付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0001, Subject ID=000284, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=										
000284	Treatment Cycle 10	253	Malignant melanoma	1 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=000286, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=64										
000286	Safety Follow-up	70	Confusional state	1.43 Weeks	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=000422, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=1										
000422	Extended Safety Follow-up	39	Septic shock	4 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0010, Subject ID=000250, Gender=F, Race=White, Age=25 Years, Rel Day of Study Medication Discontinuance†=337										
000250	Treatment Cycle 13	253	Spinal cord compression	2.43 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000265, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=211										
000265	Treatment Cycle 8	170	Pneumonitis	1.86 Weeks	Severe	3	Y	Y	Interrupted	Resolved
	Safety Follow-up	229	Pneumonitis	5.16 Months	Moderate	2	Y	Y	Interrupted	Resolved
	Extended Safety Follow-up	294	Pneumonia	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000295, Gender=M, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=64										
000295	Treatment Cycle 3	48	Pneumonia	1.29 Weeks	Severe	3	Y	N		Resolved
		48	Sepsis	1.29 Weeks	Severe	3	Y	N		Resolved

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0010, Subject ID=000295, Gender=M, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=64										
000295	Safety Follow-up	66	Dyspnoea	2.57 Weeks	Severe	3	Y	N		Resolved
		66	Failure to thrive	2.57 Weeks	Severe	3	Y	N		Resolved
		66	Generalised oedema	2.57 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000340, Gender=F, Race=Black Or African American, Age=51 Years, Rel Day of Study Medication Discontinuance†=129										
000340	Extended Safety Follow-up	169	Ascites	1 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000341, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=										
000341	Treatment Cycle 2	43	Basal cell carcinoma	3.14 Weeks	Mild	1	Y	N		Resolved
		43	Basal cell carcinoma	4.29 Weeks	Mild	1	Y	N		Resolved
		43	Basal cell carcinoma	1.68 Months	Mild	1	Y	N		Resolved
		43	Basal cell carcinoma	5.36 Months	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000363, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=400										
000363	Treatment Cycle 17	374	Basal cell carcinoma	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000371, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=317										
000371	Safety Follow-up	325	Dyspnoea	3 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000289, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=129										

C Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0011, Subject ID=000289, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=129										
000289	Safety Follow-up	148	Metastases to central nervous system	5 Days	Severe	3	Y	N	Interrupted	Resolved
	Extended Safety Follow-up	191	Constipation	6 Days	Moderate	2	Y	N		Resolved
		196	Pleural effusion	2 Days	Moderate	2	Y	N		Resolved
		211	Pleural effusion	4 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000291, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=44										
000291	Safety Follow-up	52	Hypophysitis	6 Days	Severe	4	Y	Y	Interrupted	Resolved
	Extended Safety Follow-up	131	Urinary tract infection	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000307, Gender=M, Race=White, Age=88 Years, Rel Day of Study Medication Discontinuance†=										
000307	Treatment Cycle 7	154	Diabetes mellitus	1 Days	Severe	4	Y	N		Resolved
		154	Pneumonia	6 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000315, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=										
000315	Treatment Cycle 10	202	Small intestinal obstruction	4 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 17	354	Small intestinal obstruction	5 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 18	369	Small intestinal obstruction	6 Days	Severe	3	Y	N	Interrupted	Resolved

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0012, Subject ID=000259, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=190										
000259	Safety Follow-up	197	Partial seizures	Continuing	Mild	1	Y	Y	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000389, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=22										
000389	Safety Follow-up	40	Hyperthyroidism	6.08 Months	Moderate	2	Y	Y	Discontinued	Resolved
		40	Hypophysitis	3.32 Months	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000404, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=63										
000404	Treatment Cycle 1	1	Atrial fibrillation	1 Weeks	Severe	3	Y	N		Resolved
		5	Atrial flutter	3 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	68	Haemorrhage subcutaneous	1 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000261, Gender=M, Race=White, Age=84 Years, Rel Day of Study Medication Discontinuance†=65										
000261	Treatment Cycle 2	30	Squamous cell carcinoma	1.81 Months	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000310, Gender=F, Race=White, Age=29 Years, Rel Day of Study Medication Discontinuance†=20										
000310	Safety Follow-up	37	Non-cardiac chest pain	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000336, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1										
000336	Safety Follow-up	22	Autoimmune hepatitis	1.08 Months	Severe	4	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000376, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=108										

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0015, Subject ID=000376, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=108										
000376	Treatment Cycle 2	35	Haemorrhage intracranial	2 Days	Severe	4	Y	N		Resolved
	Treatment Cycle 4	80	Dehydration	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=000313, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=65										
000313	Extended Safety Follow-up	129	Dyspnoea	1.43 Weeks	Moderate	2	Y	N	Discontinued	Resolved
		129	Hypoxia	6 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=000326, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=22										
000326	Safety Follow-up	23	Encephalopathy	3 Days	Severe	3	Y	Y		Resolved
		43	Tumour pain	3.57 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=000362, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=20										
000362	Treatment Cycle 1	15	Tumour pain	5 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	33	Dehydration	1 Weeks	Severe	3	Y	N		Resolved
		37	Pneumonia	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000258, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=85										
000258	Extended Safety Follow-up	143	Malignant melanoma	2 Days	Moderate	2	Y	N		Resolved

Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0019, Subject ID=000328, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=442										
000328	Treatment Cycle 4	65	Upper respiratory tract infection	1.29 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 12	251	Hyponatraemia	4.14 Weeks	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000407, Gender=F, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=217										
000407	Treatment Cycle 5	97	Wound infection	1.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000290, Gender=F, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=										
000290	Treatment Cycle 14	321	Musculoskeletal pain	2.14 Weeks	Severe	3	Y	N		Resolved
		321	Pain in extremity	2.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000322, Gender=M, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†=										
000322	Treatment Cycle 1	13	Pleural effusion	6 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000366, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=45										
000366	Treatment Cycle 1	11	Dyspnoea	1.43 Weeks	Moderate	2	Y	N		Resolved
	Safety Follow-up	57	Dyspnoea	3.71 Weeks	Moderate	2	Y	N		Resolved
		57	Lung infection	3.71 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000369, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=										
000369	Treatment Cycle 3	45	Metastatic pain	Continuing	Moderate	2	Y	N		Not Resolved
	Treatment Cycle 11	211	Basal cell carcinoma	Continuing	Mild	1	Y	N	N/A	Not Resolved

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0001, Subject ID=000364, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=										
000364	Treatment Cycle 15	316	Cholecystitis	2 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0002, Subject ID=000395, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=64										
000395	Safety Follow-up	76	Pancreatitis	Continuing	Severe	3	Y	Y	Discontinued	Not Resolved
	Extended Safety Follow-up	102	Hyperglycaemia	Continuing	Severe	3	Y	Y	N/A	Not Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000267, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=										
000267	Treatment Cycle 25	524	Asthenia	Continuing	Severe	3	Y	Y	Interrupted	Not Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000332, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=1										
000332	Safety Follow-up	20	Failure to thrive	1.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000358, Gender=F, Race=White, Age=41 Years, Rel Day of Study Medication Discontinuance†=										
000358	Treatment Cycle 13	327	Impaired healing	1 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 16	392	Hip fracture	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000361, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=22										
000361	Safety Follow-up	23	Cardiac failure congestive	1 Weeks	Severe	3	Y	N		Resolved
		23	Renal failure acute	1 Weeks	Severe	3	Y	N		Resolved

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0010, Subject ID=000374, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=64										
000374	Safety Follow-up	85	Bilirubin conjugated increased	Continuing	Severe	4	Y	N	Interrupted	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000390, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=104										
000390	Treatment Cycle 1	16	Diarrhoea	6 Days	Severe	3	Y	N		Resolved
		18	Humerus fracture	5 Days	Severe	3	Y	N		Resolved
		34	Humerus fracture	3 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 2	86	Embolism	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000413, Gender=M, Race=White, Age=87 Years, Rel Day of Study Medication Discontinuance†=										
000413	Treatment Cycle 13	360	Adrenal insufficiency	4 Days	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000305, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=										
000305	Treatment Cycle 21	492	Squamous cell carcinoma	1.45 Months	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000386, Gender=F, Race=White, Age=30 Years, Rel Day of Study Medication Discontinuance†=1										
000386	Safety Follow-up	10	Metastases to meninges	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=000423, Gender=M, Race=White, Age=86 Years, Rel Day of Study Medication Discontinuance†=										
000423	Treatment Cycle 8	154	Abdominal pain	4.29 Weeks	Mild	1	Y	N		Resolved
		154	Renal failure	5 Days	Severe	3	Y	N	N/A	Resolved
		154	Urinary tract infection	1.86 Weeks	Moderate	2	Y	N		Resolved

C Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0013, Subject ID=000275, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=22										
000275	Treatment Cycle 1	1	Electrocardiogram change	4 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	42	Cellulitis	1.29 Weeks	Severe	3	Y	N		Resolved
		42	Pneumonia	1.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000329, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=106										
000329	Treatment Cycle 4	77	Dyspnoea	2 Days	Severe	3	Y	N		Resolved
		77	Muscular weakness	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000349, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=										
000349	Treatment Cycle 6	121	Cellulitis	Continuing	Severe	3	Y	N		Not Resolved
	Treatment Cycle 20	412	Intestinal obstruction	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000355, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=113										
000355	Treatment Cycle 2	37	Lethargy	5 Days	Severe	3	Y	N		Resolved
		37	Pain	5 Days	Severe	3	Y	N	Discontinued	Resolved
	Treatment Cycle 4	99	Dizziness	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000360, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=1										
000360	Safety Follow-up	7	Hypoglycaemia	1.29 Weeks	Severe	3	Y	N	Discontinued	Resolved
		7	Hyponatraemia	1.29 Weeks	Severe	3	Y	N		Resolved

Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0015, Subject ID=000398, Gender=M, Race=Multiracial, Age=60 Years, Rel Day of Study Medication Discontinuance†=										
000398	Treatment Cycle 14	281	Adenocarcinoma	2.17 Months	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000406, Gender=M, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=419										
000406	Treatment Cycle 8	155	Sepsis	1.14 Weeks	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=000300, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=65										
000300	Treatment Cycle 1	9	Constipation	1.29 Weeks	Severe	3	Y	N		Resolved
		9	Dehydration	1.29 Weeks	Severe	3	Y	N		Resolved
		9	Nausea	1.29 Weeks	Severe	3	Y	N		Resolved
		9	Pain	1.29 Weeks	Severe	3	Y	N		Resolved
		9	Renal failure acute	1.29 Weeks	Mild	1	Y	N		Resolved
	Treatment Cycle 2	34	Dyspnoea	3 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	77	Abdominal pain	1.43 Weeks	Moderate	2	Y	N		Resolved
		77	Constipation	1.43 Weeks	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000262, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=231										
000262	Treatment Cycle 8	161	Abdominal pain	2 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000264, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=										
000264	Treatment Cycle 18	367	Abdominal pain	3 Days	Moderate	2	Y	N		Resolved
		367	Constipation	3 Days	Moderate	2	Y	N		Resolved

C Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0019, Subject ID=000264, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=										
000264	Treatment Cycle 18	375	Diverticulitis	1.43 Weeks	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000350, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=156										
000350	Treatment Cycle 3	62	Tumour pain	4 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=000367, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=168										
000367	Treatment Cycle 4	64	Skin infection	2.86 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000372, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=85										
000372	Treatment Cycle 2	34	Tumour haemorrhage	4 Days	Moderate	2	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000399, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43										
000399	Safety Follow-up	49	Ascites	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000400, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=										
000400	Treatment Cycle 18	386	Type 1 diabetes mellitus	Continuing	Moderate	2	Y	Y		Not Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=000427, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=										
000427	Treatment Cycle 8	158	Squamous cell carcinoma	1 Days	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000271, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=										

C Confidential

付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0021, Subject ID=000271, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=										
000271	Treatment Cycle 6	122	Pleural effusion	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000323, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=										
000323	Treatment Cycle 19	400	Synovial cyst	5 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000357, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=64										
000357	Treatment Cycle 1	11	Anaemia	3 Days	Severe	3	Y	N		Resolved
		11	Tumour haemorrhage	3 Days	Moderate	2	Y	N		Resolved
	Treatment Cycle 2	33	Tumour haemorrhage	2 Days	Moderate	2	Y	N		Resolved
	Treatment Cycle 3	47	Anaemia	2 Days	Severe	3	Y	N		Resolved
		47	Haemorrhage	1 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	65	Tumour haemorrhage	6 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000378, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=42										
000378	Treatment Cycle 2	22	Visual acuity reduced	2 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000392, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=106										

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付録 2.7.4-21 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B2（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0023, Subject ID=000392, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=106										
000392	Treatment Cycle 5	92	Constipation	5 Days	Severe	3	Y	N		Resolved

†Relative Day of Study Medication Discontinuance is defined as the day of the last recorded dose of study medication for the patient relative to the start of study medication.

Action Taken: None = DOSE NOT CHANGED, Reduced = DOSE REDUCED, Interrupted = DRUG INTERRUPTED, Discontinued = DRUG WITHDRAWN, Increased = DOSE INCREASED, N/A = NOT APPLICABLE.

Outcome: Resolved = RECOVERED/RESOLVED, Resolving = RECOVERING/RESOLVING, Sequelae = RECOVERED/RESOLVED WITH SEQUELAE, Not resolved = NOT RECOVERED/NOT RESOLVED.

Related: Investigator-assessed relationship of the adverse event to study medication.

Grades are based on NCI CTCAE version 4.0.

MedDRA preferred terms 'Malignant neoplasm progression' not related to the drug is excluded.

(Database Cutoff Date [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0008, Subject ID=000539, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=64										
000539	Treatment Cycle 1	13	Atelectasis	5 Days	Moderate	2	Y	N		Resolved
		13	Pericardial effusion	5 Days	Moderate	2	Y	N		Resolved
		13	Pleural effusion	5 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000457, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=43										
000457	Treatment Cycle 2	26	Hyperuricaemia	Continuing	Severe	4	Y	N	Interrupted	Not Resolved
	Safety Follow-up	48	Confusional state	1 Weeks	Severe	3	Y	N		Resolved
		48	Nausea	1 Weeks	Severe	3	Y	Y		Resolved
		48	Vomiting	1 Weeks	Severe	3	Y	Y		Resolved
		66	Asthenia	5 Days	Severe	3	Y	N		Resolved
		66	Confusional state	Continuing	Severe	4	Y	N		Not Resolved
		66	Nausea	5 Days	Severe	3	Y	Y		Resolved
		66	Vomiting	5 Days	Severe	3	Y	Y		Resolved
		71	Cardiac failure congestive	1.71 Weeks	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000471, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=22										
000471	Safety Follow-up	25	Gastritis	1.14 Weeks	Severe	3	Y	N		Resolved
		25	Oesophagitis	1.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000503, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=197										
000503	Treatment Cycle 4	70	Colitis	2.6 Months	Moderate	2	Y	Y	Interrupted	Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧
001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0011, Subject ID=000503, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=197										
000503	Treatment Cycle 6	127	Hyperglycaemia	1 Weeks	Severe	4	Y	N		Resolved
	Safety Follow-up	211	Colitis	1.77 Months	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000520, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=44										
000520	Treatment Cycle 2	26	Pneumonia	2.29 Weeks	Moderate	2	Y	N		Resolved
		40	Chills	Continuing	Mild	1	Y	N		Not Resolved
		40	Malaise	Continuing	Mild	1	Y	N		Not Resolved
		40	Pyrexia	Continuing	Mild	1	Y	N		Not Resolved
	Safety Follow-up	54	Abdominal pain	Continuing	Severe	3	Y	N		Not Resolved
		54	Dizziness	Continuing	Moderate	2	Y	N		Not Resolved
		54	Dyspnoea	Continuing	Severe	3	Y	Y		Not Resolved
		54	Pneumonia	Continuing	Severe	3	Y	N		Not Resolved
		58	Cerebrovascular accident	1.86 Weeks	Moderate	2	Y	N	Discontinued	Resolved
		69	Thrombocytopenia	Continuing	Severe	4	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000453, Gender=M, Race=White, Age=35 Years, Rel Day of Study Medication Discontinuance†=82										
000453	Safety Follow-up	89	Diarrhoea	2.43 Weeks	Severe	3	Y	N		Resolved
		89	Vomiting	2.43 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=000469, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=239										
000469	Safety Follow-up	243	Fatigue	2.57 Weeks	Severe	3	Y	Y		Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧
001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0020, Subject ID=000501, Gender=M, Race=Asian, Age=59 Years, Rel Day of Study Medication Discontinuance†=1										
000501	Extended Safety Follow-up	37	Bile duct obstruction	1.57 Weeks	Severe	3	Y	N	Discontinued	Resolved
		44	Cardiac failure congestive	4 Days	Severe	4	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000483, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=85										
000483	Treatment Cycle 4	71	Intestinal obstruction	5 Days	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000493, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=190										
000493	Safety Follow-up	208	Insulin resistant diabetes	1.08 Months	Severe	3	Y	Y	Discontinued	Resolved
		208	Peripheral ischaemia	1.43 Weeks	Severe	4	Y	Y		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000496, Gender=M, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=526										
000496	Treatment Cycle 1	3	Pericarditis	1.57 Weeks	Severe	3	Y	Y		Resolved
		7	Pericardial effusion	1 Days	Severe	3	Y	Y		Resolved
	Treatment Cycle 2	34	Pleural effusion	1.43 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000528, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=										
000528	Treatment Cycle 3	48	Erysipelas	1.71 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 4	70	Tumour haemorrhage	1.43 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 18	367	Pyrexia	6 Days	Mild	1	Y	N	Interrupted	Resolved
		367	Rash maculo-papular	3 Days	Moderate	2	Y	N	Interrupted	Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W										
Trial Number=3475-001, Site Number=0021, Subject ID=000538, Gender=F, Race=White, Age=36 Years, Rel Day of Study Medication Discontinuance†=64										
000538	Treatment Cycle 1	2	Spinal pain	2.46 Months	Moderate	2	Y	N		Resolved
Trial Number=3475-001, Site Number=0024, Subject ID=000459, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=246										
000459	Treatment Cycle 1	3	Bronchial obstruction	1.71 Weeks	Severe	3	Y	N		Resolved
		3	Lung consolidation	1.71 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 5	90	Neuropathy peripheral	2 Days	Moderate	2	Y	N		Resolved
		113	Catheter site infection	1.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 8	188	Dehydration	2 Days	Severe	3	Y	Y	Interrupted	Resolved
		188	Diarrhoea	2 Days	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0024, Subject ID=000527, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=65										
000527	Treatment Cycle 3	60	Back pain	1.84 Months	Severe	3	Y	N		Resolved
		60	Pain in extremity	1.84 Months	Severe	3	Y	N		Resolved
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0003, Subject ID=000516, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=22										
000516	Safety Follow-up	34	Hyponatraemia	Continuing	Mild	1	Y	N		Not Resolved
		34	Leukocytosis	Continuing	Mild	1	Y	N		Not Resolved
		34	Tachycardia	Continuing	Mild	1	Y	N		Not Resolved
		34	Urinary tract infection	Continuing	Severe	3	Y	N		Not Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0008, Subject ID=000515, Gender=F, Race=Asian, Age=36 Years, Rel Day of Study Medication Discontinuance†=65										
000515	Treatment Cycle 2	39	Hydronephrosis	4 Days	Moderate	2	Y	N		Resolved
		39	Renal failure acute	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000452, Gender=F, Race=White, Age=33 Years, Rel Day of Study Medication Discontinuance†=233										
000452	Treatment Cycle 6	117	Rash generalised	4 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000479, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=526										
000479	Treatment Cycle 8	168	Pulmonary embolism	1.58 Months	Severe	3	Y	N		Resolved
		168	Vena cava thrombosis	1.64 Months	Severe	3	Y	N		Resolved
	Treatment Cycle 10	214	Bronchitis	1.14 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 14	303	Vena cava thrombosis	1.86 Weeks	Severe	4	Y	N		Resolved
	Treatment Cycle 17	373	Atrial thrombosis	1.28 Months	Severe	4	Y	N	Interrupted	Resolved
	Treatment Cycle 21	502	Pulmonary embolism	5 Days	Severe	3	Y	N	Interrupted	Resolved
	Safety Follow-up	547	Haemoptysis	4 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=000499, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=190										
000499	Extended Safety Follow-up	256	Hypoglycaemia	1 Days	Severe	3	Y	N		Resolved
		257	Pneumonia	2.86 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000511, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=64										

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0011, Subject ID=000511, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=64										
000511	Extended Safety Follow-up	109	Colitis	5 Days	Severe	3	Y	Y		Resolved
		109	Pyrexia	5 Days	Moderate	2	Y	Y		Resolved
		119	Embolism	1 Weeks	Severe	4	Y	N		Resolved
		119	Lung infection	1 Weeks	Severe	3	Y	N		Resolved
		136	Femoral neck fracture	6 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000513, Gender=M, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=64										
000513	Safety Follow-up	85	Musculoskeletal chest pain	3.14 Weeks	Severe	3	Y	N		Resolved
	Extended Safety Follow-up	124	Oesophagitis	1.57 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=000535, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=429										
000535	Treatment Cycle 6	125	Cellulitis	1.86 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000454, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=1										
000454	Safety Follow-up	6	Pulmonary embolism	1 Days	Severe	4	Y	N	N/A	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000455, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=228										
000455	Safety Follow-up	254	Retroperitoneal haemorrhage	5 Days	Moderate	2	Y	N	Discontinued	Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧
001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0015, Subject ID=000485, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
000485	Treatment Cycle 25	547	Ischaemic stroke	5 Days	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=000519, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
000519	Treatment Cycle 9	180	Gastric ulcer haemorrhage	Continuing	Severe	3	Y	N		Not Resolved
	Treatment Cycle 22	452	Gastrointestinal haemorrhage	Continuing	Severe	3	Y	N	Interrupted	Not Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=000474, Gender=F, Race=Asian, Age=61 Years, Rel Day of Study Medication Discontinuance†=113										
000474	Treatment Cycle 1	22	Dehydration	5 Days	Severe	3	Y	N	Interrupted	Resolved
		22	Nausea	5 Days	Severe	3	Y	N	Interrupted	Resolved
		22	Vomiting	5 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000476, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=295										
000476	Treatment Cycle 1	7	Prostatitis	5 Days	Moderate	2	Y	N		Resolved
		13	Urinary retention	1.43 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 7	127	Basal cell carcinoma	1 Days	Mild	1	Y	N		Resolved
	Safety Follow-up	296	Colitis	1.35 Months	Moderate	2	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000484, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=106										
000484	Treatment Cycle 2	42	Sciatica	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000500, Gender=F, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=22										

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0021, Subject ID=000500, Gender=F, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=22										
000500	Treatment Cycle 2	22	Electrolyte imbalance	3 Days	Severe	3	Y	N		Resolved
		22	General physical health deterioration	3 Weeks	Mild	1	Y	Y		Resolved
		22	Malnutrition	6 Days	Moderate	2	Y	N		Resolved
		22	Renal failure acute	2 Days	Mild	1	Y	Y		Resolved
	Safety Follow-up	43	General physical health deterioration	1 Weeks	Severe	4	Y	N		Resolved
		43	Urinary tract infection	1 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000534, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=65										
000534	Treatment Cycle 2	27	Dyspnoea	4 Days	Moderate	2	Y	N		Resolved
	Treatment Cycle 3	54	Neuralgia	2.86 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000537, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=										
000537	Treatment Cycle 4	85	Tuberculosis	1.21 Years	Mild	1	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=000553, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=1										
000553	Extended Safety Follow-up	51	Abdominal pain	1.43 Weeks	Moderate	2	Y	N		Resolved
		51	Asthenia	1.43 Weeks	Severe	3	Y	N		Resolved
		51	Decreased appetite	1.43 Weeks	Severe	3	Y	N		Resolved

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付録 2.7.4-22 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート D（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0023, Subject ID=000505, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=378										
000505	Treatment Cycle 6	123	Cellulitis	2.29 Weeks	Severe	3	Y	N		Resolved
		123	Cellulitis	2.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=000524, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=										
000524	Treatment Cycle 10	196	Cellulitis	Continuing	Severe	3	Y	N		Not Resolved

†Relative Day of Study Medication Discontinuance is defined as the day of the last recorded dose of study medication for the patient relative to the start of study medication.
Action Taken: None = DOSE NOT CHANGED, Reduced = DOSE REDUCED, Interrupted = DRUG INTERRUPTED, Discontinued = DRUG WITHDRAWN, Increased = DOSE INCREASED, N/A = NOT APPLICABLE.
Outcome: Resolved = RECOVERED/RESOLVED, Resolving = RECOVERING/RESOLVING, Sequelae = RECOVERED/RESOLVED WITH SEQUELAE, Not resolved = NOT RECOVERED/NOT RESOLVED.
Related: Investigator-assessed relationship of the adverse event to study medication.
Grades are based on NCI CTCAE version 4.0.
MedDRA preferred terms 'Malignant neoplasm progression' not related to the drug is excluded.
(Database Cutoff Date[redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-23 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
Patients in population	121		123		244	
with one or more adverse events	30	(24.8)	38	(30.9)	68	(27.9)
with no adverse events	91	(75.2)	85	(69.1)	176	(72.1)
Blood and lymphatic system disorders	**2**	**(1.7)**	**4**	**(3.3)**	**6**	**(2.5)**
Anaemia	1	(0.8)	3	(2.4)	4	(1.6)
Immune thrombocytopenic purpura	0	(0.0)	1	(0.8)	1	(0.4)
Thrombocytopenia	1	(0.8)	0	(0.0)	1	(0.4)
Cardiac disorders	**4**	**(3.3)**	**2**	**(1.6)**	**6**	**(2.5)**
Acute myocardial infarction	1	(0.8)	0	(0.0)	1	(0.4)
Atrial fibrillation	2	(1.7)	1	(0.8)	3	(1.2)
Cardiac arrest	1	(0.8)	0	(0.0)	1	(0.4)
Cardiac failure congestive	0	(0.0)	1	(0.8)	1	(0.4)
Endocrine disorders	**2**	**(1.7)**	**0**	**(0.0)**	**2**	**(0.8)**
Adrenal insufficiency	1	(0.8)	0	(0.0)	1	(0.4)
Hyperthyroidism	1	(0.8)	0	(0.0)	1	(0.4)
Gastrointestinal disorders	**9**	**(7.4)**	**12**	**(9.8)**	**21**	**(8.6)**
Colitis	3	(2.5)	2	(1.6)	5	(2.0)
Diarrhoea	0	(0.0)	5	(4.1)	5	(2.0)
Diverticulitis intestinal haemorrhagic	1	(0.8)	0	(0.0)	1	(0.4)
Dysphagia	1	(0.8)	0	(0.0)	1	(0.4)
Enterocolitis	0	(0.0)	1	(0.8)	1	(0.4)
Gastrointestinal haemorrhage	0	(0.0)	2	(1.6)	2	(0.8)
Gastrointestinal ulcer	0	(0.0)	1	(0.8)	1	(0.4)
Intestinal obstruction	1	(0.8)	0	(0.0)	1	(0.4)
Intussusception	1	(0.8)	0	(0.0)	1	(0.4)
Nausea	1	(0.8)	2	(1.6)	3	(1.2)
Obstruction gastric	0	(0.0)	1	(0.8)	1	(0.4)
Proctalgia	1	(0.8)	0	(0.0)	1	(0.4)
Vomiting	2	(1.7)	1	(0.8)	3	(1.2)
General disorders and administration site conditions	**7**	**(5.8)**	**5**	**(4.1)**	**12**	**(4.9)**
Asthenia	0	(0.0)	1	(0.8)	1	(0.4)
Chest pain	0	(0.0)	1	(0.8)	1	(0.4)

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付録 2.7.4-23 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）（続き）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	**7**	**(5.8)**	**5**	**(4.1)**	**12**	**(4.9)**
Death	1	(0.8)	1	(0.8)	2	(0.8)
Fatigue	1	(0.8)	0	(0.0)	1	(0.4)
Gait disturbance	0	(0.0)	1	(0.8)	1	(0.4)
Influenza like illness	0	(0.0)	1	(0.8)	1	(0.4)
Oedema peripheral	1	(0.8)	0	(0.0)	1	(0.4)
Pain	2	(1.7)	0	(0.0)	2	(0.8)
Pyrexia	3	(2.5)	0	(0.0)	3	(1.2)
Infections and infestations	**4**	**(3.3)**	**13**	**(10.6)**	**17**	**(7.0)**
Cellulitis	0	(0.0)	2	(1.6)	2	(0.8)
Clostridium difficile infection	0	(0.0)	1	(0.8)	1	(0.4)
Herpes simplex encephalitis	0	(0.0)	1	(0.8)	1	(0.4)
Influenza	0	(0.0)	1	(0.8)	1	(0.4)
Localised infection	0	(0.0)	1	(0.8)	1	(0.4)
Lyme disease	1	(0.8)	0	(0.0)	1	(0.4)
Pneumonia	2	(1.7)	6	(4.9)	8	(3.3)
Sepsis	0	(0.0)	1	(0.8)	1	(0.4)
Upper respiratory tract infection	0	(0.0)	1	(0.8)	1	(0.4)
Urinary tract infection	1	(0.8)	2	(1.6)	3	(1.2)
Injury, poisoning and procedural complications	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Rib fracture	1	(0.8)	0	(0.0)	1	(0.4)
Investigations	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Medical observation	1	(0.8)	0	(0.0)	1	(0.4)
Metabolism and nutrition disorders	**3**	**(2.5)**	**5**	**(4.1)**	**8**	**(3.3)**
Dehydration	0	(0.0)	1	(0.8)	1	(0.4)
Failure to thrive	0	(0.0)	2	(1.6)	2	(0.8)
Hyperkalaemia	0	(0.0)	1	(0.8)	1	(0.4)
Hyperuricaemia	1	(0.8)	0	(0.0)	1	(0.4)
Hypoalbuminaemia	0	(0.0)	1	(0.8)	1	(0.4)
Hypokalaemia	1	(0.8)	0	(0.0)	1	(0.4)
Hyponatraemia	1	(0.8)	3	(2.4)	4	(1.6)
Musculoskeletal and connective tissue disorders	**1**	**(0.8)**	**4**	**(3.3)**	**5**	**(2.0)**

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付録 2.7.4-23 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）（続き）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**1**	**(0.8)**	**4**	**(3.3)**	**5**	**(2.0)**
Arthralgia	1	(0.8)	0	(0.0)	1	(0.4)
Back pain	0	(0.0)	2	(1.6)	2	(0.8)
Costochondritis	0	(0.0)	1	(0.8)	1	(0.4)
Polyarthritis	0	(0.0)	1	(0.8)	1	(0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**1**	**(0.8)**	**4**	**(3.3)**	**5**	**(2.0)**
Basal cell carcinoma	1	(0.8)	1	(0.8)	2	(0.8)
Cancer pain	0	(0.0)	1	(0.8)	1	(0.4)
Malignant melanoma	0	(0.0)	2	(1.6)	2	(0.8)
Nervous system disorders	**6**	**(5.0)**	**3**	**(2.4)**	**9**	**(3.7)**
Brain oedema	1	(0.8)	0	(0.0)	1	(0.4)
Cerebrovascular accident	1	(0.8)	0	(0.0)	1	(0.4)
Convulsion	2	(1.7)	0	(0.0)	2	(0.8)
Depressed level of consciousness	1	(0.8)	0	(0.0)	1	(0.4)
Dizziness	1	(0.8)	0	(0.0)	1	(0.4)
Epilepsy	1	(0.8)	0	(0.0)	1	(0.4)
Spinal cord compression	1	(0.8)	1	(0.8)	2	(0.8)
Syncope	0	(0.0)	2	(1.6)	2	(0.8)
Psychiatric disorders	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Confusional state	1	(0.8)	0	(0.0)	1	(0.4)
Renal and urinary disorders	**0**	**(0.0)**	**2**	**(1.6)**	**2**	**(0.8)**
Renal failure acute	0	(0.0)	2	(1.6)	2	(0.8)
Reproductive system and breast disorders	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Metrorrhagia	1	(0.8)	0	(0.0)	1	(0.4)
Respiratory, thoracic and mediastinal disorders	**5**	**(4.1)**	**6**	**(4.9)**	**11**	**(4.5)**
Cough	0	(0.0)	1	(0.8)	1	(0.4)
Dyspnoea	1	(0.8)	1	(0.8)	2	(0.8)
Hiccups	0	(0.0)	1	(0.8)	1	(0.4)
Hypoxia	1	(0.8)	0	(0.0)	1	(0.4)
Pleural effusion	2	(1.7)	1	(0.8)	3	(1.2)
Pneumonitis	1	(0.8)	1	(0.8)	2	(0.8)

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付録 2.7.4-23 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）（続き）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**5**	**(4.1)**	**6**	**(4.9)**	**11**	**(4.5)**
Pneumothorax	0	(0.0)	1	(0.8)	1	(0.4)
Pulmonary embolism	1	(0.8)	0	(0.0)	1	(0.4)
Pulmonary haemorrhage	1	(0.8)	0	(0.0)	1	(0.4)
Respiratory failure	0	(0.0)	1	(0.8)	1	(0.4)
Skin and subcutaneous tissue disorders	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Rash	1	(0.8)	0	(0.0)	1	(0.4)
Vascular disorders	**0**	**(0.0)**	**2**	**(1.6)**	**2**	**(0.8)**
Hypotension	0	(0.0)	2	(1.6)	2	(0.8)

Every patient is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA preferred terms 'Malignant neoplasm progression' not related to the drug is excluded.
(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0002, Subject ID=001228, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=86										
001228	Safety Follow-up	107	Hyperuricaemia	Continuing	Severe	4	Y	N	N/A	Not Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001278, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=22										
001278	Treatment Cycle 1	11	Confusional state	3 Days	Moderate	2	Y	N		Resolved
		11	Hypoxia	Continuing	Mild	1	Y	N		Not Resolved
		11	Pyrexia	3 Days	Moderate	2	Y	N		Resolved
		11	Vomiting	3 Days	Mild	1	Y	N		Resolved
	Safety Follow-up	32	Pleural effusion	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001367, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=										
001367	Treatment Cycle 9	172	Rash	1.71 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001202, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=										
001202	Treatment Cycle 4	64	Basal cell carcinoma	2.14 Months	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001213, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=21										
001213	Treatment Cycle 1	2	Intestinal obstruction	2 Days	Severe	4	Y	N		Resolved
	Safety Follow-up	39	Convulsion	1 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001217, Gender=F, Race=White, Age=86 Years, Rel Day of Study Medication Discontinuance†=168										
001217	Treatment Cycle 4	67	Cerebrovascular accident	1 Days	Severe	3	Y	N	Interrupted	Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0010, Subject ID=001217, Gender=F, Race=White, Age=86 Years, Rel Day of Study Medication Discontinuance†=168										
001217	Treatment Cycle 4	89	Diverticulitis intestinal haemorrhagic	4 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 6	147	Urinary tract infection	4 Days	Severe	3	Y	N	Interrupted	Resolved
		163	Atrial fibrillation	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001220, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=										
001220	Treatment Cycle 10	194	Adrenal insufficiency	3 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001222, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=85										
001222	Extended Safety Follow-up	119	Oedema peripheral	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001324, Gender=F, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=1										
001324	Safety Follow-up	8	Pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001327, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=141										
001327	Treatment Cycle 2	43	Pulmonary haemorrhage	3 Days	Severe	3	Y	N		Resolved
		47	Pulmonary haemorrhage	3 Days	Moderate	2	Y	N		Resolved
	Treatment Cycle 3	80	Colitis	Continuing	Mild	1	Y	N	Interrupted	Not Resolved
		92	Nausea	Continuing	Moderate	2	Y	N	Interrupted	Not Resolved
		92	Vomiting	3 Days	Moderate	2	Y	N	Interrupted	Resolved
	Treatment Cycle 4	119	Hypokalaemia	3 Days	Severe	3	Y	N	Interrupted	Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0011, Subject ID=001327, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=141										
001327	Treatment Cycle 5	141	Pneumonia	Continuing	Severe	3	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001368, Gender=F, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†=194										
001368	Safety Follow-up	216	Pleural effusion	Continuing	Moderate	2	Y	N		Not Resolved
		216	Proctalgia	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001372, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=208										
001372	Safety Follow-up	222	Colitis	3.29 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001399, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=										
001399	Treatment Cycle 5	107	Colitis	2 Weeks	Severe	3	Y	Y		Resolved
		136	Lyme disease	1.22 Months	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001441, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=										
001441	Treatment Cycle 6	113	Atrial fibrillation	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001450, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=22										
001450	Safety Follow-up	34	Spinal cord compression	2 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=001302, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=22										
001302	Safety Follow-up	25	Death	1 Days		5	Y	N	Discontinued	Fatal

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0012, Subject ID=001370, Gender=F, Race=White, Age=81 Years, Rel Day of Study Medication Discontinuance†=1										
001370	Safety Follow-up	20	Fatigue	Continuing	Moderate	2	Y	N		Not Resolved
		20	Hyponatraemia	Continuing	Severe	3	Y	N		Not Resolved
		20	Pain	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0016, Subject ID=001235, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=61										
001235	Treatment Cycle 1	8	Pneumonia	2 Weeks	Severe	3	Y	N		Resolved
	Treatment Cycle 2	25	Dysphagia	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=001385, Gender=M, Race=White, Age=81 Years, Rel Day of Study Medication Discontinuance†=										
001385	Treatment Cycle 5	100	Dizziness	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0019, Subject ID=001442, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=42										
001442	Safety Follow-up	59	Intussusception	1 Weeks	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001298, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=1										
001298	Safety Follow-up	3	Acute myocardial infarction	1.29 Weeks	Severe	3	Y	N	N/A	Resolved
		3	Rib fracture	1.29 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001320, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=										
001320	Treatment Cycle 1	22	Thrombocytopenia	2 Days	Moderate	2	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001332, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=22										

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0020, Subject ID=001332, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=22										
001332	Safety Follow-up	37	Convulsion	3 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001403, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=64										
001403	Treatment Cycle 1	18	Pyrexia	2 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001439, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=20										
001439	Extended Safety Follow-up	83	Pneumonitis	6 Days	Severe	3	Y	Y	Discontinued	Resolved
		109	Pulmonary embolism	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=001312, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=22										
001312	Treatment Cycle 1	3	Pyrexia	2.71 Weeks	Moderate	2	Y	Y		Resolved
		21	Arthralgia	1.41 Months	Moderate	2	Y	N		Resolved
	Treatment Cycle 2	22	Medical observation	4 Days	Mild	1	Y	N		Resolved
	Safety Follow-up	36	Dyspnoea	Continuing	Severe	3	Y	Y		Not Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=001347, Gender=F, Race=Native Hawaiian Or Other Pacific Islander, Age=39 Years, Rel Day of Study Medication Discontinuance†=316										
001347	Treatment Cycle 2	22	Anaemia	2 Days	Severe	3	Y	N		Resolved
		22	Metrorrhagia	1.86 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=001412, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=										
001412	Treatment Cycle 2	37	Hyperthyroidism	4 Weeks	Severe	3	Y	Y	Interrupted	Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W										
Trial Number=3475-001, Site Number=0021, Subject ID=001434, Gender=M, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=46										
001434	Treatment Cycle 2	43	Brain oedema	1.18 Months	Severe	3	Y	Y		Resolved
	Safety Follow-up	55	Epilepsy	3 Days	Severe	3	Y	Y		Resolved
		61	Depressed level of consciousness	4 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0024, Subject ID=001334, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=30										
001334	Safety Follow-up	35	Cardiac arrest	1 Days		5	Y	N	Discontinued	Fatal
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0001, Subject ID=001209, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=										
001209	Treatment Cycle 13	182	Hyponatraemia	4 Days	Severe	3	Y	Y	Interrupted	Resolved
	Treatment Cycle 14	195	Hyponatraemia	3 Days	Severe	3	Y	Y		Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001218, Gender=M, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=183										
001218	Treatment Cycle 4	43	Malignant melanoma	2.14 Weeks	Moderate	2	Y	Y	N/A	Resolved
Trial Number=3475-001, Site Number=0001, Subject ID=001393, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=71										
001393	Safety Follow-up	83	Pneumonitis	1.57 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0003, Subject ID=001274, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=100										
001274	Safety Follow-up	126	Pneumonia	1 Weeks	Severe	3	Y	Y		Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0003, Subject ID=001424, Gender=M, Race=White, Age=30 Years, Rel Day of Study Medication Discontinuance†=169										
001424	Treatment Cycle 4	48	Costochondritis	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001283, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=71										
001283	Treatment Cycle 5	57	Hyperkalaemia	1.57 Weeks	Severe	4	Y	N		Resolved
		57	Hyponatraemia	Continuing	Severe	3	Y	N		Not Resolved
		63	Hiccups	Continuing	Severe	3	Y	N		Not Resolved
	Safety Follow-up	72	Hypoalbuminaemia	3 Days	Severe	3	Y	N		Resolved
		75	Dyspnoea	1.57 Weeks	Severe	4	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001303, Gender=F, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=										
001303	Treatment Cycle 17	229	Upper respiratory tract infection	1.57 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001305, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=1										
001305	Safety Follow-up	13	Urinary tract infection	3 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001321, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=										
001321	Treatment Cycle 12	161	Anaemia	1.14 Weeks	Severe	4	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0008, Subject ID=001380, Gender=M, Race=White, Age=88 Years, Rel Day of Study Medication Discontinuance†=43										
001380	Treatment Cycle 1	5	Diarrhoea	6 Days	Mild	1	Y	N		Resolved
		5	Gait disturbance	1 Weeks	Mild	1	Y	N		Resolved
		9	Renal failure acute	3 Days	Moderate	2	Y	N		Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0010, Subject ID=001201, Gender=M, Race=Asian, Age=74 Years, Rel Day of Study Medication Discontinuance†=										
001201	Treatment Cycle 3	39	Pneumonia	2.43 Weeks	Severe	3	Y	N	Interrupted	Resolved
		44	Renal failure acute	1.71 Weeks	Severe	3	Y	N	Interrupted	Resolved
		44	Respiratory failure	1.71 Weeks	Severe	4	Y	N		Resolved
		44	Sepsis	1.71 Weeks	Severe	3	Y	N	Interrupted	Resolved
	Treatment Cycle 22	331	Cellulitis	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001211, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=										
001211	Treatment Cycle 5	72	Chest pain	2 Days	Severe	3	Y	N		Resolved
	Treatment Cycle 8	132	Basal cell carcinoma	1 Days	Moderate	2	Y	N	N/A	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001215, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=29										
001215	Safety Follow-up	36	Cough	1.22 Months	Severe	3	Y	Y	Interrupted	Resolved
		36	Dehydration	1.22 Months	Severe	3	Y	Y	Interrupted	Resolved
		36	Failure to thrive	1.22 Months	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0010, Subject ID=001328, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=153										
001328	Safety Follow-up	179	Syncope	3 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001319, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=1										
001319	Safety Follow-up	2	Diarrhoea	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001340, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=83										

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0011, Subject ID=001340, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=83										
001340	Safety Follow-up	85	Syncope	2 Days	Moderate	2	Y	N		Resolved
		95	Colitis	1.45 Months	Severe	3	Y	Y	Interrupted	Resolved
	Extended Safety Follow-up	145	Herpes simplex encephalitis	1.29 Weeks	Severe	3	Y	N		Resolved
		155	Herpes simplex encephalitis	2 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001421, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=15										
001421	Treatment Cycle 2	15	Cellulitis	Continuing	Severe	3	Y	N		Not Resolved
	Safety Follow-up	43	Pleural effusion	Continuing	Moderate	2	Y	N		Not Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001449, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=1										
001449	Safety Follow-up	3	Cancer pain	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		30	Clostridium difficile infection	2 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0011, Subject ID=001451, Gender=M, Race=White, Age=28 Years, Rel Day of Study Medication Discontinuance†=										
001451	Treatment Cycle 11	144	Influenza	2.71 Weeks	Moderate	2	Y	N		Resolved
	Treatment Cycle 13	182	Diarrhoea	2 Days	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0012, Subject ID=001316, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=13										
001316	Safety Follow-up	33	Death	1 Days		5	Y	N	Discontinued	Fatal
Trial Number=3475-001, Site Number=0012, Subject ID=001360, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=41										

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0012, Subject ID=001360, Gender=F, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=41										
001360	Safety Follow-up	57	Failure to thrive	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		57	Localised infection	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
		57	Urinary tract infection	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0013, Subject ID=001259, Gender=F, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=58										
001259	Safety Follow-up	72	Spinal cord compression	Continuing	Severe	3	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001267, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=										
001267	Treatment Cycle 13	195	Hypotension	1.29 Weeks	Severe	3	Y	N	Interrupted	Resolved
		223	Colitis	4 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001285, Gender=M, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=										
001285	Treatment Cycle 9	125	Diarrhoea	3 Days	Moderate	2	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001402, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=100										
001402	Treatment Cycle 6	77	Gastrointestinal haemorrhage	4 Days	Severe	3	Y	N		Resolved
	Safety Follow-up	113	Pneumonia	6 Days	Mild	1	Y	N		Resolved
		124	Anaemia	1 Weeks	Severe	3	Y	N		Resolved
		128	Hypotension	5 Days	Mild	1	Y	N		Resolved
Trial Number=3475-001, Site Number=0015, Subject ID=001426, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=29										
001426	Safety Follow-up	37	Diarrhoea	3 Days	Severe	3	Y	Y	Discontinued	Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0016, Subject ID=001265, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=27										
001265	Treatment Cycle 1	7	Gastrointestinal ulcer	5 Days	Moderate	2	Y	N		Resolved
	Safety Follow-up	34	Back pain	Continuing	Severe	3	Y	N		Not Resolved
		34	Nausea	Continuing	Severe	3	Y	N		Not Resolved
		35	Immune thrombocytopenic purpura	Continuing	Severe	4	Y	Y		Not Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=001227, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=										
001227	Treatment Cycle 16	228	Pneumonia	2 Weeks	Severe	3	Y	N	Interrupted	Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=001308, Gender=F, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=165										
001308	Treatment Cycle 13	165	Enterocolitis	1.86 Weeks	Severe	3	Y	Y	Discontinued	Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=001398, Gender=M, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=										
001398	Treatment Cycle 10	141	Asthenia	3 Days	Severe	3	Y	Y	Interrupted	Resolved
		141	Nausea	3 Days	Severe	3	Y	Y	Interrupted	Resolved
		141	Vomiting	3 Days	Severe	3	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0018, Subject ID=001432, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=44										
001432	Safety Follow-up	47	Pneumonia	4 Days	Severe	3	Y	N		Resolved
		59	Anaemia	2 Weeks	Severe	3	Y	N	Discontinued	Resolved
		59	Cardiac failure congestive	Continuing	Severe	3	Y	N	Discontinued	Not Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0019, Subject ID=001247, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=337										
001247	Treatment Cycle 1	4	Hyponatraemia	1.14 Weeks	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001377, Gender=M, Race=White, Age=35 Years, Rel Day of Study Medication Discontinuance†=182										
001377	Treatment Cycle 6	78	Polyarthritis	1.45 Months	Mild	1	Y	Y		Resolved
	Treatment Cycle 9	122	Polyarthritis	4.14 Weeks	Moderate	2	Y	Y		Resolved
	Treatment Cycle 10	151	Polyarthritis	1.43 Weeks	Mild	1	Y	Y	Interrupted	Resolved
Trial Number=3475-001, Site Number=0020, Subject ID=001433, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=35										
001433	Safety Follow-up	43	Atrial fibrillation	4 Days	Severe	3	Y	N	Discontinued	Resolved
Trial Number=3475-001, Site Number=0021, Subject ID=001363, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=127										
001363	Treatment Cycle 5	57	Back pain	Continuing	Moderate	2	Y	N	Discontinued	Not Resolved
Trial Number=3475-001, Site Number=0023, Subject ID=001428, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=85										
001428	Treatment Cycle 5	63	Malignant melanoma	3 Days	Severe	3	Y	N		Resolved
Trial Number=3475-001, Site Number=0030, Subject ID=001207, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=154										
001207	Safety Follow-up	183	Pneumonia	2 Days	Moderate	2	Y	N		Resolved
	Extended Safety Follow-up	206	Pneumothorax	2 Days	Severe	3	Y	N		Resolved
		215	Gastrointestinal haemorrhage	3 Days	Moderate	2	Y	N		Resolved
		223	Obstruction gastric	Continuing	Severe	3	Y	N		Not Resolved

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付録 2.7.4-24 最終投与後 90 日までに発現した重篤な有害事象の一覧

001 試験パート B3（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W										
Trial Number=3475-001, Site Number=0135, Subject ID=001310, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=										
001310	Treatment Cycle 15	203	Influenza like illness	3 Days	Severe	3	Y	N		Resolved

†Relative Day of Study Medication Discontinuance is defined as the day of the last recorded dose of study medication for the patient relative to the start of study medication.

Action Taken: None = DOSE NOT CHANGED, Reduced = DOSE REDUCED, Interrupted = DRUG INTERRUPTED, Discontinued = DRUG WITHDRAWN, Increased = DOSE INCREASED, N/A = NOT APPLICABLE.

Outcome: Resolved = RECOVERED/RESOLVED, Resolving = RECOVERING/RESOLVING, Sequelae = RECOVERED/RESOLVED WITH SEQUELAE, Not resolved = NOT RECOVERED/NOT RESOLVED.

Related: Investigator-assessed relationship of the adverse event to study medication.

Grades are based on NCI CTCAE version 4.0.

MedDRA preferred terms 'Malignant neoplasm progression' not related to the drug is excluded.

(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-25 最終投与後 90 日までに発現した重篤な副作用（いずれかの投与群で発現割合 0%超）001 試験パート B2+D（APaT 集団）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Patients in population	51		52		89		84	
with one or more adverse events	7	(13.7)	4	(7.7)	7	(7.9)	5	(6.0)
with no adverse events	44	(86.3)	48	(92.3)	82	(92.1)	79	(94.0)
Cardiac disorders	**1**	**(2.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Pericardial effusion	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pericarditis	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Endocrine disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(2.2)**	**1**	**(1.2)**
Adrenal insufficiency	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Hyperthyroidism	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Hypophysitis	0	(0.0)	0	(0.0)	2	(2.2)	0	(0.0)
Gastrointestinal disorders	**3**	**(5.9)**	**2**	**(3.8)**	**0**	**(0.0)**	**1**	**(1.2)**
Colitis	1	(2.0)	2	(3.8)	0	(0.0)	0	(0.0)
Diarrhoea	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Nausea	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pancreatitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Vomiting	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
General disorders and administration site conditions	**1**	**(2.0)**	**2**	**(3.8)**	**0**	**(0.0)**	**1**	**(1.2)**
Asthenia	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Fatigue	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
General physical health deterioration	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Pyrexia	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Hepatobiliary disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(1.1)**	**0**	**(0.0)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Infections and infestations	**0**	**(0.0)**	**1**	**(1.9)**	**0**	**(0.0)**	**1**	**(1.2)**
Diverticulitis	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Tuberculosis	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)

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付録 2.7.4-25 最終投与後 90 日までに発現した重篤な副作用
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Patients in population	276	
with one or more adverse events	23	(8.3)
with no adverse events	253	(91.7)
Cardiac disorders	**1**	**(0.4)**
Pericardial effusion	1	(0.4)
Pericarditis	1	(0.4)
Endocrine disorders	**3**	**(1.1)**
Adrenal insufficiency	1	(0.4)
Hyperthyroidism	1	(0.4)
Hypophysitis	2	(0.7)
Gastrointestinal disorders	**6**	**(2.2)**
Colitis	3	(1.1)
Diarrhoea	1	(0.4)
Nausea	1	(0.4)
Pancreatitis	1	(0.4)
Vomiting	1	(0.4)
General disorders and administration site conditions	**4**	**(1.4)**
Asthenia	1	(0.4)
Fatigue	1	(0.4)
General physical health deterioration	1	(0.4)
Pyrexia	1	(0.4)
Hepatobiliary disorders	**1**	**(0.4)**
Autoimmune hepatitis	1	(0.4)
Infections and infestations	**2**	**(0.7)**
Diverticulitis	1	(0.4)
Tuberculosis	1	(0.4)

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付録 2.7.4-25 最終投与後 90 日までに発現した重篤な副作用
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Ipi-naïve 2 mg/kg Q3W		Ipi-naïve 10 mg/kg Q3W		Ipi-exposed 2 mg/kg Q3W		Ipi-exposed 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)	n	(%)
Metabolism and nutrition disorders	**2**	**(3.9)**	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(2.4)**
Dehydration	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Hyperglycaemia	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Insulin resistant diabetes	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Type 1 diabetes mellitus	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.2)
Nervous system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(2.2)**	**0**	**(0.0)**
Encephalopathy	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Partial seizures	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Psychiatric disorders	**0**	**(0.0)**	**0**	**(0.0)**	**1**	**(1.1)**	**0**	**(0.0)**
Confusional state	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Renal and urinary disorders	**0**	**(0.0)**	**1**	**(1.9)**	**0**	**(0.0)**	**0**	**(0.0)**
Renal failure acute	0	(0.0)	1	(1.9)	0	(0.0)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**1**	**(2.0)**	**0**	**(0.0)**	**1**	**(1.1)**	**0**	**(0.0)**
Dyspnoea	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)
Pneumonitis	0	(0.0)	0	(0.0)	1	(1.1)	0	(0.0)
Vascular disorders	**1**	**(2.0)**	**0**	**(0.0)**	**0**	**(0.0)**	**0**	**(0.0)**
Peripheral ischaemia	1	(2.0)	0	(0.0)	0	(0.0)	0	(0.0)

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付録 2.7.4-25 最終投与後 90 日までに発現した重篤な副作用
（いずれかの投与群で発現割合 0%超）
001 試験パート B2+D（APaT 集団）（続き）

	Total	
	n	(%)
Metabolism and nutrition disorders	**4**	**(1.4)**
Dehydration	1	(0.4)
Hyperglycaemia	1	(0.4)
Insulin resistant diabetes	1	(0.4)
Type 1 diabetes mellitus	1	(0.4)
Nervous system disorders	**2**	**(0.7)**
Encephalopathy	1	(0.4)
Partial seizures	1	(0.4)
Psychiatric disorders	**1**	**(0.4)**
Confusional state	1	(0.4)
Renal and urinary disorders	**1**	**(0.4)**
Renal failure acute	1	(0.4)
Respiratory, thoracic and mediastinal disorders	**2**	**(0.7)**
Dyspnoea	1	(0.4)
Pneumonitis	1	(0.4)
Vascular disorders	**1**	**(0.4)**
Peripheral ischaemia	1	(0.4)

Every patient is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-26 最終投与後 90 日までに発現した重篤な副作用
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
Patients in population	121		123		244	
with one or more adverse events	9	(7.4)	12	(9.8)	21	(8.6)
with no adverse events	112	(92.6)	111	(90.2)	223	(91.4)
Blood and lymphatic system disorders	**1**	**(0.8)**	**1**	**(0.8)**	**2**	**(0.8)**
Immune thrombocytopenic purpura	0	(0.0)	1	(0.8)	1	(0.4)
Thrombocytopenia	1	(0.8)	0	(0.0)	1	(0.4)
Endocrine disorders	**2**	**(1.7)**	**0**	**(0.0)**	**2**	**(0.8)**
Adrenal insufficiency	1	(0.8)	0	(0.0)	1	(0.4)
Hyperthyroidism	1	(0.8)	0	(0.0)	1	(0.4)
Gastrointestinal disorders	**2**	**(1.7)**	**5**	**(4.1)**	**7**	**(2.9)**
Colitis	2	(1.7)	1	(0.8)	3	(1.2)
Diarrhoea	0	(0.0)	2	(1.6)	2	(0.8)
Enterocolitis	0	(0.0)	1	(0.8)	1	(0.4)
Nausea	0	(0.0)	1	(0.8)	1	(0.4)
Vomiting	0	(0.0)	1	(0.8)	1	(0.4)
General disorders and administration site conditions	**2**	**(1.7)**	**1**	**(0.8)**	**3**	**(1.2)**
Asthenia	0	(0.0)	1	(0.8)	1	(0.4)
Pyrexia	2	(1.7)	0	(0.0)	2	(0.8)
Infections and infestations	**0**	**(0.0)**	**1**	**(0.8)**	**1**	**(0.4)**
Pneumonia	0	(0.0)	1	(0.8)	1	(0.4)
Metabolism and nutrition disorders	**0**	**(0.0)**	**2**	**(1.6)**	**2**	**(0.8)**
Dehydration	0	(0.0)	1	(0.8)	1	(0.4)
Failure to thrive	0	(0.0)	1	(0.8)	1	(0.4)
Hyponatraemia	0	(0.0)	1	(0.8)	1	(0.4)
Musculoskeletal and connective tissue disorders	**0**	**(0.0)**	**1**	**(0.8)**	**1**	**(0.4)**
Polyarthritis	0	(0.0)	1	(0.8)	1	(0.4)

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付録 2.7.4-26 最終投与後 90 日までに発現した重篤な副作用
（いずれかの投与群で発現割合 0%超）
001 試験パート B3（APaT 集団）（続き）

	MK-3475 10 mg/kg Q3W		MK-3475 10 mg/kg Q2W		Total	
	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**1**	**(0.8)**	**1**	**(0.4)**
Malignant melanoma	0	(0.0)	1	(0.8)	1	(0.4)
Nervous system disorders	**1**	**(0.8)**	**0**	**(0.0)**	**1**	**(0.4)**
Brain oedema	1	(0.8)	0	(0.0)	1	(0.4)
Depressed level of consciousness	1	(0.8)	0	(0.0)	1	(0.4)
Epilepsy	1	(0.8)	0	(0.0)	1	(0.4)
Respiratory, thoracic and mediastinal disorders	**2**	**(1.7)**	**2**	**(1.6)**	**4**	**(1.6)**
Cough	0	(0.0)	1	(0.8)	1	(0.4)
Dyspnoea	1	(0.8)	0	(0.0)	1	(0.4)
Pneumonitis	1	(0.8)	1	(0.8)	2	(0.8)

Every patient is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
(Database Cutoff Date: [redacted]

Data Source: [資料5.3.5.2.1.2: P001V02]

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Subjects in population	171		178		179	
with one or more adverse events	59	(34.5)	83	(46.6)	68	(38.0)
with no adverse events	112	(65.5)	95	(53.4)	111	(62.0)
Blood and lymphatic system disorders	**9**	**(5.3)**	**7**	**(3.9)**	**0**	**(0.0)**
Anaemia	4	(2.3)	7	(3.9)	0	(0.0)
Febrile neutropenia	3	(1.8)	0	(0.0)	0	(0.0)
Leukopenia	1	(0.6)	0	(0.0)	0	(0.0)
Neutropenia	1	(0.6)	0	(0.0)	0	(0.0)
Thrombocytopenia	2	(1.2)	0	(0.0)	0	(0.0)
Cardiac disorders	**1**	**(0.6)**	**3**	**(1.7)**	**2**	**(1.1)**
Angina pectoris	0	(0.0)	1	(0.6)	0	(0.0)
Cardiac failure	0	(0.0)	0	(0.0)	1	(0.6)
Cardiac ventricular disorder	0	(0.0)	0	(0.0)	1	(0.6)
Cardiogenic shock	0	(0.0)	1	(0.6)	0	(0.0)
Myocardial infarction	1	(0.6)	0	(0.0)	0	(0.0)
Pericardial effusion	0	(0.0)	1	(0.6)	0	(0.0)
Congenital, familial and genetic disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Aplasia	0	(0.0)	1	(0.6)	0	(0.0)
Ear and labyrinth disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Vertigo positional	0	(0.0)	1	(0.6)	0	(0.0)
Endocrine disorders	**0**	**(0.0)**	**2**	**(1.1)**	**4**	**(2.2)**
Adrenocortical insufficiency acute	0	(0.0)	1	(0.6)	1	(0.6)
Hyperparathyroidism	0	(0.0)	0	(0.0)	1	(0.6)
Hypophysitis	0	(0.0)	1	(0.6)	0	(0.0)
Hypopituitarism	0	(0.0)	0	(0.0)	2	(1.1)
Eye disorders	**0**	**(0.0)**	**1**	**(0.6)**	**1**	**(0.6)**
Eye movement disorder	0	(0.0)	1	(0.6)	0	(0.0)
Iritis	0	(0.0)	0	(0.0)	1	(0.6)
Gastrointestinal disorders	**11**	**(6.4)**	**19**	**(10.7)**	**16**	**(8.9)**
Abdominal pain	1	(0.6)	2	(1.1)	4	(2.2)
Ascites	1	(0.6)	0	(0.0)	1	(0.6)
Colitis	1	(0.6)	2	(1.1)	1	(0.6)
Constipation	1	(0.6)	2	(1.1)	1	(0.6)
Diarrhoea	1	(0.6)	0	(0.0)	3	(1.7)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Gastrointestinal disorders	**11**	**(6.4)**	**19**	**(10.7)**	**16**	**(8.9)**
Diverticulum	0	(0.0)	1	(0.6)	0	(0.0)
Dysphagia	0	(0.0)	1	(0.6)	0	(0.0)
Gastric disorder	0	(0.0)	0	(0.0)	1	(0.6)
Gastrointestinal disorder	0	(0.0)	0	(0.0)	1	(0.6)
Gastrointestinal pain	0	(0.0)	1	(0.6)	0	(0.0)
Haematemesis	0	(0.0)	1	(0.6)	0	(0.0)
Haematochezia	1	(0.6)	0	(0.0)	0	(0.0)
Ileus	0	(0.0)	1	(0.6)	2	(1.1)
Intestinal obstruction	0	(0.0)	1	(0.6)	0	(0.0)
Intussusception	0	(0.0)	1	(0.6)	0	(0.0)
Large intestinal ulcer	0	(0.0)	1	(0.6)	0	(0.0)
Malabsorption	0	(0.0)	1	(0.6)	0	(0.0)
Nausea	3	(1.8)	1	(0.6)	0	(0.0)
Odynophagia	0	(0.0)	0	(0.0)	1	(0.6)
Pancreatitis	0	(0.0)	1	(0.6)	0	(0.0)
Rectal haemorrhage	1	(0.6)	0	(0.0)	0	(0.0)
Small intestinal obstruction	1	(0.6)	0	(0.0)	0	(0.0)
Small intestinal perforation	0	(0.0)	1	(0.6)	0	(0.0)
Upper gastrointestinal haemorrhage	0	(0.0)	1	(0.6)	1	(0.6)
Vomiting	1	(0.6)	3	(1.7)	1	(0.6)
General disorders and administration site conditions	**7**	**(4.1)**	**13**	**(7.3)**	**13**	**(7.3)**
Asthenia	0	(0.0)	1	(0.6)	1	(0.6)
Chest pain	0	(0.0)	2	(1.1)	0	(0.0)
Death	2	(1.2)	3	(1.7)	2	(1.1)
Device dislocation	0	(0.0)	1	(0.6)	0	(0.0)
Fatigue	0	(0.0)	0	(0.0)	1	(0.6)
General physical health deterioration	3	(1.8)	1	(0.6)	5	(2.8)
Generalised oedema	1	(0.6)	3	(1.7)	0	(0.0)
Infusion site extravasation	0	(0.0)	0	(0.0)	1	(0.6)
Malaise	0	(0.0)	1	(0.6)	0	(0.0)
Oedema	0	(0.0)	1	(0.6)	0	(0.0)
Pain	0	(0.0)	0	(0.0)	1	(0.6)
Pyrexia	2	(1.2)	3	(1.7)	3	(1.7)
Hepatobiliary disorders	**2**	**(1.2)**	**3**	**(1.7)**	**2**	**(1.1)**
Autoimmune hepatitis	0	(0.0)	0	(0.0)	1	(0.6)
Cholecystitis	0	(0.0)	2	(1.1)	0	(0.0)
Hepatic failure	0	(0.0)	1	(0.6)	1	(0.6)
Hepatitis	1	(0.6)	0	(0.0)	0	(0.0)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Hepatobiliary disorders	**2**	**(1.2)**	**3**	**(1.7)**	**2**	**(1.1)**
Hyperbilirubinaemia	1	(0.6)	0	(0.0)	0	(0.0)
Immune system disorders	**0**	**(0.0)**	**0**	**(0.0)**	**2**	**(1.1)**
Anaphylactic reaction	0	(0.0)	0	(0.0)	1	(0.6)
Hypersensitivity	0	(0.0)	0	(0.0)	1	(0.6)
Infections and infestations	**19**	**(11.1)**	**19**	**(10.7)**	**9**	**(5.0)**
Appendicitis perforated	0	(0.0)	0	(0.0)	1	(0.6)
Atypical pneumonia	1	(0.6)	0	(0.0)	0	(0.0)
Bacteraemia	1	(0.6)	0	(0.0)	0	(0.0)
Bronchitis	0	(0.0)	2	(1.1)	0	(0.0)
Candida infection	0	(0.0)	0	(0.0)	1	(0.6)
Cellulitis	1	(0.6)	1	(0.6)	0	(0.0)
Clostridium difficile colitis	0	(0.0)	1	(0.6)	0	(0.0)
Diverticulitis	0	(0.0)	1	(0.6)	0	(0.0)
Enterocolitis infectious	1	(0.6)	0	(0.0)	0	(0.0)
Erysipelas	2	(1.2)	1	(0.6)	1	(0.6)
Herpes zoster	0	(0.0)	0	(0.0)	1	(0.6)
Infection	2	(1.2)	0	(0.0)	0	(0.0)
Infectious pleural effusion	0	(0.0)	1	(0.6)	0	(0.0)
Influenza	1	(0.6)	0	(0.0)	1	(0.6)
Lobar pneumonia	1	(0.6)	0	(0.0)	0	(0.0)
Mastitis	0	(0.0)	1	(0.6)	0	(0.0)
Pelvic abscess	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonia	4	(2.3)	3	(1.7)	2	(1.1)
Respiratory syncytial virus infection	1	(0.6)	0	(0.0)	0	(0.0)
Salmonellosis	0	(0.0)	0	(0.0)	1	(0.6)
Sepsis	3	(1.8)	1	(0.6)	0	(0.0)
Septic shock	0	(0.0)	1	(0.6)	0	(0.0)
Skin infection	0	(0.0)	2	(1.1)	0	(0.0)
Soft tissue infection	1	(0.6)	1	(0.6)	0	(0.0)
Urinary tract infection	1	(0.6)	1	(0.6)	1	(0.6)
Viral infection	0	(0.0)	1	(0.6)	0	(0.0)
Viral upper respiratory tract infection	1	(0.6)	0	(0.0)	0	(0.0)
Wound infection	0	(0.0)	1	(0.6)	0	(0.0)
Injury, poisoning and procedural complications	**2**	**(1.2)**	**4**	**(2.2)**	**2**	**(1.1)**
Fall	0	(0.0)	1	(0.6)	0	(0.0)
Femur fracture	1	(0.6)	0	(0.0)	0	(0.0)
Lower limb fracture	0	(0.0)	1	(0.6)	0	(0.0)
Procedural pain	0	(0.0)	0	(0.0)	1	(0.6)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Injury, poisoning and procedural complications	**2**	**(1.2)**	**4**	**(2.2)**	**2**	**(1.1)**
Radiation injury	0	(0.0)	1	(0.6)	0	(0.0)
Rib fracture	0	(0.0)	1	(0.6)	0	(0.0)
Spinal fracture	0	(0.0)	0	(0.0)	1	(0.6)
Subdural haematoma	1	(0.6)	0	(0.0)	0	(0.0)
Investigations	**3**	**(1.8)**	**0**	**(0.0)**	**1**	**(0.6)**
Alanine aminotransferase	1	(0.6)	0	(0.0)	0	(0.0)
Alanine aminotransferase increased	0	(0.0)	0	(0.0)	1	(0.6)
Aspartate aminotransferase increased	1	(0.6)	0	(0.0)	1	(0.6)
Blood bilirubin increased	1	(0.6)	0	(0.0)	0	(0.0)
Neutrophil count decreased	1	(0.6)	0	(0.0)	0	(0.0)
Platelet count decreased	2	(1.2)	0	(0.0)	0	(0.0)
White blood cell count decreased	1	(0.6)	0	(0.0)	0	(0.0)
Metabolism and nutrition disorders	**3**	**(1.8)**	**8**	**(4.5)**	**4**	**(2.2)**
Cachexia	0	(0.0)	1	(0.6)	0	(0.0)
Dehydration	2	(1.2)	3	(1.7)	1	(0.6)
Diabetes mellitus	0	(0.0)	1	(0.6)	0	(0.0)
Hypercalcaemia	0	(0.0)	1	(0.6)	0	(0.0)
Hyperglycaemia	0	(0.0)	1	(0.6)	0	(0.0)
Hypocalcaemia	1	(0.6)	0	(0.0)	0	(0.0)
Hyponatraemia	0	(0.0)	1	(0.6)	3	(1.7)
Musculoskeletal and connective tissue disorders	**2**	**(1.2)**	**1**	**(0.6)**	**9**	**(5.0)**
Arthralgia	0	(0.0)	0	(0.0)	2	(1.1)
Back pain	1	(0.6)	0	(0.0)	1	(0.6)
Groin pain	0	(0.0)	0	(0.0)	1	(0.6)
Muscular weakness	0	(0.0)	0	(0.0)	1	(0.6)
Musculoskeletal pain	0	(0.0)	1	(0.6)	1	(0.6)
Neck pain	0	(0.0)	0	(0.0)	1	(0.6)
Osteolysis	0	(0.0)	0	(0.0)	1	(0.6)
Pain in extremity	1	(0.6)	0	(0.0)	0	(0.0)
Spondylolisthesis	0	(0.0)	0	(0.0)	1	(0.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**3**	**(1.8)**	**8**	**(4.5)**	**0**	**(0.0)**
Basal cell carcinoma	0	(0.0)	1	(0.6)	0	(0.0)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**3**	**(1.8)**	**8**	**(4.5)**	**0**	**(0.0)**
Intracranial tumour haemorrhage	1	(0.6)	0	(0.0)	0	(0.0)
Metastases to central nervous system	0	(0.0)	2	(1.1)	0	(0.0)
Metastases to lymph nodes	0	(0.0)	1	(0.6)	0	(0.0)
Metastatic pain	0	(0.0)	1	(0.6)	0	(0.0)
Oncologic complication	0	(0.0)	1	(0.6)	0	(0.0)
Tumour haemorrhage	1	(0.6)	0	(0.0)	0	(0.0)
Tumour pain	1	(0.6)	2	(1.1)	0	(0.0)
Nervous system disorders	**5**	**(2.9)**	**11**	**(6.2)**	**7**	**(3.9)**
Ataxia	1	(0.6)	0	(0.0)	0	(0.0)
Cerebrovascular accident	0	(0.0)	1	(0.6)	0	(0.0)
Convulsion	0	(0.0)	1	(0.6)	0	(0.0)
Dizziness	0	(0.0)	1	(0.6)	1	(0.6)
Encephalopathy	0	(0.0)	1	(0.6)	0	(0.0)
Epilepsy	0	(0.0)	1	(0.6)	0	(0.0)
Haemorrhage intracranial	1	(0.6)	0	(0.0)	0	(0.0)
Hemiparesis	0	(0.0)	0	(0.0)	1	(0.6)
Lumbar radiculopathy	0	(0.0)	0	(0.0)	1	(0.6)
Meningitis noninfective	0	(0.0)	0	(0.0)	1	(0.6)
Myasthenic syndrome	0	(0.0)	0	(0.0)	1	(0.6)
Myoclonus	1	(0.6)	0	(0.0)	0	(0.0)
Paraesthesia	0	(0.0)	1	(0.6)	0	(0.0)
Partial seizures	0	(0.0)	2	(1.1)	0	(0.0)
Peripheral motor neuropathy	0	(0.0)	0	(0.0)	1	(0.6)
Sciatica	0	(0.0)	0	(0.0)	1	(0.6)
Spinal cord compression	0	(0.0)	1	(0.6)	0	(0.0)
Syncope	1	(0.6)	2	(1.1)	0	(0.0)
Transient ischaemic attack	1	(0.6)	0	(0.0)	0	(0.0)
Psychiatric disorders	**1**	**(0.6)**	**5**	**(2.8)**	**3**	**(1.7)**
Confusional state	1	(0.6)	2	(1.1)	3	(1.7)
Delirium	0	(0.0)	1	(0.6)	0	(0.0)
Mental status changes	0	(0.0)	2	(1.1)	0	(0.0)
Renal and urinary disorders	**1**	**(0.6)**	**4**	**(2.2)**	**1**	**(0.6)**
Hydronephrosis	0	(0.0)	1	(0.6)	0	(0.0)
Postrenal failure	0	(0.0)	1	(0.6)	0	(0.0)
Renal failure	0	(0.0)	0	(0.0)	1	(0.6)
Renal failure acute	1	(0.6)	1	(0.6)	0	(0.0)
Tubulointerstitial nephritis	0	(0.0)	1	(0.6)	0	(0.0)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Reproductive system and breast disorders	**0**	**(0.0)**	**1**	**(0.6)**	**0**	**(0.0)**
Pelvic pain	0	(0.0)	1	(0.6)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	**10**	**(5.8)**	**11**	**(6.2)**	**12**	**(6.7)**
Chronic obstructive pulmonary disease	1	(0.6)	1	(0.6)	0	(0.0)
Cough	0	(0.0)	1	(0.6)	0	(0.0)
Dyspnoea	4	(2.3)	3	(1.7)	5	(2.8)
Dyspnoea exertional	0	(0.0)	1	(0.6)	0	(0.0)
Epistaxis	1	(0.6)	0	(0.0)	0	(0.0)
Haemoptysis	1	(0.6)	1	(0.6)	0	(0.0)
Haemothorax	0	(0.0)	1	(0.6)	0	(0.0)
Hypoxia	0	(0.0)	0	(0.0)	1	(0.6)
Interstitial lung disease	0	(0.0)	0	(0.0)	1	(0.6)
Laryngeal inflammation	0	(0.0)	1	(0.6)	0	(0.0)
Pleural effusion	0	(0.0)	1	(0.6)	1	(0.6)
Pneumonia aspiration	0	(0.0)	0	(0.0)	1	(0.6)
Pneumonitis	0	(0.0)	0	(0.0)	3	(1.7)
Pulmonary embolism	4	(2.3)	2	(1.1)	1	(0.6)
Pulmonary thrombosis	0	(0.0)	0	(0.0)	1	(0.6)
Skin and subcutaneous tissue disorders	**0**	**(0.0)**	**3**	**(1.7)**	**1**	**(0.6)**
Erythema multiforme	0	(0.0)	0	(0.0)	1	(0.6)
Rash maculo-papular	0	(0.0)	1	(0.6)	0	(0.0)
Skin mass	0	(0.0)	1	(0.6)	0	(0.0)
Stevens-Johnson syndrome	0	(0.0)	1	(0.6)	0	(0.0)
Vascular disorders	**3**	**(1.8)**	**5**	**(2.8)**	**4**	**(2.2)**
Deep vein thrombosis	1	(0.6)	1	(0.6)	1	(0.6)
Haemorrhagic infarction	0	(0.0)	1	(0.6)	0	(0.0)
Hypotension	1	(0.6)	1	(0.6)	0	(0.0)
Lymphoedema	1	(0.6)	0	(0.0)	0	(0.0)
Orthostatic hypotension	0	(0.0)	0	(0.0)	1	(0.6)
Phlebitis	0	(0.0)	1	(0.6)	0	(0.0)
Poor venous access	0	(0.0)	1	(0.6)	0	(0.0)
Superior vena cava syndrome	0	(0.0)	0	(0.0)	1	(0.6)

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付録 2.7.4-27 最終投与後 90 日までに発現した重篤な有害事象
（いずれかの投与群で発現割合 0%超）
002 試験（APaT 集団）（続き）

	Control		MK-3475 2 mg/kg Q3W		MK-3475 10 mg/kg Q3W	
	n	(%)	n	(%)	n	(%)
Vascular disorders	**3**	**(1.8)**	**5**	**(2.8)**	**4**	**(2.2)**
Venous thrombosis	0	(0.0)	0	(0.0)	1	(0.6)

Every subject is counted a single time for each applicable row and column.
A system organ class or specific adverse event appears on this report only if its incidence in one or more of the columns meets the incidence criterion in the report title, after rounding.
MedDRA preferred terms "Neoplasm Progression", "Malignant Neoplasm Progression" and "Disease Progression" not related to the drug are excluded.
(Database Cutoff Date: 12MAY2014).

Data Source: [資料5.3.5.1.1: P002V01]

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