付録 2.7.4-49 治験薬の投与中止に至った有害事象の一覧
002 試験（APaT 集団）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
Control									
Study Number=3475-002, Site Number=0001, AN=100035, Gender=F, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=227									
100035	Treatment Cycle 8	165	Neuropathy peripheral	Continuing	2	N	Y	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0001, AN=101266, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=175									
101266	Chemotherapy Washout	99	Hyperbilirubinaemia	1.81 Months	4	Y	N	Discontinued	Resolved
Study Number=3475-002, Site Number=0011, AN=100111, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=127									
100111	Chemotherapy Washout	2	Alopecia	2.53 Months	2	N	Y	Discontinued	Resolved
		16	Gingival bleeding	3 Days	2	N	N	Discontinued	Resolved
		16	Pancytopenia	2.07 Months	1	N	Y	Discontinued	Resolved
		18	Bacterial sepsis	6 Days	3	N	Y	Discontinued	Resolved
		18	Renal failure acute	6 Days	4	Y	Y	Discontinued	Resolved
		18	Urosepsis	6 Days	2	N	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0025, AN=102133, Gender=M, Race=White, Age=37 Years, Rel Day of Study Medication Discontinuance†=35									
102133	Safety Follow-up	59	Death	23 Hours	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0036, AN=100302, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=1									
100302	Safety Follow-up	7	Fatigue	Unknown	2	N	Y	Discontinued	Unknown
Study Number=3475-002, Site Number=0036, AN=101210, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=489									
101210	Treatment Cycle 8	215	Sepsis	1.14 Weeks	4	Y	N	Discontinued	Resolved

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付録 2.7.4-49 治験薬の投与中止に至った有害事象の一覧

002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
Control									
Study Number=3475-002, Site Number=0053, AN=101214, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=113									
101214	Safety Follow-up	99	Neuropathy peripheral	Continuing	3	N	Y	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0053, AN=101215, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=57									
101215	Safety Follow-up	57	Dyspnoea	Continuing	4	Y	N	Discontinued	Not Resolved
		57	Haemoptysis	Continuing	3	Y	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0061, AN=102118, Gender=M, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=15									
102118	Treatment Cycle 1	2	Colitis	1.31 Months	3	Y	N	Discontinued	Resolved
Study Number=3475-002, Site Number=0073, AN=101880, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=5									
101880	Safety Follow-up	24	Thrombocytopenia	Continuing	1	Y	Y	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0080, AN=100906, Gender=F, Race=White, Age=47 Years, Rel Day of Study Medication Discontinuance†=53									
100906	Safety Follow-up	57	General physical health deterioration	1.71 Weeks	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0081, AN=100103, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=1									
100103	Safety Follow-up	6	General physical health deterioration	4 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0087, AN=100912, Gender=F, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=1									
100912	Treatment Cycle 1	1	Anaphylactic reaction	1.17 Hours	2	N	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0088, AN=101822, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=115									

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
Control									
Study Number=3475-002, Site Number=0088, AN=101822, Gender=M, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=115									
101822	Chemotherapy Washout	7	Soft tissue infection	2.1 Months	3	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0090, AN=100914, Gender=F, Race=White, Age=31 Years, Rel Day of Study Medication Discontinuance†=1									
100914	Safety Follow-up	3	Anaemia	Continuing	3	N	Y	Discontinued	Resolving
		3	Thrombocytopenia	Unknown	4	Y	Y	Discontinued	Unknown
Study Number=3475-002, Site Number=0090, AN=101508, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=30									
101508	Safety Follow-up	44	Anaemia	Unknown	2	N	Y	Discontinued	Unknown
		44	Asthenia	Unknown	2	N	Y	Discontinued	Unknown
		44	Thrombocytopenia	Unknown	2	N	Y	Discontinued	Unknown
Study Number=3475-002, Site Number=0101, AN=100069, Gender=F, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=61									
100069	Safety Follow-up	77	Myoclonus	5 Days	1	Y	N	Discontinued	Resolved
Study Number=3475-002, Site Number=0101, AN=102129, Gender=M, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=5									
102129	Treatment Cycle 1	5	Haemorrhage intracranial	3.14 Weeks	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0184, AN=102140, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=22									
102140	Safety Follow-up	32	Atrial fibrillation	Continuing	3	N	N	Discontinued	Not Resolved
		32	C-reactive protein increased	Continuing	2	N	N	Discontinued	Not Resolved
		32	Pulmonary embolism	2 Days	5	Y	N	Discontinued	Fatal

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付録 2.7.4-49 治験薬の投与中止に至った有害事象の一覧

002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
Control									
Study Number=3475-002, Site Number=0189, AN=100646, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=149									
100646	Chemotherapy Washout	67	Lymphocyte count decreased	2.86 Weeks	1	N	Y	Discontinued	Resolved
MK-3475 2 mg/kg Q3W									
Study Number=3475-002, Site Number=0021, AN=101251, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=32									
101251	Treatment Cycle 1	19	Pulmonary embolism	Continuing	3	Y	N	Discontinued	Resolving
Study Number=3475-002, Site Number=0031, AN=101270, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=85									
101270	Safety Follow-up	104	Generalised oedema	4.63 Months	4	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0054, AN=100064, Gender=M, Race=White, Age=87 Years, Rel Day of Study Medication Discontinuance†=44									
100064	Safety Follow-up	45	Neck pain	Continuing	2	N	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0080, AN=100617, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=216									
100617	Safety Follow-up	231	General physical health deterioration	3.35 Months	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0081, AN=101820, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=1									
101820	Safety Follow-up	19	Hepatic failure	3 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0082, AN=100636, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=60									
100636	Treatment Cycle 1	11	Oedema	1.91 Months	3	Y	N	Discontinued	Resolved

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付録 2.7.4-49 治験薬の投与中止に至った有害事象の一覧

002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W									
Study Number=3475-002, Site Number=0087, AN=102107, Gender=M, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†=70									
102107	Treatment Cycle 2	41	Generalised oedema	1.77 Months	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0088, AN=101866, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=43									
101866	Treatment Cycle 2	37	Hydronephrosis	Continuing	2	Y	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0090, AN=100309, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=43									
100309	Safety Follow-up	48	Generalised oedema	1.48 Months	3	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0090, AN=101830, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=50									
101830	Treatment Cycle 2	33	Asthenia	1.28 Months	3	N	N	Discontinued	Sequelae
Study Number=3475-002, Site Number=0100, AN=100607, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=153									
100607	Treatment Cycle 5	110	Anaemia	Continuing	3	N	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0100, AN=102105, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=1									
102105	Safety Follow-up	5	Death	1 Days	5	Y	Y	Discontinued	Fatal
Study Number=3475-002, Site Number=0102, AN=101241, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=106									
101241	Safety Follow-up	118	Septic shock	4 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0120, AN=101853, Gender=M, Race=White, Age=21 Years, Rel Day of Study Medication Discontinuance†=1									
101853	Safety Follow-up	28	Hypercalcaemia	6 Days	3	Y	N	Discontinued	Resolved

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 2 mg/kg Q3W									
Study Number=3475-002, Site Number=0140, AN=100006, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=1									
100006	Safety Follow-up	4	Stevens-Johnson syndrome	4.14 Months	3	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0170, AN=101510, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=1									
101510	Treatment Cycle 1	1	Hypophysitis	4.14 Weeks	3	Y	Y	Discontinued	Sequelae
Study Number=3475-002, Site Number=0185, AN=101236, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=1									
101236	Safety Follow-up	16	Infectious pleural effusion	2.57 Weeks	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0189, AN=100656, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=22									
100656	Safety Follow-up	35	Cachexia	1.43 Weeks	5	Y	N	Discontinued	Fatal
MK-3475 10 mg/kg Q3W									
Study Number=3475-002, Site Number=0001, AN=100615, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†=21									
100615	Safety Follow-up	35	Upper gastrointestinal haemorrhage	6 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0007, AN=101222, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=1									
101222	Safety Follow-up	13	Asthenia	Continuing	3	Y	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0010, AN=101857, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=64									
101857	Safety Follow-up	93	Pneumonitis	2 Days	2	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0011, AN=100139, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=22									

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Study Number=3475-002, Site Number=0011, AN=100139, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=22									
100139	Safety Follow-up	35	Pneumonitis	3.57 Weeks	3	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0016, AN=100040, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=1									
100040	Safety Follow-up	14	Hyponatraemia	2 Weeks	4	Y	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0016, AN=100627, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=127									
100627	Safety Follow-up	145	Colitis	3.52 Months	3	N	Y	Discontinued	Resolved
Study Number=3475-002, Site Number=0025, AN=100676, Gender=M, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†=84									
100676	Treatment Cycle 1	2	Fatigue	Continuing	3	N	Y	Discontinued	Not Resolved
		2	Nausea	Continuing	3	N	Y	Discontinued	Not Resolved
		20	Vomiting	Continuing	3	N	Y	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0032, AN=101271, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=63									
101271	Safety Follow-up	77	Pneumonitis	5 Days	3	Y	Y	Discontinued	Resolved
		82	Dyspnoea	1.58 Months	2	N	Y	Discontinued	Resolved
		82	Pneumonitis	1.58 Months	2	N	N	Discontinued	Resolved
Study Number=3475-002, Site Number=0033, AN=101504, Gender=F, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†=112									
101504	Safety Follow-up	122	Cardiac ventricular disorder	1.71 Weeks	3	Y	N	Discontinued	Sequelae
Study Number=3475-002, Site Number=0053, AN=100661, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=211									
100661	Treatment Cycle 6	123	Colitis	4.3 Months	3	N	Y	Discontinued	Resolved

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Study Number=3475-002, Site Number=0053, AN=101848, Gender=F, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=64									
101848	Safety Follow-up	72	General physical health deterioration	Continuing	4	Y	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0054, AN=101874, Gender=M, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=1									
101874	Safety Follow-up	22	Asthenia	Continuing	3	N	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0070, AN=101879, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=43									
101879	Treatment Cycle 2	21	Cell death	Continuing	1	N	Y	Discontinued	Not Resolved
	Safety Follow-up	71	Asthenia	Continuing	3	N	N	Discontinued	Not Resolved
		71	Oedema peripheral	Continuing	3	N	N	Discontinued	Not Resolved
		71	Pleural effusion	Continuing	3	N	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0080, AN=100674, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†=23									
100674	Safety Follow-up	28	Hypopituitarism	Continuing	3	Y	Y	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0080, AN=100909, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=1									
100909	Safety Follow-up	19	General physical health deterioration	6 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0080, AN=100913, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=1									
100913	Safety Follow-up	8	Autoimmune hepatitis	Continuing	3	Y	Y	Discontinued	Resolving
Study Number=3475-002, Site Number=0080, AN=101813, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=1									
101813	Safety Follow-up	9	General physical health deterioration	1 Days	5	Y	N	Discontinued	Fatal

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Study Number=3475-002, Site Number=0080, AN=102131, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=1									
102131	Safety Follow-up	22	Hepatic failure	2 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0081, AN=100628, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=64									
100628	Safety Follow-up	85	Death	1 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0088, AN=100928, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=22									
100928	Safety Follow-up	43	Gamma-glutamyltransferase increased	Continuing	3	N	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0090, AN=100911, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=22									
100911	Safety Follow-up	39	Dyspnoea	1.71 Weeks	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0090, AN=101225, Gender=F, Race=White, Age=29 Years, Rel Day of Study Medication Discontinuance†=1									
101225	Safety Follow-up	10	Dyspnoea	5 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0101, AN=101804, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=43									
101804	Safety Follow-up	61	Back pain	Continuing	3	Y	N	Discontinued	Not Resolved
Study Number=3475-002, Site Number=0150, AN=101808, Gender=F, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=211									
101808	Safety Follow-up	218	Death	1 Days	5	Y	N	Discontinued	Fatal
Study Number=3475-002, Site Number=0170, AN=100622, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=1									
100622	Safety Follow-up	13	Hypopituitarism	1.02 Months	3	Y	Y	Discontinued	Sequelae

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002 試験（APaT 集団）（続き）

AN	Epoch	Rel Day of Onset	Adverse Event	Duration	Toxicity Grade	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Study Number=3475-002, Site Number=0180, AN=101272, Gender=F, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance[†]=64									
101272	Safety Follow-up	85	Interstitial lung disease	Continuing	3	Y	Y	Discontinued	Resolving

[†]Relative Day of Study Medication Discontinuance is defined as the day of the last recorded dose of study medication for the subject 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 "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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付録 2.7.4-50 休薬に至った有害事象（いずれかの投与群で発現割合 0%超）
006 試験（MK-3475 併合）（APaT 集団）

	Control		MK-3475 combined	
	n	(%)	n	(%)
Subjects in population	256		555	
with one or more adverse events	22	(8.6)	117	(21.1)
with no adverse events	234	(91.4)	438	(78.9)
Blood and lymphatic system disorders	**1**	**(0.4)**	**6**	**(1.1)**
Anaemia	0	(0.0)	5	(0.9)
Eosinophilia	1	(0.4)	0	(0.0)
Thrombocytopenia	0	(0.0)	1	(0.2)
Cardiac disorders	**1**	**(0.4)**	**5**	**(0.9)**
Angina unstable	0	(0.0)	1	(0.2)
Atrial fibrillation	0	(0.0)	2	(0.4)
Atrial flutter	1	(0.4)	0	(0.0)
Cardiac failure congestive	0	(0.0)	1	(0.2)
Pericardial effusion	0	(0.0)	1	(0.2)
Ear and labyrinth disorders	**0**	**(0.0)**	**1**	**(0.2)**
Deafness	0	(0.0)	1	(0.2)
Endocrine disorders	**1**	**(0.4)**	**9**	**(1.6)**
Adrenal insufficiency	0	(0.0)	1	(0.2)
Hyperthyroidism	0	(0.0)	2	(0.4)
Hypophysitis	1	(0.4)	2	(0.4)
Hypopituitarism	0	(0.0)	1	(0.2)
Hypothyroidism	0	(0.0)	3	(0.5)
Thyroiditis	0	(0.0)	1	(0.2)
Eye disorders	**0**	**(0.0)**	**3**	**(0.5)**
Eyelash discolouration	0	(0.0)	1	(0.2)
Papilloedema	0	(0.0)	1	(0.2)
Uveitis	0	(0.0)	2	(0.4)
Gastrointestinal disorders	**9**	**(3.5)**	**23**	**(4.1)**
Abdominal pain	2	(0.8)	1	(0.2)
Colitis	2	(0.8)	2	(0.4)
Constipation	0	(0.0)	1	(0.2)

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付録 2.7.4-50 休薬に至った有害事象（いずれかの投与群で発現割合 0%超）
006 試験（MK-3475 併合）（APaT 集団）（続き）

	Control		MK-3475 combined	
	n	(%)	n	(%)
Gastrointestinal disorders	**9**	**(3.5)**	**23**	**(4.1)**
Diarrhoea	4	(1.6)	14	(2.5)
Enterocolitis	1	(0.4)	0	(0.0)
Gastritis	0	(0.0)	1	(0.2)
Intestinal obstruction	0	(0.0)	1	(0.2)
Intestinal stenosis	1	(0.4)	0	(0.0)
Nausea	0	(0.0)	3	(0.5)
Pancreatitis	0	(0.0)	2	(0.4)
Rectal haemorrhage	0	(0.0)	1	(0.2)
Stomatitis	0	(0.0)	1	(0.2)
General disorders and administration site conditions	**5**	**(2.0)**	**16**	**(2.9)**
Adverse drug reaction	0	(0.0)	1	(0.2)
Asthenia	0	(0.0)	1	(0.2)
Chest pain	2	(0.8)	0	(0.0)
Fatigue	0	(0.0)	2	(0.4)
Generalised oedema	0	(0.0)	1	(0.2)
Influenza like illness	1	(0.4)	1	(0.2)
Infusion site extravasation	0	(0.0)	1	(0.2)
Malaise	0	(0.0)	3	(0.5)
Nodule	0	(0.0)	1	(0.2)
Oedema	0	(0.0)	1	(0.2)
Oedema peripheral	0	(0.0)	1	(0.2)
Pain	0	(0.0)	1	(0.2)
Pyrexia	2	(0.8)	2	(0.4)
Systemic inflammatory response syndrome	0	(0.0)	1	(0.2)
Hepatobiliary disorders	**0**	**(0.0)**	**5**	**(0.9)**
Drug-induced liver injury	0	(0.0)	1	(0.2)
Hepatitis	0	(0.0)	2	(0.4)
Hyperbilirubinaemia	0	(0.0)	2	(0.4)
Immune system disorders	**1**	**(0.4)**	**3**	**(0.5)**
Hypersensitivity	1	(0.4)	3	(0.5)

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付録 2.7.4-50 休薬に至った有害事象（いずれかの投与群で発現割合 0%超）
006 試験（MK-3475 併合）（APaT 集団）（続き）

	Control		MK-3475 combined	
	n	(%)	n	(%)
Infections and infestations	**1**	**(0.4)**	**9**	**(1.6)**
Bronchitis	0	(0.0)	1	(0.2)
Erysipelas	0	(0.0)	1	(0.2)
Lower respiratory tract infection	0	(0.0)	2	(0.4)
Nasopharyngitis	0	(0.0)	2	(0.4)
Respiratory tract infection viral	0	(0.0)	1	(0.2)
Sepsis	1	(0.4)	1	(0.2)
Upper respiratory tract infection	0	(0.0)	2	(0.4)
Urinary tract infection	0	(0.0)	1	(0.2)
Injury, poisoning and procedural complications	**0**	**(0.0)**	**4**	**(0.7)**
Infusion related reaction	0	(0.0)	4	(0.7)
Investigations	**1**	**(0.4)**	**15**	**(2.7)**
Alanine aminotransferase increased	1	(0.4)	5	(0.9)
Amylase increased	0	(0.0)	1	(0.2)
Aspartate aminotransferase increased	1	(0.4)	5	(0.9)
Bilirubin conjugated increased	1	(0.4)	1	(0.2)
Blood bilirubin increased	1	(0.4)	3	(0.5)
Blood corticotrophin decreased	0	(0.0)	1	(0.2)
Blood cortisol decreased	0	(0.0)	1	(0.2)
Blood creatinine increased	0	(0.0)	2	(0.4)
C-reactive protein increased	0	(0.0)	1	(0.2)
Cardiac murmur functional	0	(0.0)	1	(0.2)
Liver function test abnormal	0	(0.0)	1	(0.2)
Metabolism and nutrition disorders	**1**	**(0.4)**	**9**	**(1.6)**
Decreased appetite	0	(0.0)	1	(0.2)
Dehydration	0	(0.0)	1	(0.2)
Hypercalcaemia	1	(0.4)	0	(0.0)
Hypertriglyceridaemia	0	(0.0)	1	(0.2)
Hypoalbuminaemia	0	(0.0)	1	(0.2)
Hyponatraemia	0	(0.0)	2	(0.4)
Hypophosphataemia	0	(0.0)	2	(0.4)
Metabolic disorder	0	(0.0)	1	(0.2)

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付録 2.7.4-50 休薬に至った有害事象（いずれかの投与群で発現割合 0%超）
006 試験（MK-3475 併合）（APaT 集団）（続き）

	Control		MK-3475 combined	
	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	**1**	**(0.4)**	**13**	**(2.3)**
Arthralgia	1	(0.4)	4	(0.7)
Arthritis	0	(0.0)	2	(0.4)
Arthropathy	0	(0.0)	1	(0.2)
Back pain	0	(0.0)	3	(0.5)
Chondrocalcinosis pyrophosphate	0	(0.0)	1	(0.2)
Myalgia	0	(0.0)	2	(0.4)
Myositis	0	(0.0)	1	(0.2)
Pathological fracture	0	(0.0)	1	(0.2)
Spinal osteoarthritis	0	(0.0)	1	(0.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**0**	**(0.0)**	**1**	**(0.2)**
Metastatic malignant melanoma	0	(0.0)	1	(0.2)
Nervous system disorders	**1**	**(0.4)**	**6**	**(1.1)**
Aphasia	0	(0.0)	1	(0.2)
Epilepsy	0	(0.0)	1	(0.2)
Headache	0	(0.0)	1	(0.2)
Hydrocephalus	0	(0.0)	1	(0.2)
Memory impairment	0	(0.0)	1	(0.2)
Neuralgia	1	(0.4)	1	(0.2)
Normal pressure hydrocephalus	0	(0.0)	1	(0.2)
Psychiatric disorders	**0**	**(0.0)**	**2**	**(0.4)**
Anxiety	0	(0.0)	1	(0.2)
Confusional state	0	(0.0)	1	(0.2)
Insomnia	0	(0.0)	1	(0.2)
Renal and urinary disorders	**0**	**(0.0)**	**4**	**(0.7)**
Renal failure	0	(0.0)	2	(0.4)
Renal failure acute	0	(0.0)	1	(0.2)
Tubulointerstitial nephritis	0	(0.0)	1	(0.2)

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付録 2.7.4-50 休薬に至った有害事象（いずれかの投与群で発現割合 0%超）
006 試験（MK-3475 併合）（APaT 集団）（続き）

	Control		MK-3475 combined	
	n	(%)	n	(%)
Respiratory, thoracic and mediastinal disorders	**2**	**(0.8)**	**13**	**(2.3)**
Cough	0	(0.0)	1	(0.2)
Dyspnoea	2	(0.8)	2	(0.4)
Nasal congestion	0	(0.0)	1	(0.2)
Pleural effusion	0	(0.0)	1	(0.2)
Pneumonitis	0	(0.0)	3	(0.5)
Productive cough	0	(0.0)	2	(0.4)
Pulmonary embolism	0	(0.0)	4	(0.7)
Pulmonary oedema	0	(0.0)	1	(0.2)
Pulmonary thrombosis	0	(0.0)	1	(0.2)
Skin and subcutaneous tissue disorders	**1**	**(0.4)**	**11**	**(2.0)**
Erythema	0	(0.0)	1	(0.2)
Erythema multiforme	1	(0.4)	0	(0.0)
Lichen planus	0	(0.0)	1	(0.2)
Penile ulceration	0	(0.0)	1	(0.2)
Pruritus	0	(0.0)	2	(0.4)
Rash	0	(0.0)	3	(0.5)
Rash maculo-papular	0	(0.0)	2	(0.4)
Rash papular	1	(0.4)	0	(0.0)
Vitiligo	0	(0.0)	1	(0.2)
Vascular disorders	**0**	**(0.0)**	**2**	**(0.4)**
Aortic stenosis	0	(0.0)	1	(0.2)
Hypertension	0	(0.0)	1	(0.2)

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 'Malignant neoplasm progression' and 'Neoplasm progression' not related to the drug are excluded.
AEs were followed 30 days after last dose of study treatment
(Database Cutoff Date: 03SEP2014).

Data Source: [資料5.3.5.1.2: P006V01]

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=0001, Subject ID=362053, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=71									
362053	Treatment Cycle 3	52	Hypophysitis	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0004, Subject ID=369055, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=65									
369055	Treatment Cycle 2	24	Chest pain	50 Minutes		N	Y	Interrupted	Resolved
		24	Dyspnoea	50 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0007, Subject ID=366167, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=44									
366167	Treatment Cycle 2	23	Hypersensitivity	40 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0102, Subject ID=366755, Gender=F, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=22									
366755	Safety Follow-up	43	Pyrexia	1.57 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0309, Subject ID=363628, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=79									
363628	Treatment Cycle 3	52	Diarrhoea	1.14 Weeks		Y	Y	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=0309, Subject ID=363628, Gender=F, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=79									
363628	Treatment Cycle 3	61	Diarrhoea	1.14 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0400, Subject ID=363227, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=71									
363227	Treatment Cycle 1	18	Enterocolitis	4 Days		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0507, Subject ID=362215, Gender=F, Race=Multiple, Age=66 Years, Rel Day of Study Medication Discontinuance†=69									
362215	Treatment Cycle 3	61	Diarrhoea	6 Days		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=364560, Gender=F, Race=White, Age=81 Years, Rel Day of Study Medication Discontinuance†=64									
364560	Treatment Cycle 1	7	Abdominal pain	4.01 Months		N	Y	Interrupted	Resolved
		7	Intestinal stenosis	3 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0611, Subject ID=368270, Gender=F, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=71									
368270	Treatment Cycle 2	41	Eosinophilia	Continuing		N	Y	Interrupted	Not Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=0612, Subject ID=364286, Gender=M, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=22									
364286	Safety Follow-up	39	Chest pain	Continuing		N	N	Interrupted	Not Resolved
		39	Dyspnoea	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0702, Subject ID=360465, Gender=F, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=42									
360465	Safety Follow-up	71	Atrial flutter	2 Days		Y	N	Interrupted	Sequelae
Trial Number=3475-006, Site Number=0900, Subject ID=360551, Gender=F, Race=White, Age=50 Years, Rel Day of Study Medication Discontinuance†=78									
360551	Treatment Cycle 1	12	Erythema multiforme	3.57 Weeks		N	Y	Interrupted	Resolved
		12	Rash papular	3.57 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1502, Subject ID=361277, Gender=F, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†=65									
361277	Treatment Cycle 2	34	Diarrhoea	2.29 Weeks		Y	Y	Interrupted	Resolved
		57	Diarrhoea	5 Days		N	N	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=1502, Subject ID=366455, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=45									
366455	Treatment Cycle 2	42	Hypercalcaemia	1.43 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1703, Subject ID=361155, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=22									
361155	Safety Follow-up	37	Sepsis	1.43 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1708, Subject ID=367184, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=92									
367184	Treatment Cycle 3	85	Diarrhoea	Unknown		N	Y	Interrupted	Unknown
Trial Number=3475-006, Site Number=1810, Subject ID=367702, Gender=M, Race=White, Age=45 Years, Rel Day of Study Medication Discontinuance†=22									
367702	Safety Follow-up	40	Colitis	5 Days		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1812, Subject ID=363484, Gender=M, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=43									
363484	Treatment Cycle 1	23	Influenza like illness	3 Weeks		N	N	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=1815, Subject ID=366663, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=43									
366663	Safety Follow-up	46	Arthralgia	3.81 Months		N	Y	Interrupted	Resolved
		46	Neuralgia	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1816, Subject ID=361035, Gender=F, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=20									
361035	Safety Follow-up	41	Alanine aminotransferase increased	2.86 Weeks		N	N	Interrupted	Resolved
		41	Aspartate aminotransferase increased	2.86 Weeks		N	N	Interrupted	Resolved
		41	Bilirubin conjugated increased	2.86 Weeks		N	N	Interrupted	Resolved
		41	Blood bilirubin increased	2.86 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1900, Subject ID=364341, Gender=F, Race=White, Age=32 Years, Rel Day of Study Medication Discontinuance†=32									
364341	Treatment Cycle 1	11	Colitis	3.14 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1901, Subject ID=369394, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=85									

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
Control									
Trial Number=3475-006, Site Number=1901, Subject ID=369394, Gender=F, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=85									
369394	Treatment Cycle 3	64	Abdominal pain	2.14 Weeks		Y	Y	Interrupted	Resolved
		64	Pyrexia	2.14 Weeks		Y	Y	Interrupted	Resolved
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0001, Subject ID=368185, Gender=F, Race=White, Age=42 Years, Rel Day of Study Medication Discontinuance†=279									
368185	Treatment Cycle 10	194	Anaemia	Continuing		Y	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0002, Subject ID=361797, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=15									
361797	Safety Follow-up	18	Lichen planus	Continuing		Y	Y	Interrupted	Resolving
		25	Stomatitis	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0003, Subject ID=362014, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†–									
362014	Treatment Cycle 11	149	Arthralgia	Continuing		N	Y	Interrupted	Not Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0003, Subject ID=362014, Gender=M, Race=White, Age=78 Years, Rel Day of Study Medication Discontinuance†–									
362014	Treatment Cycle 13	179	Arthralgia	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0003, Subject ID=362318, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†–									
362318	Treatment Cycle 10	131	Hypopituitarism	1.71 Weeks		Y	Y	Interrupted	Sequelae
	Treatment Cycle 18	261	Lower respiratory tract infection	Continuing		N	N	Interrupted	Not Resolved
		268	Upper respiratory tract infection	1.14 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0003, Subject ID=367747, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†–									
367747	Treatment Cycle 18	267	Influenza like illness	4 Days		N	N	Interrupted	Resolved
		267	Productive cough	4 Days		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0003, Subject ID=367890, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†–									
367890	Treatment Cycle 17	238	Upper respiratory tract infection	2.29 Weeks		N	Y	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0003, Subject ID=369295, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†–									
369295	Treatment Cycle 6	78	Arthropathy	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0004, Subject ID=366158, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†=57									
366158	Treatment Cycle 3	30	Nausea	Unknown		N	N	Interrupted	Unknown
Trial Number=3475-006, Site Number=0005, Subject ID=362871, Gender=M, Race=White, Age=36 Years, Rel Day of Study Medication Discontinuance†=279									
362871	Treatment Cycle 2	15	Back pain	15 Minutes		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0005, Subject ID=366940, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†–									
366940	Treatment Cycle 3	40	Aspartate aminotransferase increased	1.86 Weeks		N	Y	Interrupted	Resolved
		40	Hepatitis	4.7 Months		Y	Y	Interrupted	Resolved
		70	Aortic stenosis	11.2 Months		Y	N	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0101, Subject ID=361468, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=91									
361468	Treatment Cycle 1	14	Bronchitis	Continuing		Y	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0102, Subject ID=364052, Gender=M, Race=White, Age=29 Years, Rel Day of Study Medication Discontinuance†=141									
364052	Treatment Cycle 4	57	Liver function test abnormal	2.29 Weeks		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0300, Subject ID=366627, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†–									
366627	Treatment Cycle 4	44	Uveitis	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0300, Subject ID=369262, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†–									
369262	Treatment Cycle 3	36	Atrial fibrillation	1.14 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0301, Subject ID=362932, Gender=M, Race=White, Age=32 Years, Rel Day of Study Medication Discontinuance†–									
362932	Treatment Cycle 6	81	Diarrhoea	23 Hours		N	Y	Interrupted	Resolved

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0309, Subject ID=363424, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†–									
363424	Treatment Cycle 1	14	Alanine aminotransferase increased	1.14 Weeks		N	Y	Interrupted	Resolved
		14	Aspartate aminotransferase increased	3.14 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0312, Subject ID=362979, Gender=F, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†=210									
362979	Treatment Cycle 10	131	Arthritis	Continuing		N	Y	Interrupted	Resolving
Trial Number=3475-006, Site Number=0400, Subject ID=363379, Gender=M, Race=White, Age=54 Years, Rel Day of Study Medication Discontinuance†–									
363379	Treatment Cycle 3	42	Hypophosphataemia	1.14 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0600, Subject ID=368594, Gender=F, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†–									
368594	Treatment Cycle 5	56	Pulmonary embolism	30 Minutes		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0601, Subject ID=366173, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†–									

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付録 2.7.4-51 休薬に至った有害事象の一覧

006 試験（APaT 集団）（続き）

Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0601, Subject ID=366173, Gender=F, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†–									
366173	Treatment Cycle 1	3	Respiratory tract infection viral	6 Days		N	N	Interrupted	Resolved
		21	Deafness	Continuing		N	N	Interrupted	Resolving
Trial Number=3475-006, Site Number=0605, Subject ID=360713, Gender=M, Race=White, Age=66 Years, Rel Day of Study Medication Discontinuance†=153									
360713	Treatment Cycle 8	98	Diarrhoea	3.29 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=362398, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=43									
362398	Treatment Cycle 2	14	Anaemia	Continuing		Y	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=362886, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=43									
362886	Treatment Cycle 2	29	Renal failure acute	1.57 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=363884, Gender=F, Race=White, Age=70 Years, Rel Day of Study Medication Discontinuance†=351									
363884	Treatment Cycle 6	85	Cardiac murmur functional	Continuing		N	N	Interrupted	Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0605, Subject ID=364326, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=252									
364326	Treatment Cycle 9	113	Productive cough	Continuing		N	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=367585, Gender=M, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=99									
367585	Treatment Cycle 3	42	Malaise	24 Hours		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=367617, Gender=M, Race=White, Age=86 Years, Rel Day of Study Medication Discontinuance†–									
367617	Treatment Cycle 20	278	Malaise	3 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=367764, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†–									
367764	Treatment Cycle 13	181	Erythema	Continuing		N	N	Interrupted	Not Resolved
		181	Oedema	3.14 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0611, Subject ID=368616, Gender=F, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†–									
368616	Treatment Cycle 11	147	Blood corticotrophin decreased	Continuing		Y	Y	Interrupted	Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0612, Subject ID=360425, Gender=M, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=88									
360425	Treatment Cycle 4	58	Generalised oedema	Continuing		Y	N	Interrupted	Not Resolved
	Treatment Cycle 5	73	Hypoalbuminaemia	Continuing		Y	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0612, Subject ID=365175, Gender=M, Race=White, Age=72 Years, Rel Day of Study Medication Discontinuance†–									
365175	Treatment Cycle 11	144	Neuralgia	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0700, Subject ID=363097, Gender=F, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†–									
363097	Treatment Cycle 13	169	Diarrhoea	2.57 Weeks		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0700, Subject ID=365186, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=65									
365186	Treatment Cycle 1	14	Diarrhoea	1.18 Months		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0702, Subject ID=365600, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=85									
365600	Treatment Cycle 4	52	Metastatic malignant melanoma	2.23 Months		Y	N	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0704, Subject ID=360742, Gender=F, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†=154									
360742	Treatment Cycle 4	42	Hypothyroidism	Continuing		N	Y	Interrupted	Not Resolved
	Treatment Cycle 6	83	Adrenal insufficiency	Continuing		Y	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0704, Subject ID=366882, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=144									
366882	Safety Follow-up	153	Rash	1.28 Months		N	Y	Interrupted	Resolved
		155	Decreased appetite	1.22 Months		N	Y	Interrupted	Resolved
		155	Fatigue	2.83 Months		N	Y	Interrupted	Resolved
		157	Nausea	2 Days		N	Y	Interrupted	Resolved
		158	Bilirubin conjugated increased	5 Days		N	Y	Interrupted	Resolved
		158	Blood bilirubin increased	6 Days		N	Y	Interrupted	Resolved
		158	Blood cortisol decreased	Unknown		N	Y	Interrupted	Unknown
		158	C-reactive protein increased	2 Weeks		N	Y	Interrupted	Unknown
		159	Systemic inflammatory response syndrome	1.86 Weeks		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=0704, Subject ID=366882, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†=144									
366882	Safety Follow-up	161	Epilepsy	1 Hours		N	Y	Interrupted	Resolved
		169	Anaemia	Unknown		N	Y	Interrupted	Unknown
Trial Number=3475-006, Site Number=0706, Subject ID=365429, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†–									
365429	Treatment Cycle 4	45	Arthralgia	Unknown		N	Y	Interrupted	Unknown
Trial Number=3475-006, Site Number=0706, Subject ID=369101, Gender=M, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†–									
369101	Treatment Cycle 2	23	Diarrhoea	3.43 Weeks		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0901, Subject ID=368897, Gender=M, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†–									
368897	Treatment Cycle 4	64	Intestinal obstruction	4 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0902, Subject ID=369337, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†–									
369337	Treatment Cycle 3	44	Hyperthyroidism	3.43 Weeks		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1301, Subject ID=360072, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†–									
360072	Treatment Cycle 4	50	Rash maculo-papular	3 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1401, Subject ID=361560, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=355									
361560	Treatment Cycle 8	102	Back pain	15 Minutes		N	Y	Interrupted	Resolved
		106	Diarrhoea	3.29 Weeks		Y	Y	Interrupted	Resolved
	Treatment Cycle 10	171	Rectal haemorrhage	1.81 Months		N	Y	Interrupted	Resolved
		178	Amylase increased	1.48 Months		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1402, Subject ID=361567, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=43									
361567	Safety Follow-up	58	Aphasia	Continuing		N	N	Interrupted	Not Resolved
		58	Headache	Continuing		N	N	Interrupted	Not Resolved
		59	Anxiety	Continuing		N	N	Interrupted	Not Resolved
		59	Insomnia	Continuing		N	N	Interrupted	Not Resolved
		59	Nausea	Continuing		N	N	Interrupted	Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1402, Subject ID=361567, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=43									
361567	Safety Follow-up	60	Constipation	Continuing		N	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1500, Subject ID=362525, Gender=F, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=106									
362525	Treatment Cycle 5	86	Diarrhoea	1 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1502, Subject ID=367365, Gender=M, Race=White, Age=43 Years, Rel Day of Study Medication Discontinuance†–									
367365	Treatment Cycle 8	113	Blood bilirubin increased	1.38 Months		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1700, Subject ID=365574, Gender=M, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†–									
365574	Treatment Cycle 2	15	Thyroiditis	Continuing		Y	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1703, Subject ID=361701, Gender=F, Race=Asian, Age=42 Years, Rel Day of Study Medication Discontinuance†=41									
361701	Safety Follow-up	54	Alanine aminotransferase increased	1.02 Months		Y	N	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1703, Subject ID=361701, Gender=F, Race=Asian, Age=42 Years, Rel Day of Study Medication Discontinuance†=41									
361701	Safety Follow-up	54	Aspartate aminotransferase increased	1.02 Months		Y	N	Interrupted	Resolved
		58	Hyperbilirubinaemia	3.86 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1705, Subject ID=361816, Gender=F, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=288									
361816	Treatment Cycle 12	155	Nodule	Continuing		N	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1705, Subject ID=367425, Gender=M, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†–									
367425	Treatment Cycle 14	187	Diarrhoea	Continuing		Y	Y	Interrupted	Resolving
Trial Number=3475-006, Site Number=1710, Subject ID=364232, Gender=F, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†=121									
364232	Treatment Cycle 2	29	Pneumonitis	4.14 Weeks		Y	Y	Interrupted	Resolved
		33	Pericardial effusion	1.57 Weeks		N	Y	Interrupted	Resolved
		33	Pleural effusion	1.57 Weeks		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1710, Subject ID=364232, Gender=F, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†=121									
364232	Treatment Cycle 2	33	Pulmonary oedema	1.57 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1710, Subject ID=365809, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†–									
365809	Treatment Cycle 15	197	Memory impairment	Continuing		N	N	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1710, Subject ID=366818, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=78									
366818	Treatment Cycle 2	17	Pathological fracture	Continuing		Y	N	Interrupted	Resolving
Trial Number=3475-006, Site Number=1711, Subject ID=368852, Gender=F, Race=White, Age=48 Years, Rel Day of Study Medication Discontinuance†=29									
368852	Treatment Cycle 3	29	Adverse drug reaction	30 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1808, Subject ID=361958, Gender=M, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=323									
361958	Treatment Cycle 11	141	Hypophosphataemia	Continuing		N	N	Interrupted	Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1810, Subject ID=366537, Gender=M, Race=Asian, Age=79 Years, Rel Day of Study Medication Discontinuance†=17									
366537	Safety Follow-up	29	Dehydration	3 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1816, Subject ID=362402, Gender=M, Race=White, Age=73 Years, Rel Day of Study Medication Discontinuance†=323									
362402	Treatment Cycle 3	29	Infusion site extravasation	30 Minutes		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1818, Subject ID=367651, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=309									
367651	Treatment Cycle 14	184	Myalgia	2.29 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1819, Subject ID=366350, Gender=M, Race=White, Age=77 Years, Rel Day of Study Medication Discontinuance†–									
366350	Treatment Cycle 8	130	Chondrocalcinosis pyrophosphate	1.08 Months		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1823, Subject ID=360915, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=146									
360915	Treatment Cycle 6	126	Pulmonary thrombosis	3 Days		Y	N	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q2W									
Trial Number=3475-006, Site Number=1824, Subject ID=360306, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=183									
360306	Treatment Cycle 11	153	Nasal congestion	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1825, Subject ID=368965, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†–									
368965	Treatment Cycle 7	94	Atrial fibrillation	3.14 Weeks		Y	N	Interrupted	Resolved
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0001, Subject ID=368720, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†=254									
368720	Treatment Cycle 10	192	Confusional state	Continuing		Y	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0002, Subject ID=361272, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†–									
361272	Treatment Cycle 9	183	Pancreatitis	4 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0004, Subject ID=363267, Gender=M, Race=White, Age=37 Years, Rel Day of Study Medication Discontinuance†–									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0004, Subject ID=363267, Gender=M, Race=White, Age=37 Years, Rel Day of Study Medication Discontinuance†–									
363267	Treatment Cycle 9	169	Alanine aminotransferase increased	Continuing		N	N	Interrupted	Resolving
	Treatment Cycle 12	231	Aspartate aminotransferase increased	3.02 Months		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0005, Subject ID=363154, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=76									
363154	Treatment Cycle 3	64	Hypertension	1.86 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0007, Subject ID=367327, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†=29									
367327	Treatment Cycle 1	3	Gastritis	1.81 Months		Y	N	Interrupted	Resolved
		17	Back pain	3.84 Months		Y	N	Interrupted	Resolved
	Treatment Cycle 2	29	Hypersensitivity	31 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0100, Subject ID=364614, Gender=M, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=63									
364614	Safety Follow-up	84	Pancreatitis	3.86 Weeks		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0300, Subject ID=362752, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†=211									
362752	Treatment Cycle 4	64	Infusion related reaction	1 Hours		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0301, Subject ID=362086, Gender=M, Race=White, Age=85 Years, Rel Day of Study Medication Discontinuance†=148									
362086	Treatment Cycle 5	91	Diarrhoea	2.71 Weeks		N	Y	Interrupted	Resolved
	Treatment Cycle 6	122	Diarrhoea	3.71 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0309, Subject ID=363895, Gender=F, Race=White, Age=49 Years, Rel Day of Study Medication Discontinuance†=115									
363895	Treatment Cycle 1	3	Diarrhoea	Continuing		N	Y	Interrupted	Resolving
	Treatment Cycle 5	96	Colitis	23 Hours		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0309, Subject ID=366971, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=1									
366971	Safety Follow-up	22	Alanine aminotransferase increased	2.57 Weeks		N	Y	Interrupted	Resolved
		22	Aspartate aminotransferase increased	4.76 Months		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0309, Subject ID=366971, Gender=M, Race=White, Age=79 Years, Rel Day of Study Medication Discontinuance†=1									
366971	Safety Follow-up	25	Arthralgia	1.12 Months		N	Y	Interrupted	Resolved
		25	Myalgia	1.12 Months		N	Y	Interrupted	Resolved
		29	Dyspnoea	6 Days		N	Y	Interrupted	Resolved
		29	Fatigue	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0312, Subject ID=363354, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=22									
363354	Treatment Cycle 2	22	Infusion related reaction	15 Minutes		N	Y	Interrupted	Resolved
	Safety Follow-up	43	Alanine aminotransferase increased	Continuing		N	N	Interrupted	Not Resolved
		43	Hyperbilirubinaemia	Unknown		N	N	Interrupted	Unknown
Trial Number=3475-006, Site Number=0312, Subject ID=363673, Gender=M, Race=White, Age=88 Years, Rel Day of Study Medication Discontinuance†=42									
363673	Treatment Cycle 2	21	Infusion related reaction	25 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0400, Subject ID=360321, Gender=M, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†–									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0400, Subject ID=360321, Gender=M, Race=White, Age=34 Years, Rel Day of Study Medication Discontinuance†–									
360321	Treatment Cycle 11	232	Hypertriglyceridaemia	1.14 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0601, Subject ID=360385, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=57									
360385	Treatment Cycle 1	22	Blood creatinine increased	2.33 Months		N	N	Interrupted	Unknown
		22	Renal failure	Continuing		N	N	Interrupted	Not Resolved
	Safety Follow-up	76	Abdominal pain	2.43 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=360080, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=274									
360080	Treatment Cycle 9	190	Malaise	5 Minutes		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=360314, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=244									
360314	Treatment Cycle 3	63	Pyrexia	6 Days		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=360489, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=54									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0605, Subject ID=360489, Gender=F, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=54									
360489	Treatment Cycle 1	19	Urinary tract infection	2.43 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=361293, Gender=F, Race=White, Age=51 Years, Rel Day of Study Medication Discontinuance†=191									
361293	Safety Follow-up	212	Thrombocytopenia	6 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=362662, Gender=F, Race=White, Age=38 Years, Rel Day of Study Medication Discontinuance†=232									
362662	Safety Follow-up	253	Metabolic disorder	5 Days		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=363218, Gender=M, Race=White, Age=75 Years, Rel Day of Study Medication Discontinuance†=190									
363218	Safety Follow-up	191	Hydrocephalus	1.91 Months		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0605, Subject ID=364113, Gender=F, Race=White, Age=52 Years, Rel Day of Study Medication Discontinuance†–									
364113	Treatment Cycle 12	248	Diarrhoea	2 Days		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0605, Subject ID=367815, Gender=F, Race=White, Age=83 Years, Rel Day of Study Medication Discontinuance†–									
367815	Treatment Cycle 8	149	Asthenia	Continuing		N	Y	Interrupted	Resolving
Trial Number=3475-006, Site Number=0610, Subject ID=360172, Gender=M, Race=White, Age=60 Years, Rel Day of Study Medication Discontinuance†=127									
360172	Treatment Cycle 5	86	Diarrhoea	4 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0611, Subject ID=365059, Gender=M, Race=White, Age=80 Years, Rel Day of Study Medication Discontinuance†=99									
365059	Treatment Cycle 2	22	Hepatitis	1.18 Months		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0612, Subject ID=361134, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†–									
361134	Treatment Cycle 1	26	Hyperthyroidism	3.86 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=0612, Subject ID=363119, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=173									
363119	Safety Follow-up	179 180	Papilloedema Eyelash discolouration	Continuing Continuing		N N	Y Y	Interrupted Interrupted	Not Resolved Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=0612, Subject ID=363119, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=173									
363119	Safety Follow-up	184	Vitiligo	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=0612, Subject ID=365642, Gender=M, Race=White, Age=82 Years, Rel Day of Study Medication Discontinuance†=85									
365642	Treatment Cycle 2	22	Dyspnoea	2.1 Months		N	N	Interrupted	Resolved
		45	Pulmonary embolism	2.86 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0706, Subject ID=369387, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†=128									
369387	Safety Follow-up	136	Hyponatraemia	4.29 Weeks		Y	N	Interrupted	Resolved
		148	Hypophysitis	2.57 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=0902, Subject ID=361025, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†–									
361025	Treatment Cycle 1	2	Normal pressure hydrocephalus	Continuing		N	N	Interrupted	Not Resolved
	Treatment Cycle 7	156	Tubulointerstitial nephritis	1.08 Months		Y	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1201, Subject ID=364788, Gender=F, Race=White, Age=53 Years, Rel Day of Study Medication Discontinuance†=41									
364788	Treatment Cycle 2	22	Hypersensitivity	7 Minutes		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1300, Subject ID=360851, Gender=M, Race=White, Age=71 Years, Rel Day of Study Medication Discontinuance†=93									
360851	Treatment Cycle 3	63	Uveitis	4.29 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1401, Subject ID=362977, Gender=M, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=259									
362977	Treatment Cycle 2	42	Angina unstable	4 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1402, Subject ID=368856, Gender=M, Race=White, Age=61 Years, Rel Day of Study Medication Discontinuance†=85									
368856	Treatment Cycle 2	22	Hypersensitivity	1 Hours		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1500, Subject ID=366146, Gender=M, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†–									
366146	Treatment Cycle 11	244	Blood bilirubin increased	Continuing		N	N	Interrupted	Resolving

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1501, Subject ID=366985, Gender=M, Race=White, Age=40 Years, Rel Day of Study Medication Discontinuance†=64									
366985	Treatment Cycle 3	43	Nasopharyngitis	1.97 Months		N	N	Interrupted	Resolved
	Safety Follow-up	84	Penile ulceration	2.71 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1502, Subject ID=365987, Gender=F, Race=White, Age=76 Years, Rel Day of Study Medication Discontinuance†=44									
365987	Safety Follow-up	65	Anaemia	Unknown		N	N	Interrupted	Unknown
Trial Number=3475-006, Site Number=1502, Subject ID=368887, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†=142									
368887	Treatment Cycle 1	3	Rash	1.74 Months		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1504, Subject ID=365695, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†–									
365695	Treatment Cycle 6	128	Blood creatinine increased	Continuing		N	N	Interrupted	Resolving
	Treatment Cycle 8	170	Renal failure	6 Days		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1600, Subject ID=364068, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=135									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1600, Subject ID=364068, Gender=M, Race=White, Age=62 Years, Rel Day of Study Medication Discontinuance†=135									
364068	Treatment Cycle 2	48	Pulmonary embolism	1.51 Months		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1703, Subject ID=362670, Gender=M, Race=White, Age=63 Years, Rel Day of Study Medication Discontinuance†–									
362670	Treatment Cycle 10	219	Hypophysitis	2.04 Months		Y	Y	Interrupted	Sequelae
Trial Number=3475-006, Site Number=1703, Subject ID=363479, Gender=M, Race=White, Age=64 Years, Rel Day of Study Medication Discontinuance†–									
363479	Treatment Cycle 7	148	Hypothyroidism	4.93 Months		N	Y	Interrupted	Resolved
		148	Pruritus	3.48 Months		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1707, Subject ID=362376, Gender=F, Race=White, Age=68 Years, Rel Day of Study Medication Discontinuance†–									
362376	Treatment Cycle 4	83	Hypothyroidism	1.68 Months		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1707, Subject ID=364017, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†–									
364017	Treatment Cycle 2	28	Rash	3 Weeks		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1707, Subject ID=364017, Gender=M, Race=White, Age=74 Years, Rel Day of Study Medication Discontinuance†–									
364017	Treatment Cycle 3	52	Hyponatraemia	1.29 Weeks		Y	Y	Interrupted	Resolved
		66	Sepsis	2.14 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1707, Subject ID=364658, Gender=M, Race=White, Age=58 Years, Rel Day of Study Medication Discontinuance†=1									
364658	Safety Follow-up	22	Drug-induced liver injury	4.29 Weeks		Y	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1707, Subject ID=366130, Gender=F, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†–									
366130	Treatment Cycle 12	252	Pulmonary embolism	Continuing		N	N	Interrupted	Resolving
Trial Number=3475-006, Site Number=1707, Subject ID=368329, Gender=F, Race=White, Age=87 Years, Rel Day of Study Medication Discontinuance†=64									
368329	Safety Follow-up	71	Anaemia	1.43 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1708, Subject ID=366213, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=309									
366213	Treatment Cycle 7	127	Pain	2.1 Months		N	Y	Interrupted	Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1708, Subject ID=366213, Gender=F, Race=White, Age=67 Years, Rel Day of Study Medication Discontinuance†=309									
366213	Treatment Cycle 8	169	Pneumonitis	4.14 Weeks		N	Y	Interrupted	Resolved
	Treatment Cycle 10	229	Lower respiratory tract infection	2.57 Weeks		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1711, Subject ID=363852, Gender=M, Race=White, Age=65 Years, Rel Day of Study Medication Discontinuance†–									
363852	Treatment Cycle 1	8	Arthralgia	Continuing		N	Y	Interrupted	Resolving
Trial Number=3475-006, Site Number=1804, Subject ID=364357, Gender=F, Race=White, Age=57 Years, Rel Day of Study Medication Discontinuance†=182									
364357	Treatment Cycle 3	56	Diarrhoea	1.71 Weeks		N	Y	Interrupted	Resolved
	Treatment Cycle 7	134	Colitis	1.51 Months		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1804, Subject ID=367122, Gender=F, Race=White, Age=89 Years, Rel Day of Study Medication Discontinuance†=190									
367122	Safety Follow-up	209	Pneumonitis	Continuing		N	Y	Interrupted	Not Resolved
Trial Number=3475-006, Site Number=1807, Subject ID=365454, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=141									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1807, Subject ID=365454, Gender=F, Race=White, Age=59 Years, Rel Day of Study Medication Discontinuance†=141									
365454	Treatment Cycle 2	22	Infusion related reaction	55 Minutes		N	Y	Interrupted	Resolved
	Treatment Cycle 3	49	Cardiac failure congestive	3 Weeks		Y	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1809, Subject ID=362764, Gender=M, Race=White, Age=55 Years, Rel Day of Study Medication Discontinuance†=232									
362764	Treatment Cycle 7	144	Diarrhoea	1 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1809, Subject ID=362971, Gender=M, Race=White, Age=56 Years, Rel Day of Study Medication Discontinuance†–									
362971	Treatment Cycle 8	169	Rash maculo-papular	3.29 Weeks		N	Y	Interrupted	Resolved
Trial Number=3475-006, Site Number=1815, Subject ID=369449, Gender=M, Race=White, Age=69 Years, Rel Day of Study Medication Discontinuance†=148									
369449	Treatment Cycle 2	20	Myositis	4.24 Months		N	Y	Interrupted	Resolved
	Treatment Cycle 3	78	Arthritis	Continuing		N	Y	Interrupted	Not Resolved
		78	Oedema peripheral	Continuing		N	Y	Interrupted	Not Resolved
		78	Spinal osteoarthritis	Continuing		N	N	Interrupted	Not Resolved

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1900, Subject ID=363717, Gender=F, Race=White, Age=44 Years, Rel Day of Study Medication Discontinuance†–									
363717	Treatment Cycle 4	85	Cough	1.54 Months		N	N	Interrupted	Resolved
		85	Nasopharyngitis	4 Days		N	N	Interrupted	Resolved
		85	Pyrexia	4 Days		N	N	Interrupted	Resolved
	Treatment Cycle 9	209	Erysipelas	1.61 Months		N	N	Interrupted	Resolved
Trial Number=3475-006, Site Number=1901, Subject ID=361928, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=71									

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Subject ID	Epoch	Rel Day of Onset	Adverse Event	Duration	Intensity	Ser-ious	Related	Action Taken	Outcome
MK-3475 10 mg/kg Q3W									
Trial Number=3475-006, Site Number=1901, Subject ID=361928, Gender=F, Race=White, Age=46 Years, Rel Day of Study Medication Discontinuance†=71									
361928	Treatment Cycle 2	43	Pruritus	1.14 Weeks		N	Y	Interrupted	Resolved

†Relative Day of Study Medication Discontinuance is defined as the day of the last recorded dose of study medication for the subject 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.

MedDRA preferred terms 'Malignant neoplasm progression' and 'Neoplasm progression' not related to the drug are excluded.

AEs were followed 30 days after last dose of study.

(Database Cutoff Date: 03SEP2014).

Data Source: [資料5.3.5.1.2: P006V01]

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