatal	FATAL	NA	Yes
	REP	[redacted]	6[redacted]/M	202	202	1	5	No	No	No	Fatal	FATAL/REQ/PROL HSP	NA	No
	REP	[redacted]	4[redacted]/M	206	206	1	5	No	Yes	No	Fatal	FATAL	NA	No
	REP	[redacted]	6[redacted]/F	97	97	1	5	No	Yes	No	Fatal	FATAL/REQ/PROL HSP	NA	No
Neoplasms benign, malignant and unspecified (incl cysts and polyps)（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））/														
Lung neoplasm malignant（肺の悪性新生物）	REP	[redacted]	4[redacted]/M	42	42	1	5	No	Yes	No	Fatal	FATAL/LIFE THR/REQ/PROL HSP	NA	No
Neoplasm progression（新生物進行）	REP	[redacted]	5[redacted]/M	92	92	1	5	No	Yes	No	Fatal	FATAL	NA	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0

Listing J.3.7.4: 8 Patient with fatal adverse events by treatment, primary system organ class and preferred term for SAF-3J - on-treatment period

Treatment: BI 240 mg QD, Study: 1479.1, Cohort: 5

System organ class/ Preferred term	Actual TRT at onset of AE	Patient	Age/ Sex	Start day[1]	Stop day[1]	Dura- tion	CTCAE grade	Related to zonger- tinib	Underlying malignancy ex. cause	AE of spec. inter.	Out- come	Serious	Action taken with zonger- tinib	Therapy for event
Nervous system disorders (神経系障害)/ Depressed level of consciousness (意識レベルの低下)	REP	[redacted]	5[redacted]/F	91	91	1	5	No	Yes	Yes	Fatal	FATAL/LIFE THR/REQ/PROL HSP	NA	Yes

AE events may be intermittent, i.e. not always continuing from start to stop day.
[1] = Related to start of treatment, [a] = partial or missing date imputed,
NoChg = Dose not changed, Reduc = Dose reduced, Incr = Dose increased, Withdr = Drug withdrawn, NA = Not applicable, Rcver = Recovered/resolved, Nrec = Not recovered/not resolved, Seq = Recovered/resolved with sequelae, Unk = Unknown, FATAL = Results in Death, LIFE THR = Is Life Threatening, DISABL = Persist or signif disability/incapacity, REQ/PROL HSP = Requires or prolongs hospitalization, CONG AB = Congenital anomaly or birth defect, OTHER = Other medically important serious event.
MedDRA version used for reporting: 27.0